National Institute of Diabetes and Digestive and Kidney Diseases

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Advisory Council Orientation Handbook

January 2025

National Institutes of Health
U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Orientation for New Advisory Council Members

A MESSAGE FROM THE DIRECTOR, NIDDK

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is one of 27 Institutes and Centers that make up the National Institutes of Health (NIH), part of the Public Health Service in the U.S. Department of Health and Human Services. The Institute conducts and supports basic and clinical research in some of the most serious, common, disabling, and costly conditions affecting the public's health. The diseases in NIDDK's research mission cut across the full spectrum of medicine and include:

- Diabetes and other endocrine diseases;
- Cystic fibrosis and other inherited diseases;
- Digestive diseases;
- Obesity;
- Nutrition;
- Diseases of the kidney, genitourinary tract, and blood.

Most arise from the complex interaction of genetic, autoimmune, neuroendocrine, metabolic, nutritional, and environmental factors. Some diseases such as diabetes, obesity, hepatitis, and kidney failure disproportionately affect minority populations. NIDDK funds research projects that relate directly to these diseases, but it also places a high priority on fundamental, untargeted research.

Training is critically important to continued progress in medical research. NIDDK supports research training and career development, with special emphasis on increasing the ranks of physician scientists and recruiting underrepresented minorities and women into biomedical research careers.

The National Diabetes and Digestive and Kidney Diseases Advisory Council's most important purpose is to make recommendations regarding the funding of grant applications, focusing primarily on the relevance to the programmatic missions and priorities of the Institute. The Council also has the responsibility to ensure the adequacy of the scientific review by the initial review groups. In addition, the Council offers advice on a wide variety of policies and programs within the Institute.

As you begin service on the National Diabetes and Digestive and Kidney Diseases Advisory Council, we hope this orientation material will help answer some of your questions and provide the information you will need in your role as a Council member. In addition, your comments on the usefulness of this material and suggestions for improvement will be appreciated.

Griffin P. Rodgers, M.D., M.A.C.P.,
Director,
National Institute of Diabetes
and Digestive
and Kidney Diseases
National Institutes of Health

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NIH Gateway Center Map

Main Visitor Entrance: NIH Gateway Drive

Gateway Center - Building 66 (for pedestrians entering campus)

- Open Monday – Friday, 6am – 10pm
- Closed on Weekends and Observed Holidays
- After 10pm weekdays, all day weekends and holidays, pedestrian visitors enter via the Commercial Vehicle Inspection Facility (CVIF) – Building 67 (on Rockville Pike between North Drive and Wilson Drive)

Gateway Inspection Station - Building 66A (for vehicles entering campus)

- Monday-Friday: 5am – 10pm
  Weekends and After Hours: Closed
  After 10pm on weekdays, all day weekends and holidays, visitors in vehicles should enter campus via the CVIF – Building 67 (on Rockville Pike between North Drive and Wilson Drive)
- All vehicles and their contents will be inspected upon entering the campus.
- After inspection, vehicles enter campus at Center Drive
- Roadway at Center Drive is for entering campus only; visitors exiting campus may exit from other open locations.

Multi-Level Parking Garage 11 – MLP-11 (car inspection not required; visitor badges obtained at Gateway Visitor Center – Bldg 66) Hours: Monday - Friday: 6am – 9pm (entrance) 6am – 11pm (exit) Cost: $2 per hour for the first three hours, $12 maximum for entire day. Closed weekends.

Security Procedures for Entering the NIH Campus:
All visitors and patients – **please be aware**: Federal law prohibits the following items on Federal property: firearms, explosives, archery equipment, dangerous weapons, knives with blades over 2 ½ inches, alcoholic beverages and open containers of alcohol.
The NIH has implemented security measures to help ensure the safety of our patients, employees, guests and facilities. All visitors must enter through the NIH Gateway Center at Metro or the West Gate Center. You will be asked to submit to a vehicle or personal inspection.
Whether arriving by Metro, hotel shuttle, or private or commercial vehicle, visitors over 15 years of age must show one (1) form of a government-issued photo ID—driver's license, passport, green card, etc**.** Visitors under 16 years of age must be accompanied by an adult.

Tobacco-Free Campus – Effective October 1, 2008, the use of all tobacco products (including cigarettes, cigars, pipes, smokeless tobacco, or other tobacco products) is prohibited at all times in all buildings; on all outside property or grounds, including parking areas; and in government vehicles.

Vehicle Inspections – Except for those parked in MLP-11, all vehicles and their contents will be inspected upon entering the campus. Additionally, all vehicles entering certain parking areas will be inspected, regardless of any prior inspection. Drivers will be required to present their driver's license and may be asked to open the trunk and hood. If you are physically unable to perform this function, please inform the inspector and they will assist you. Vehicle inspection may consist of any combination of the following: Detection Dogs Teams (K-9), Electronic Detection Devices and Manual Inspection.

After inspection, you will be issued a vehicle inspection pass. It must be displayed on your vehicle's dashboard while you are on campus. The inspection pass is not a "parking permit." It only grants your vehicle access to enter the campus. You can only park in designated parking areas.

Personal Inspections – All visitors should be prepared to submit to a personal inspection prior to entering the campus. These inspections may be conducted with a handheld monitoring device, a metal detector and by visible inspection. Additionally, your personal belongings may be inspected and passed through an x-ray machine.

If driving onto campus, the personal inspection and issuance of a visitor badge will take place where your private or commercial vehicle (including a taxi) is inspected.

If you parked in the NIH Gateway Center multi-level garage (MPL-11), the personal inspection and issuance of a visitor badge will take place in the Visitor's Center. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://www.ors.od.nih.gov/pes/dats/nihshuttleservices/Pages/shuttle.aspx. Directional signs within Building 31 will guide you to the meeting room.

Visitor passes must be prominently displayed at all times while on the NIH campus.

To learn more about visitor and security issues at the NIH, visit: http://www.nih.gov/about/visitor/index.htm.

For questions about campus access, please contact the ORS Information Line at orsinfo@mail.nih.gov or 301-594-6677, TTY - 301-435-1908.

NIH Visitors Map of Campus

General Visitor Parking Information

Parking:

Visitors may park at the **Gateway Parking Garage (MLP-11)** (see Gateway Center Map) or in designated visitor parking lots (see Campus Map):
Monday – Friday, 6am – 9pm (entrance); 6am – 11pm (exit):
$2.00 per hour for the first three hours
$12.00 for the entire day

Lot 53 (between Buildings 10, 13, and 50): Monday – Friday, 6am – 11pm (entrance and exit)

Metered parking lots:
Monday – Friday, enforced 7am – 7pm
Available in up to 2-hour increments; $2 per hour ($1.50 per hour in front of Building 31A)

Arriving at NIH:

When traveling to the main NIH campus, use of the Metro is strongly encouraged. Visitor parking lots on the NIH campus fill up quickly.

The NIH Has implemented security measures to help ensure the safety of our patients, employees, guests, and facilities. All visitors must enter through the NIH Gateway Center at Metro or the West Gateway Visitor Center. You will be asked to submit to a vehicle and personal inspection.

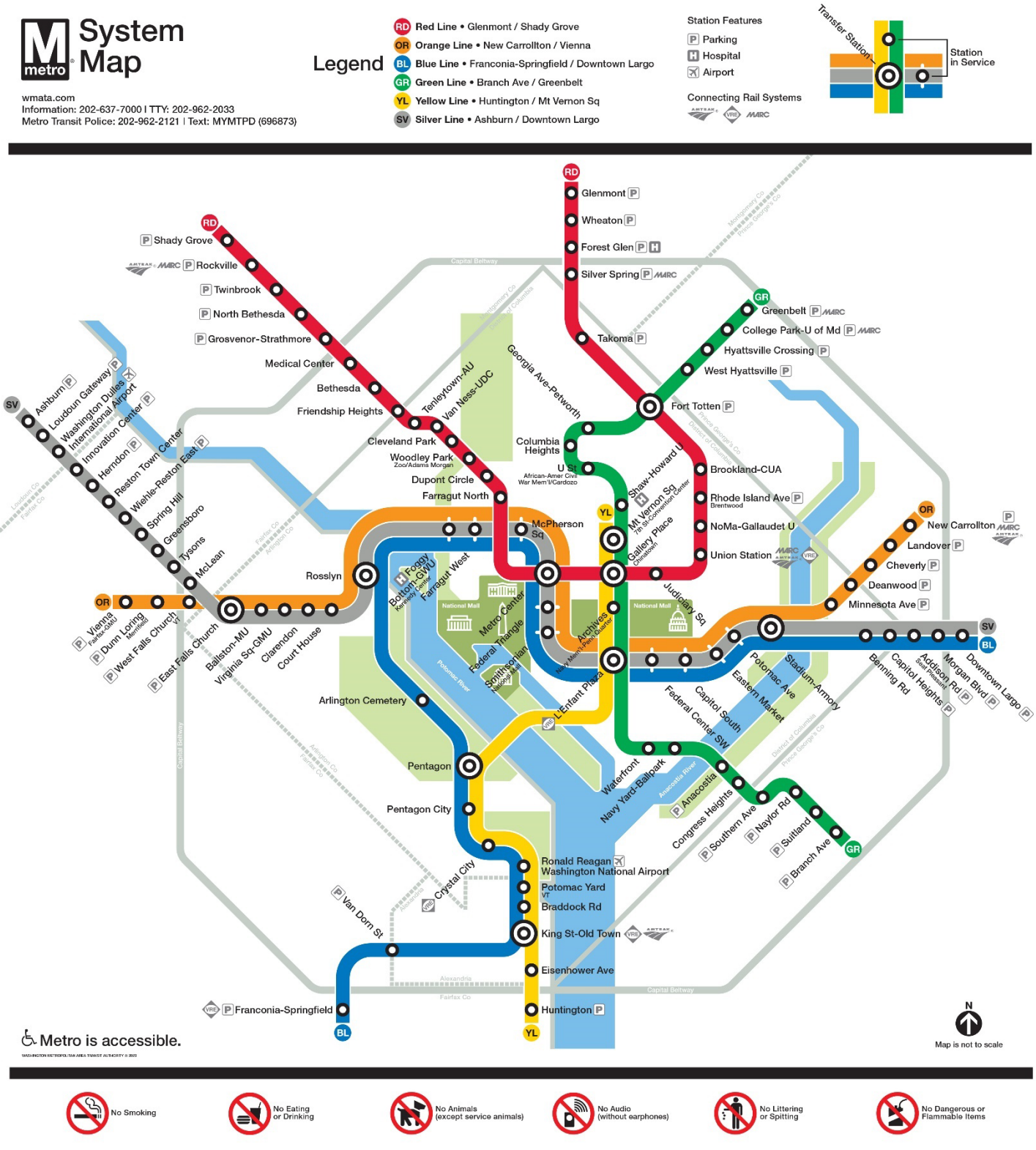
Visitors over 15 years of age must provide a form of government-issued ID such as a driver's license or passport. Visitors under 16 years of age must be accompanied by an adult.

If traveling via Metro or hotel shuttle to Medical Center Metro stop: The Washington D.C. Metro-Rail system Red Line has a station right on the NIH campus, called "Medical Center." Once you're out of the station, it's a short walk to the NIH Visitor Center where you will go through the NIH security procedures and receive a visitor's badge. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://www.ors.od.nih.gov/pes/dats/nihshuttleservices/Pages/shuttle.aspx. Directional signs within Building 31 will guide you to the meeting room

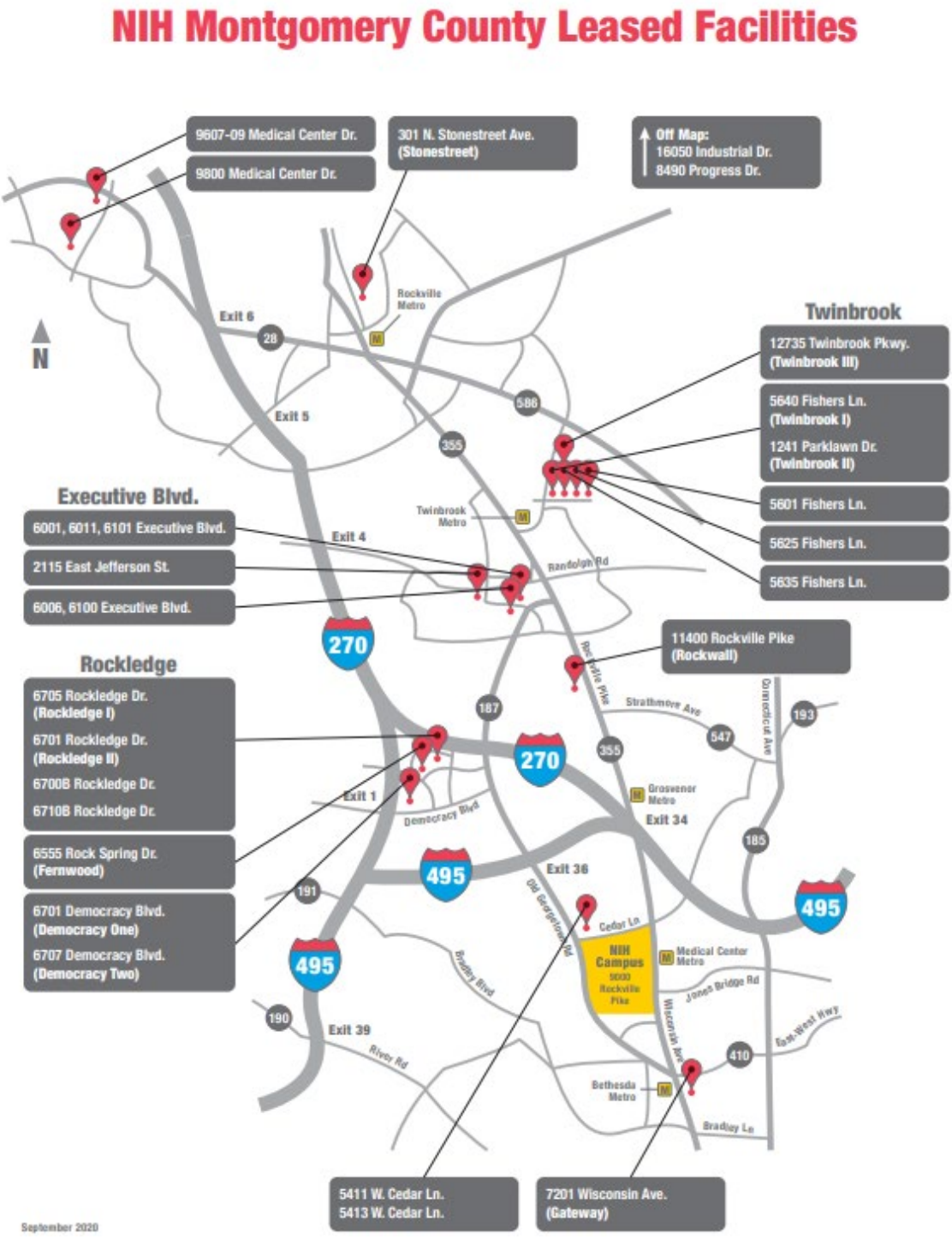
If taking a taxi directly to the meeting site: Upon entering the campus, please let the driver know that you wish to be dropped off in front of Building 31. **The taxi must first go through an NIH security inspection of the car, and you and the driver must go through the security procedures and receive visitor badges**. Directional signs within Building 31 will guide you to the meeting room.

If driving private vehicle to the meeting site: Unless you choose to park in the NIH Gateway Center parking garage, receive your security processing at the Visitor Center, and take a shuttle to Building 31(see **circle** on map), you and your car must first go through security procedures. Visitor parking is located in Lot 53. Parking fees are $12 per day and are fully reimbursable. Directional signs within Building 31 will guide you to the meeting room.

Vehicle and Visitor passes must be prominently displayed at all times while on the NIH campus.


System Map
wmata.com
Information: 202-637-7000 | TTY: 202-962-2033
Metro Transit Police: 202-962-2121 | Text: MYMTPD (696873)
Legend
RD Red Line • Glenmont / Shady Grove
OR Orange Line • New Carrollton / Vienna
BL Blue Line • Franconia-Springfield / Downtown Largo
GR Green Line • Branch Ave / Greenbelt
YL Yellow Line • Huntington / Mt Vernon Sq
SV Silver Line • Ashburn / Downtown Largo
Station Features
Parking
Hospital
Airport
Connecting Rail Systems
Transfer Station
Station in Service
Glenmont
Wheaton
Forest Glen
Silver Spring
Shady Grove
Rockville
Twinbrook
North Bethesda
Grosvenor-Strathmore
Medical Center
Bethesda
Friendship Heights
Tenleytown-AU
Van Ness-UDC
Cleveland Park
Woodley Park
Dupont Circle
Farragut North
McPherson Sq
Takoma
Georgia Ave-Petworth
Columbia Heights
U St
Fort Totten
Greenbelt
College Park-U of Md
Hyattsville Crossing
West Hyattsville
Brookland-CUA
Rhode Island Ave
NoMa-Gallaudet U
Union Station
Shaw-Howard U
Mt Vernon Sq
Gallery Place
Judiciary Sq
New Carrollton
Landover
Cheverly
Deanwood
Minnesota Ave
Downtown Largo
Morgan Blvd
Addison Rd
Capitol Heights
Benning Rd
Stadium-Armory
Potomac Ave
Eastern Market
Capitol South
Federal Center SW
Ashburn
Loudoun Gateway
Washington Dulles International Airport
Innovation Center
Herndon
Reston Town Center
Wiehle-Reston East
Spring Hill
Greensboro
Tysons
McLean
Rosslyn
Foggy Bottom-GWU
Farragut West
Metro Center
Federal Triangle
Smithsonian
Archives
L'Enfant Plaza
Vienna
Dunn Loring
West Falls Church
East Falls Church
Ballston-MU
Virginia Sq-GMU
Clarendon
Court House
Arlington Cemetery
Pentagon
Pentagon City
Crystal City
Ronald Reagan Washington National Airport
Potomac Yard
Braddock Rd
King St-Old Town
Eisenhower Ave
Huntington
Van Dorn St
Franconia-Springfield
Waterfront
Navy Yard-Ballpark
Anacostia
Congress Heights
Southern Ave
Naylor Rd
Suitland
Branch Ave
Metro is accessible.
Map is not to scale
No Smoking
No Eating or Drinking
No Animals (except service animals)
No Audio (without earphones)
No Littering or Spitting
No Dangerous or Flammable Items

Bethesda Area Map Showing NIH Campus and Off-Campus Facilities



Glossary of Terms

For extensive list of grant terms see http://grants.nih.gov/grants/glossary.htm

A

Accession Number – Related to electronic submission of applications, the Accession number is the Agency tracking number provided for the application after Agency validations.

Acquisition – Obtaining supplies or services by the Federal Government with appropriated funds through purchase or lease.

Active Grant – A grant meeting the following criteria: (1) Today's date is between the budget start and end dates; (2) The grant has an eRA System (IMPAC II) application status code of "Awarded. Non-fellowships only." or "Awarded. Fellowships only."

Activity Code – A three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). *See* Funding Mechanisms in NIDDK section of Background Information.

Administrative Expenses – Expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

Administrative I/C – The NIH Institute or Center to which the Center for Scientific Review (CSR) routes NIH grant applications for a funding decision. An I/C may request to change this assignment if the application is more suited to another I/C. Also referred to as primary assignment.

Administrative Supplement – Monies added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.

Amendment (amended or revised applications) – Resubmission of an unfunded application revised in response to a prior review.

Appeal - A procedure for contesting the peer review of a grant application. Synonymous with rebuttal.

Application – A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions.

Application Identification Numbers – The application number identifies: type of application (1); activity code (R01); organization to which it is assigned (DK); serial number assigned by the Center for Scientific Review (CSR) (183723); suffix showing the support year for the grant (-01); other information identifying a supplement (S1), amendment (A1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number. *See* Sample Application Number Graphical Overview of Grants Process.

Application Types – Type 1, New; Type 2, Competing continuation (a.k.a. renewal, re-competing); Type 3, Application for additional (supplemental) support; Type 4, Competing extension for an R37 award or first non-competing year of a Fast Track SBIR/STTR award; Type 5, Non-competing continuation; Type 7. Change of grantee institution; Type 9, Change of NIH awarding Institute or Division (competing continuation.

Appropriation – Law authorizing Federal Agencies to obligate funds and make payments from the U.S. Treasury for specified purposes. Appropriations are in annual acts and permanent law.

Approved Budget – The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the Notice of Grant Award may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.

Award – The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

Awarding Office – The NIH I/C responsible for the award, administration, and monitoring of particular grants.

B

Bilateral Agreement – A general science agreement between the U.S. and a foreign country. Grant applications from institutions in these countries that have been recommended for approval by the scientific review group are given special funding consideration by Council.

Bridge Awards (R56) – Provides limited interim research support based on the merit of a pending R01 application while current researcher or new applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Investigators do not apply for Bridge Awards but are selected from R01 grants at the pay-line margin. A Bridge Award is made as an R56 with 1 year of funding, which the PI can choose to spend over a 2-year period. This enables the PI to submit an amended R01 application for the next receipt date while receiving interim (bridge) funding under the R56 mechanism. Interim funding ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

Budget Appropriation – The yearly amount given to a Government Agency by Congress.

Budget Period – The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

C

Career Development Awards (CDA K Series) – Award supporting Ph.D.'s and clinicians who wish to develop a career in biomedical research.

Capital Expenditure – The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient's regular accounting practices consistently applied regardless of the source of funds.

Clinical Research – Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies using human tissues not linked to a living individual.

Clinical Trial – A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g., 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects); Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety; Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use; Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Close Out – Procedure to officially conclude a grant. Institute staff must ensure necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy; includes the Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.

Co-Funding – Funding arrangement through which two or more Institutes or Centers pay for a grant.

Co-Investigator – An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS). Note: NIH does not recognize the term "co-PI."

Commitment Base – Funds used for non-competing (type 5 or ongoing awards), typically 70-80 percent of the dollars spent for research project grants.

Competing Applications – Either new or re-competing applications that must undergo initial peer review.

Competing Continuation – Application requiring competitive peer review and Institute/Center action to continue beyond the current competitive segment. (Also known as a Renewal or Type 2.)

Competitive Range – Contracting term denoting a group of proposals considered acceptable by the initial peer review group which are potential candidates for an award.

Concept – The earliest planning stage of an initiative [request for applications (RFA), request for proposals (RFP), or program announcement (PA)]. Concepts may be brought before the Advisory Council

for concept clearance. Not all concepts cleared by Council are published as initiatives depending on the availability of funds.

Conflict of Interest – Regulations to ensure Government employees, scientific review group members, Council members, or others having the ability to influence funding decisions have no personal interest in the outcome.

Consortium Agreement – Formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.

Constant Dollars – Dollar amounts adjusted for inflation, based on buying power in a selected base year. The BRDPI is used to determine constant dollars from current dollars.

Contract (R&D) – Award instrument establishing a binding legal procurement relationship between NIH and a recipient obligating the latter to furnish a product or service defined in detail by NIH and binding the Institute to pay for it.

Contracting Officer – Government employee authorized to execute contractual agreements on behalf of the Government.

Cooperative Agreement (U Series) – Support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Council/Board, Advisory – National Advisory Council or Board, mandated by statute, providing the second level of review for grant applications for each Institute/Center awarding grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.

Council Round – At NIH, there are typically three council rounds each fiscal year: September. January/February, and May/June. Application receipt dates, initial review dates, and council review dates all fall within one of these council rounds. Incoming grant applications all are assigned to a council round.

CR (Continuing Resolution) – An Act of Congress to fund or partially fund government operations for a limited period of time, in the absence of an appropriations.

Critique – An overall evaluation of a grant application prepared by a reviewer before an initial peer review meeting and presented to a Scientific Review Group at a meeting.

Current Dollars – Actual dollars awarded, without adjustment for inflation.

D

Direct Costs – Costs that can be specifically identified with a particular project or activity.

Direct Operations – Funds for salary and other administrative costs.

Dual Assignments – Applications simultaneously assigned to two Institutes, Centers, or Divisions. The primary Institute has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Dual Review System – Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an ICD's advisory Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.

E

Early Stage Investigator (ESI) – A Program Director / Principal Investigator (PD/PI) who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously competed successfully as PD/PI for a substantial NIH independent research award. See additional information about NIH ESI policies.

Electronic Research Administration (eRA) – NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. Registration is required.

Enrollment Data – Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began. This data is provided in competing continuation applications and annual progress reports.

Equipment – An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less.

eRA Commons – A secure meeting place on the Web where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants. Registration is required. At this site applicants access the status of their applications and grantees access the status of their awards, submit reports, and make requests electronically

Expiration Date – The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Extramural Research – Research supported by NIH to researchers and organizations outside the NIH through a grant, contract, or cooperative agreement.

F

Facilities and Administrative Costs (F&A) – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "indirect costs."

Federal Acquisition Regulations (FAR) – Laws regulating government contracting.

Federal Advisory Committee Act (FACA) – A law regulating Federal advisory committees to ensure an appropriate balance of scientists and lay persons and minority, geographical, and racial representation.

Federal Register – An official, daily publication communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance.

Federal-Wide Assurance (FWA) – Online form every institution and collaborating institution conducting human subjects research must file with the Office for Human Research Protections—HHS to establish policies and procedures to protect human subjects as required by 45 CFR 46.

Fee – An amount (in addition to actual, allowable costs) paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as "profit."

Fellowship - An NIH training program award where the NIH specifies the individual receiving the award. Fellowships comprise the F activity codes.

Fiscal Year (FY) – The annual period established for Government accounting purposes. A Fiscal Year begins on October 1 and ends September 30 of the following year. Example: FY2023 – Started October 1, 2022 and ends September 30, 2023.

Full-Time Appointment – Number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

G

Gender – Human subject term indicating a classification of research subjects into women and men.

Grant – Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grant Appeals – A DHHS policy providing for an appeal by the grantee institution of post award administrative decisions made by awarding offices. The two levels of appeal are an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.

Grant Project Period – Total period a project has been recommended for support, which may include more than one competitive segment. For example, a project period for a grant begun in 2008 can be divided into competitive segments 2008 to 2012, 2012 to 2016, etc.

Grant Start Date – Official date a grant award begins; same as the first day of the first budget period.

Grantee – Organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Grants Management Officer (GMO) – An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH Institute and Center awarding grants has one or more GMOs with responsibility for particular programs or awards.

Grants Management Specialist (GMS) – An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.

Grants.gov – An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for more than 1,000 competitive grant opportunities from the 26 Federal grant-making Agencies. The Department of Health and Human Services (DHHS) is the managing partner for the Federal Grants.gov initiative, one of 24 initiatives of the overall E-Government program for improving access to Government services via the Internet. Registration is required to apply. Go to http://www.grants.gov/.

H

High Risk/High Impact (HR/HI) – A category of applications identified by a scientific review group as having a high degree of uncertainty in approach but also a high potential for impact. NIH tracks how many of these applications are identified and funded.

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.

Human Subjects Assurance – A document filed by an institution conducting research on human subjects with the Office for Human Research Protections—HHS that formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding.

I

Identifier – Information linking specimens or data to individually identifiable living people or their medical information. Examples include names, social security numbers, medical record numbers, and pathology accession numbers.

Indirect Costs – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "Facility and Administrative Costs."

Information for Management, Planning, Analysis, and Coordination (IMPAC) – A computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs.

Informed Consent – Person's voluntary agreement, based upon adequate knowledge and understanding, to participate in human subjects research or undergo a medical procedure. In giving informed consent, people may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence.

Initial Peer Review Criteria – For application receipt dates before January 25, 2025 (i.e., Council dates through May 2025) the five following review criteria are considered in the overall impact score: ***Significance*** - Is the topic important? Will it advance Scientific Knowledge? ***Approach*** - Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed? ***Innovation*** - Does the proposal involve new ideas or methods; does it challenge existing paradigms? ***Investigator*** - Does the investigator and collaborators have the training and experience to do the work? ***Environment*** - Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations?

For application receipt dates on/after January 25, 2025 (i.e., Council dates starting with September 2025 Council) the criteria are reorganized into three "Simplified Peer Review Framework" factors:

- ***Factor 1 : Importance of the Research***
  - Significance, Innovation
  - Scored 1 - 9
- ***Factor 2 : Rigor and Feasibility***
  - Approach (also includes Inclusion and Clinical Trial (CT) Study Timeline)
  - Scored 1 - 9
- ***Factor 3 : Expertise and Resources***
  - Investigators, Environment
  - Evaluated as appropriate or gaps identified; gaps require explanation
  - Considered in overall impact; no individual score

See Simplified Peer Review Framework for full details.

Initiative – A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating the Institute or Center's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not. *See* Notice of Funding Opportunity (NOFO).

Institutional Base Salary – The annual compensation paid by an applicant/grantee organization for an employee's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

Institutional Review Board (IRB) – IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under their auspices. IRBs make an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.

Interagency Agreement – Formal agreement among Government agencies to collaborate on and fund research; Y series activity code.

Integrated Review Group (IRG) – A cluster of study sections responsible for the review of grant

applications in scientifically related areas. These study sections share common intellectual and human resources.

Internet Assisted Review (IAR) - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing. Allows Reviewers, SROs, and GTAs to view all critiques in preparation for a meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRO or GTA.

Intramural Research - Research conducted by, or in support of, employees of the NIH.

Investigational New Drug (IND) – Status given by the FDA to a new drug or biological product to be used in a clinical investigation.

Investigator-Initiated Research – Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees. Its opposite is targeted research.

J

Just-In-Time – Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred. Through this module, institutions can electronically submit the information that is requested after the review, but before award.

K

Key Personnel – The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. “Zero percent” effort or “as needed” is not an acceptable level of involvement for key personnel.

M

Matching or Cost Sharing – The value of third party in-kind contributions and the portion of the costs of a federally assisted project of program not borne by the Federal Government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH Institute or Center. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

Mechanism – Another term for Activity Code.

Minority Group – Human subject term indicating a subset of the U.S. population distinguished by racial, ethnic, or cultural heritage. Categories are: American Indian or Alaskan Native, Asian, black or African American, Hispanic or Latino, and Native Hawaiian and other Pacific Islander. Inclusion of a group should be determined by the scientific questions under examination and their relevance. Not every study will include all minority groups or subpopulations.

Model Organism – Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms.

Modular Application – A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

Monitoring – A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

Multiple Principal Investigator – Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution.

N

New Application (award, grant) – Refers to an application not previously proposed, or one that has not received prior funding. Also known as a Type 1.

New Investigator – New investigator is an individual who has not previously competed successfully for an NIH-supported research project other than the following small or early stage research awards: Pathway to Independence Award-Research Phase (R00); Small Grant (R03); Academic Research Enhancement Award (R15); Exploratory/Developmental Grant (R21); Clinical Trial Planning Grant (R34); Dissertation Award (R36); Small Business Technology Transfer Grant-Phase I (R41); Small Business Innovation Research Grant-Phase I (R43); Shannon Award (R55); NIH High Priority, Short-Term Project Award (R56). Additionally, an individual is not excluded from consideration as a "New Investigator" if he/she has received an award from the following classes of awards: Training-Related and Mentored Career Awards; Fellowships (F05, F30, F31, F32, F34, F37, F38); Mentored-career awards (K01, K08, K22, K23, K25, K99-R00; Other mentored career awards (developmental K02 as used by NINDS and the developmental K07); Loan repayment contracts (L30, L32, L40, L50, L60). Note: Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are not considered new investigators. *See* Early Stage Investigator.

Non-Competing Continuation – A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review but are administratively reviewed by the Institute/Center and receive an award based on prior award commitments. Also known as a Type 5.

Non-Competing Grant – An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Notice of Award (NoA) – The legally binding document notifying the grantee and others that an award has been made. The NoA contains or references all terms and conditions of the award documenting the obligation of Federal funds and may be in letter format and may be issued electronically. Previously known as Notice of Grant Award (NGA).

Notice of Funding Opportunity (NOFO)—*See* Initiative.

Not Recommended for Further Consideration (NRFC) – A judgment made by a scientific review group for applications when the merit of the proposed research is not significant and substantial enough to warrant a further review. The study section does not recommend funding; the application cannot be funded by an Institute.

O

Obligation – Data based on NIH funds that have been awarded by an NIH Institute/Center.

Office of Extramural Research (OER) – NIH office overseeing policies and guidelines for extramural research grants.

Office for Human Research Protections (OHRP) – HHS office overseeing human subject protection for HHS-supported research.

Office of Laboratory Animal Welfare (OLAW) – NIH office overseeing compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Office of Management and Budget (OMB) – Executive Branch office assisting the U.S. president in preparing the Federal budget, evaluating agency programs and policies, and setting funding priorities. In setting policy, OMB issues Government-wide policy directives, called circulars that apply to grants.

On Time – Applications are on time if successfully submitted to Grants.gov by 5 p.m. local time on the date indicated. Note: When these dates fall on a weekend or a federal holiday, they are extended to the next business day.

Organization – A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.

Organizational Code – A two-letter code in the grant number identifying the first major-level subdivision of the funding organization. NIDDK's organizational code is DK.

Other Research Grants – Research grants not classified as research projects or research centers.

Other Support – Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.

Overlap of Support – Other support duplicating research or budgetary items already funded by an NIH grant. Overlap also occurs when any project-supported personnel has time commitments exceeding 12 person months.

P

Program Announcement Reviewed in an Institute (PAR) – Program Announcement with special receipt, referral and/or review considerations.

Parent Announcement – NIH-wide funding opportunity announcement enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism [e.g., Research Project Grant (Parent R01)].

Payback – Time and effort fellows and T32 trainees must repay the Government. During the first year, trainees owe one month of payback for every month of support; then they start paying back one month for every month worked.

Payline – A percentile-based funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications coming to an NIH Institute with the amount of funds available.

Peer Review – A system for evaluating research applications using reviewers who are the professional equals of the applicant.

Percentile – Represents the relative position or rank of each priority score (along a 100.0 percentile band) among the scores assigned by a particular study section.

Person Months – Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort.

Pre-application – A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.

President's Budget – The annual budget request submitted to Congress by the U.S. President. The process begins with a budget request from the IC, which, as part of the entire NIH budget request, is modified by the Office of Management and Budget.

Principal Investigator – An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity. Also known as Program Director or Project Director.

Prior Approval – Written approval from the designated Grants Management Officer (GMO) required for specified post award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds.

Priority score – A numerical rating that reflects the scientific merit of the proposed research relative to stated evaluation criteria.

Privacy Act – A law protecting against needless collection or release of personal data. Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Program - A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs carrying out their missions through the award of grants or cooperative agreements to other organizations.

Program Announcement (PA) – An announcement by an NIH Institute or Center requesting applications in the stated scientific areas. Program Announcements (PA) are published in the NIH Guide for Grants and Contracts.

Program Balance – The need to balance an Institute's support of research in all its programmatic areas with its high-quality applications eligible for funding.

Program Classification Code (PCC) – An internal code unique for each I/C indicating the I/C's scientific interest and used to identify internal programs, branch classifications, the science or disease

area, and sometimes program officials.

Program Official (PO) – The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

Programmatic Reduction – The dollar amount a grant award is reduced from the amount recommended by the study section (scientific review group). This is done so Institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Progress Number – Commonly referred to as the application number or grant number, depending upon its processing status. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code.

Project Period – The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and non-competing extensions.

Protocol – Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

Public Access Policy – The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states: *The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication:* Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.*

PubMed – Provides access to citations from biomedical literature. It includes over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s, along with links to full text articles and other scientific resources. These citations are indexed with a PMCID, a series of numbers.

R

Rating Criteria – *See* Initial Peer Review Criteria.

Real Property – Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.

Rebuttal – Procedure for contesting the peer review of a grant application. Synonymous with appeal.

Receipt, Referral, and Assignment of Applications – Routing of applications arriving at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an Institute and refer it to a scientific review group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self-assign.

Recipient – Organizational entity or individual receiving a grant or cooperative agreement. *See* Grantee.

Recommended – Designation given by a study section advising funding of an application. The

application gets a priority score and summary statement. Roughly the top half of applications being reviewed are recommended for funding.

Recommended Levels of Future Support – Funding level recommended for each future year approved by the scientific review group, subject to availability of funds and scientific progress.

Re-Competing – Grant whose term (e.g., 4 years) is over and for which the applicant is again seeking NIH support. Also known as type 2, competing continuation application, and renewal.

Request for Application (RFA) – The official statement inviting grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.

Request for Proposals (RFP) – Announces that NIH would like to award a contract to meet a specific need, such as the development of an animal model. RFPs have a single application receipt date and are published in the NIH Guide for Grants and Contracts.

Research – A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed “research and development.”

Research Grants – Extramural awards made for Other Research Grants, Research Centers, Research Projects, and SBIR/STTRs. Includes the following: R,P,M,S,K,U series (excluding UC6) DP1, DP2, D42, G12.

Research Misconduct – Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Research Portfolio – The cohort of grants supported by a given NIH organization.

Research Projects – Includes the following selected Research Grant and Cooperative Agreement activities: R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, P01, P42, PN1, U01, U19, UC1, NIGMS P41.

Research Project Grant (RPG) – Supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies. *See* Research Projects.

Research Supplement – Monies adding funds to an existing grant to support and promote diversity, people with disabilities, and people returning to work from family responsibilities.

Restriction – Special term and condition in a Notice of Award or article in a contract that limits activities and expenditures for human subjects or animal research. It may be lifted or adjusted after the award if the requirements are met.

Resubmission – Grants.gov term for a grant application resubmitted to NIH after a PD/PI applicant who did not succeed in getting funded revises it based on feedback from the initial peer review. Previous NIH term was "revision." A resubmission has an entry in its application identification number (e.g., A1).

Review Cycle – Refers to the Center for Scientific Review's thrice yearly initial peer review cycle, from the receipt of applications to the date of the review.

Revision – Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review. The NIH term has been "competing supplemental." NOTE: The former NIH term, "revision," is now “resubmission” in Grants.gov.

S

Salary Cap/Limitation – A legislatively mandated provision limiting the direct salary (also known as salary or institutional base salary but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts.

Scientific Overlap – Overlap of support occurs when substantially similar research is proposed in more than one concurrent PHS grant application.

Scientific Review Officer (SRO) – Federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.

Scientific Review Group (SRG) – The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award. Also known as Study Section.

Scored – In the peer review process, applications judged by a study section to be competitive (i.e., generally in the upper half of the applications reviewed). These applications are assigned a priority score and forwarded to the appropriate Institute/Center for the second level of review.

Selective Pay – The funding of a small number of programmatically important applications at the margin of the payline as recommended by Council.

Set-Aside – Money taken out of the budget for a specific purpose, for example, to fund a congressionally mandated program.

Sex as a Biological Variable (SABV) – NIH expects that sex as a biological variable will be factored into research designs, analyses and reporting in vertebrae animals and human studies. See: Consideration of Sex as a Biological Variable in NIH-funded Research: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html

Signing Official (SO) – Person with has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The SO can register the institution and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information.

An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Small Business Concern – A business independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 Code of Federal Regulations (CFR) Part 121.

Small Business Innovation Research (SBIR) – A program designed to support small business concerns conducting innovative research/research & development with potential for commercialization. For the computation of success rates, SBIR awards are not included in the count of RPGs.

Small Business Technology Transfer (STTR) – A program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution. For the computation of success rates, STTR awards are not included in the count of RPGs.

Special Council Review (SCR) – Advisory Council members provide additional consideration of new and renewal applications from well-supported investigators who currently receive $2 million or more in total costs of NIH funding for RPGs. See: Notice of Change to NIH's Policy on Special Council Review of Research Applications: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-049.html

Special Emphasis – The NIDDK's policy to set aside funds that are used by the respective program divisions to fund meritorious grants whose competitive position places them beyond the established regular payline. It is the responsibility of the respective program divisions to identify such grants and through its established review procedures to determine which grants meet the Special Emphasis (SE) criteria and receive Subcommittee endorsement for funding. Each such application is then nominated for the Division Director's concurrence and approval by the Institute Director.

Special Government Employee (SGE) – A Special Government Employee is an officer or employee who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for not more than 130 days during any period of 365 consecutive days. This category should be distinguished from other categories of individuals who serve executive branch agencies but who are not employees, such as independent contractors.

Specific Aims – A component of an application's Research Plan which describes concisely and realistically what the proposed research or activity intends to accomplish by the end of the grant. Includes broad, long-term goals; hypothesis or hypotheses to be tested; and specific time-phased research objectives (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology).

Statement of Work (SOW) – In a contract proposal, the detailed description of the work to be performed under the contract.

Streamlined Non-Competing Award Process (SNAP) – Simplified process for the submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period. All NIH award notices identify whether the

grant is subject to or excluded from SNAP.

Streamlined Review (formerly Triage) – In the CSR peer review process, applications judged by a study section to be in the lower half of the applications evaluated in a given review round. These applications are generally not discussed during the study section meeting but returned to the applicant with the assigned reviewers' written comments with no priority score. *See* Unscored.

Study Section – Panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Also called scientific review group (SRG) or initial review group (IRG).

Subaward – Collaborative arrangement in support of a research project in which part of an activity is carried out through a formal agreement between a grantee and one or more other organizations. Also known as consortium agreement.

Success Rate – Indicates the percentage of reviewed RPG applications receiving funding computed on a fiscal year basis. It is determined by dividing the number of competing applications funded by the sum of the total number of competing applications reviewed and the number of funded carryovers. NOTE: Applications having one or more amendments in the same fiscal year are only counted once. Success rate computations exclude SBIR/STTRs.

Success Rate Base – The basis for computing the Research Project Grant (RPG) success rate. It includes the total number of competing applications reviewed (the number of applications subjected to a streamlined review process). Also known as Rate Base.

Summary Statement – A combination of the reviewers' written comments and the Scientific Review Administrator’s (SRA's) summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Supplement – A request for additional funds either for the current operating year or for any future year recommended previously. Also known as a Type 3, application or award, a supplement can be either non-competing (administrative) if there is no change in scope or competing revision (subject to peer review) to support new or additional activities that are not identified in the current award.

T

Targeted Research – Research funded as a result of an Institute set-aside of dollars for a specific scientific area. Institutes solicit applications using research initiatives (RFAs for grants, RFPs for contracts). Targeted research applications are reviewed by chartered peer review committees within Institutes. The opposite is Investigator-Initiated Research.

Technology Transfer – Sharing of knowledge and facilities among Federal laboratories, industry, universities, Government, and others to make federally generated scientific and technological advances accessible to private industry and State and local governments.

Terms and Conditions of Award – All legal requirements imposed on a grant by NIH, whether based on statue, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The Notice of Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Tethered Application/Grant – When applications are submitted for multiple PI's from multiple organizations, the application from the partnering Institutions are associated and reviewed as a single project. If an award is made, each of the involved institutions will receive a separate grant to fund the collaborative project. All applications are linked by a common project title and by cross-references within each application.

Total Project Costs – The total allowable costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

Training Awards – Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as help professional schools to establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F).

Translational Research – Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Triage – *See* Streamlined Review

Type – *See* Application Types.

U

Underrepresented Group – Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders. Used as an eligibility requirement for diversity supplements, fellowships (F31), and other NIH programs.

Unscored – In the NIH peer review process, applications judged by a study section to be in the lower half of the applications to be reviewed. These applications are not given a priority score, although they are reviewed, and applicants receive a summary statement.

V

Validation – The systematic check of applications against the NIH application guide and Funding Opportunity Announcement instructions. The process can generate errors or warnings.

W

Withholding of Support – A decision by NIH not to make a non-competing continuation award within the current competitive segment.

Book of NIH Abbreviations and Acronyms

Letter Codes Designating Funding for NIH Institutes, Centers in Grant Applications

Abbreviation	NIH Institutes, Centers	Letter Code Designating Funding Institute In Grant Applications
CC	Clinical Center*	
CIT	Center for Information Technology*	
CSR	Center for Scientific Review*	
FIC	John E. Fogarty International Center	**TW**
NCATS	National Center for Advancing Translational Sciences	**TR**
NCCIH	National Center for Complementary and Integrative Health	**AT**
NCI	National Cancer Institute	**CA**
NEI	National Eye Institute	**EY**
NHGRI	National Human Genome Research Institute	**HG**
NHLBI	National Heart, Lung, and Blood Institute	**HL**
NIA	National Institute on Aging	**AG**
NIAAA	National Institute on Alcohol Abuse and Alcoholism	**AA**
NIAID	National Institute of Allergy and Infectious Diseases	**AI**
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	**AR**
NIBIB	National Institute of Biomedical Imaging and Bioengineering	**EB**

*** Does Not Make Extramural Awards**

Abbreviation	NIH Institutes, Centers, Offices	Letter Code Designating Funding Institute In Grant Applications
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development	**HD**
NIDA	National Institute on Drug Abuse	**DA**
NIDCD	National Institute on Deafness and Other Communication Disorders	**DC**
NIDCR	National Institute of Dental and Craniofacial Research	**DE**
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	**DK**
NIEHS	National Institute of Environmental Health Sciences	**ES**
NIGMS	National Institute of General Medical Sciences	**GM**
NIH	National Institutes of Health	
NIMH	National Institute of Mental Health	**MH**
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)	**MD**
NINDS	National Institute of Neurological Disorders and Stroke	**NS**
NINR	National Institute of Nursing Research	**NR**
NLM	National Library of Medicine	**LM**
OD	Office of the Director	**OD**

Acronym	Definition
A	
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
AALAS	American Association for Laboratory Animal Science
AAMC	Association of American Medical Colleges
AAP	American Academy of Pediatrics
AAPHP	American Academy of Pediatrics
ABL	Applied BioScience Laboratories for Acquired Immunodeficiency Syndrome
ABRCMS	Annual Biomedical Research Conference for Minority Students
ABSL	American Bio-Safety Level
ACD	Advisory Committee to the Director
ACEP	American College of Emergency Physicians
ACF	Administration for Children and Families (DHHS)
ACGME	Accreditation Council for Graduate Medical Education
ACPM	American College of Preventive Medicine
ACR	American College of Radiology
ACS	American Cancer Society
ACS	American College of Surgeons
ACSI	American Customer Satisfaction Index
ACSR	AIDS and Cancer Specimen Resource, NCI
ACTG	AIDS Clinical Trials Group
ACTIS	AIDS Clinical Trials Information Service
ACTU	AIDS Clinical Trials Unit
ACUC	Animal Care and Use Committee
ADAMHA	Alcohol Drug Abuse and Mental Health Administration (now **SAMSHA**)

ADB	Automated Data Base System
ADB	Administrative Database System (NIH)
ADC	AIDS Dementia Complex
ADCR	Associate Director for Clinical Research
ADD	Attention Deficit Disorder
AdEERS	Adverse Event Expedited Reporting System
ADP	Automated Data Processing
ADR	Adverse Drug Reactions
ADR	Alternative Dispute Resolution
AE	Adverse Event
AER	Adverse Event Reporting
AFGE	American Federation of Government Employees
AFIP	Armed Forces Institute of Pathology
AFIP	Animal Facilities Improvement Program
AFL/CIO	American Federation of Labor/Congress of Industrial Organizations
AGEMAP	Atlas of Gene Expressions in Mouse Aging Project
AGRICOLA	AGRICultural OnLine Access
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AI	Amelogenesis Imperfecta
AI/ANO	American Indian/Alaskan Native Organization
AID	U.S. Agency for International Development
AIDS	Acquired Immunodeficiency Syndrome
AIDSinfo	HHS AIDS information Web site
AIEDRP	Acute Infection and Early Disease Research Program

AIRO	Agency Intramural Research Integrity Officer
AIRO	American Indian Research Opportunities
AITRC	Allergy, Immunology, and Transplantation Research Committee
AITRP	AIDS International Training and Research Program, FIC
AJCC	American Joint Committee on Cancer
AL	Annual Leave
ALAT	Assistant Laboratory Animal Technician (Certified by AALAS)
ALERT system	HHS system for disseminating information to Public Health Service officials about organizations or people charged with or found to have engaged in scientific misconduct (PHS)
ALA	Assistance Living Number
AMA	American Medical Association
AMB	AIDS Malignancy Bank
AMC	AIDS Malignancy Consortium
AMC	Acquisition Management Committee
AMD	Age-related Macular Degeneration
AMHPS	Association of Minority Health Professionals Schools
AMIA	American Medical Informatics Association
AMLCD	Active matrix liquid crystal display
AMSSC	Administrative Management Systems Steering Committee
AMWG	AIDS Malignancies Work Group
ANL	Argonne National Laboratory, Argonne, IL
ANPR	Advance Notice of Proposed Rulemaking
ANSI	American National Standards Institute
AO	Administrative Official/ Administrative Office/ Administrative Officer
AOA	Administration on Aging
AP	Acquisition Plan
APA	Administrative Program Assistant

APAC	Annual Payback Activities Certification
APAO	Asian and Pacific Islander American Organization
APC	NIH Purchase Card Program Agency Program Coordinator
APD	Animal Program Director
APHA	American Public Health Association
APHIS	USDA - Animal and Plant Health Inspection Service
API	Application Programming Interfaces
APN	Advanced Practice Nursing
ARA	Awaiting Receipt of Application
ARAC	Administrative Restructuring Advisory Committee/Work Group on Acquisition
ARAC	AIDS Research Advisory Committee (NIAID)
ARB	Architecture Review Board
ARC	Administrative Resource Center
AREA	NIH Academic Research Enhancement Award (R15)
ARL	U.S. Army Research Laboratory
ARND	Alcohol-related Neurodevelopmental Disorder
ARRA	American Recovery and Reinvestment Act of 2009
ARRR	AIDS-Related Research Review
ARS	Agriculture Research Service
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASAP	As Soon As Possible
ASB	Administrative Services Branch
ASBTF	Assistant Secretary for Budget, Technology and Finance
ASDC	Administrative Skills Development Curriculum

ASH	Assistant Secretary for Health, PHS
ASI	Addiction Severity Index
ASP	Animal Study Proposal
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPER	Assistant Secretary for Personnel Administration, DHHS
ASPH	Association of Schools of Public Health
ASTHO	Association of State and Territorial Health Officials
AT	Administrative Technician
ATCC	American Type Culture Collection, Manassas, VA
ATI	Analytic Treatment Interruption
ATIS	AIDS Treatment Information Service
ATPM	Association of Teachers and Preventive Medicine
ATSDR	Agency for Toxic Substances and Disease Registry
AVEG	AIDS Vaccine Evaluation Group
AVEU	AIDS Vaccine Evaluation Unit
AVRC	AIDS Vaccine Research Committee
AWA	Animal Welfare Act
AWOL	Absence Without Official Leave
AWS	AIDS-associated Wasting Syndrome
AZT	Zidovudine (generic name) or Azidothymidine

B

B&F	Buildings and Facilities
B&P	Bid and Proposal
B/Start	Behavioral Science Track Award for Rapid Transition

BAA	Broad Agency Announcement
BAFO	Best and Final Offer
BARC	Beltsville Agricultural Research Center
BBBP	Biobehavioral and Behavioral Processes
BC	Biomarker Consortium
BC/BS	Blue Cross/Blue Shield
BCP	Best Community Practice and Biophysical and Chemical Sciences
BCS	Biochemical Sciences
BDCN	Brain Disorders and Clinical Neuroscience
BDP	Biopharmaceutical Development Program
BDR	Budget Data Request
BEA	Bureau of Economic Analysis
BECON	Bioengineering Consortium (NIH OD)
BEMIS	Biomaterials and Medical Implant Science
BEP	Bureau of Engraving and Printing
BESA	Border Epidemiologic Study of Aging
BEST	Biomonitoring of Environmental Status and Trends
BFRL	Building and Fire Research Laboratory
BGCRG	Breast and Gynecologic Cancer Research Group
BHPr	Bureau of Health Professions
BIA	Bureau of Indian Affairs
BIC	Business Information Center
BIG	Blacks in government
BIGR	Biomaterials and Information for Genomic Research™ (Ardais Corporation)
BIMAS	Bioinformatics Molecular Analysis Section

BIO	Biotechnology Industry Organization
BIRADS	Breast Imaging Reporting and Data System
BIRN	Biomedical Informatics Research Network
BIS	Bureau of Industry and Security
BISM	Blind Industries and Services of Maryland
BISTI	Biomedical Information Science and Technology Initiative
BISTIC	Bioinformatics Consortium (NIH OD)
BITS	Business Information Technology System
BJA	Bureau of Justice Assistance
BJS	Bureau of Justice Statistics
BL-3	Biosafety Level 3
BLA	Biologics License Application
BLIRC	Biomedical Library and Informatics Review Committee
BLM	Bureau of Land Management
BLS	Board on Life Sciences
BLS	Bureau of Labor Statistics
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BMDO	Ballistic Missile Defense Organization
BML	Biological Material License
BMMR	Biological Models and Materials Research
BMO	Business Management Office
BNA	Bureau of National Affairs
BNL	Brookhaven National Laboratory, Upton, NY (Department of Energy Organization)
BOA	Basic Ordering Agreement
BOG	Board of Governors, NIH

BOP	Federal Bureau of Prisons
BOR	Board of Regents
BOR	Bureau of Reclamation
BoS	Board of Survey
BPA	Blanket Purchase Agreement
BPD	Bureau of Public Debt
BPH	Benign Prostatic Hyperplasia
BPHC	Bureau of Primary Health Care
BPSRG	Basic Prevention Science Research Group
BRB	Benefits Review Board
BRCA	Breast Cancer
BRD	Biological Resource Division,
BRDPI	Biomedical Research and Development Price Index, measures real annual changes in the prices of items and services required for research and development (R&D) activities
BRFSS	Behavioral Risk Factor Surveillance System
BRG	Biometry Research Group
BRIN	Biomedical Research Infrastructure Network
BRMP	Biological Response Modifiers Program
BSA	Board of Scientific Advisors
BSC	Board of Scientific Counselors
BSC	Business Service Centers
BSI	Brief Symptom Inventory
BSL	Bio-Safety Level
BSSC	Behavioral and Social Sciences Coordinating Committee
BTP	Biotechnology Training Program
BTR	Biomedical Technology Resource

BTS	Bureau of Transportation Statistics
BVA	Board of Veterans Appeals

C

CAM	Complementary and Alternative Medicine
CBER	Center for Biologics Evaluation and Research
CBIAC	Chemical and Biological Defense Information Analysis Center
CBO	Congressional Budget Office
CBT	Computer-Based Training
CC	Warren Grant Magnuson Clinical Center, NIH
CCB	Configuration Control Board
CCB	Child Care Bureau
CCC	Commodity Credit Corporation
CCO	Chief Contracting Officer
CCR	Center for Career Resources (OD)
CCR	Center for Cooperative Resolution
CCR	Commission on Civil Rights
CCSS	Childhood Cancer Survivor Study
CCTAT	Cooperative Clinical Trials in Adult Kidney Transplantation
CCTPT	Cooperative Clinical Trials in Pediatric Kidney Transplantation
CDA	Confidential Disclosure Agreement
CDBG	Community Development Block Grants
CDC	Centers for Disease Control and Prevention, PHS (Public Health Service)
CDE	Common Data Element
CDER	Center for Drug Evaluation and Research

CDFI	Community Development Financial Institutions
CDHR	Center for Devices and Radiological Health
CDMC	Central Data Management Center
CDMRP	Congressionally Directed Medical Research Program
cDNA	Complementary DNA
CDs	Communication Directors
CES	Central E-mail Service
CDP	Career Development Plan
CDR	Clinical Drug Request
CDUS	Clinical Data Update System
CDW	Consultant Days Worked
CEA	Council of Economic Advisers
CEC	Contractor Establishment Code
CEDR	Comprehensive Epidemiologic Data Resource
CEGS	Centers of Excellence in Genomic Science
CEL	Commercial Evaluation License
CEN	Bureau of the Census
CEPPO	Chemical Emergency Preparedness and Prevention Office
CEPS	Center for Earth and Planetary Studies
CEQ	Council on Environmental Quality
CERCLIS	Comprehensive Environmental Response, Compensation, & Liability Information System
CETEC	Topographic Engineering Center
CF	Consent Form
CFAR	Centers for AIDS Research
CFC	Combined Federal Campaign

CFDA	Catalog of Federal Domestic Assistance, a database that helps the Federal Government track all programs it has domestically funded. Federal programs are assigned a number in the database called the “CFDA number.” Now called ALA – see ALA above.
CFO	Chief Financial Office
CFOC	Chief Financial Officers Council
CFR	Code of Federal Regulations
CFS CRC	Chronic Fatigue Syndrome Cooperative Research Centers
CFSAN	National Center for Food Safety and Applied Nutrition
CGAP	Competitive Grant Application Process
CGH	Comparative genomic hybridization
CHAMPVA	Civilian Health and Medical Program of the Department of Veterans Affairs
CHB	Community Health Branch (DOHS)
CHID	Combined Health Information Database
ChiMP	NIH Chimpanzee Management Program
CHIMP	Chimpanzee Health, Improvement, Maintenance and Protection Act
CHTN	Cooperative Human Tissue Network
CIAO	Critical Infrastructure Assurance Office
CIC	Consumer Information Center
CID	Center of Infectious Diseases (CDC)
CIDI	Composite International Diagnostic Interview (Clinical Trials Standard)
CIO	Chief Information Officer
CIPRA	Comprehensive International Program for Research on AIDS
CIS	Cancer Information Service
CISET	Committee on International Sciences, Engineering, and Technology
CIT	Center for Information Technology
CJD	Creutzfeldt-Jakob Disease

CLC	Community Liaison Council
CLIA	Clinical Laboratories Improvement Act
CLM	Council of Logistics Management
CMAB	Complaints Management and Adjudication Branch (OEO)
CMAP	Cancer Molecular Analysis Project
CMB	Comparative Medicine Branch
CMBD	Collection Management & Delivery Branch (DLS)
CME	Continuing Medical Education
CMHS	Center for Mental Health Services
CML	Chronic Myeloid Leukemia
CMO	Committee Management Officer, IC person responsible for the oversight of all NIH Federal advisory committees under the auspices of the Federal Advisory Committee Act; responsible for developing committee charter, preparing nomination and appointment documents for membership to committees, providing technical assistance to committee members, providing initial review of conflict of interest disclosures, etc.
CMP	Contract Management Program
CMP/HMO	Comprehensive Medical Plans/Health Maintenance Organizations
CMPP	Center for Nutrition Policy and Promotion
CMS	Centers for Medicare and Medicaid Services
CMSP	Cooperative Medical Sciences Program
CMV	Center for Minority Veterans
CNCRIT	Collaborative Network for Clinical Research on Immune Tolerance
CNS	Central Nervous System
CO	Contracting Officer
COB	Close of Business
COBRE	Centers of Biomedical Research Excellence
CoC	Commission on Cancer

CoC	Council of Councils
COC	Certificate of Confidentiality
COG	Children's Oncology Group
COGA	Collaborative Study on the Genetics of Alcoholism
COI	Conflict of Interest
COLA	Cost of Living Allowance
CONSER	Cooperative Online Serials
COOG	Continuity of Operations Group
COOP	Continuity of Operations Plan
COP	Continuation of Pay
COP	Costal Ocean Program
COPR	Council of Public Representatives (serves NIH Director)
COPS	Office of Community Oriented Policing Services
COPTRG	Community Oncology and Prevention Trials
COR	Career Opportunities in Research Education and Training
COSEPUP	Committee on Science Engineering and Public Policy
COTA	Career Opportunities Training Agreement (HHS)
COTS	Commercial Off-The-Shelf Software Products
CPA	Cooperative Project Assurance
CPAF	Cost Plus Award Fee
CPDF	Central Personnel Data File
CPE	Continuing Professional Education
CPFP	Cancer Prevention Fellowship Program
CPI	Consumer Price Index
CPIF	Cost Plus Incentive Fee

CPMS	Defense Civilian Personnel Management Service
CPO	Corrections Program Office
CPS	Contractor Performance System
CPS	Center for Prevention Services (CDC)
CPSC	Consumer Product Safety Commission
CR	Continuing Resolution
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement
CRC	Cooperative Research Center
CRC	Civil Rights Center
CRC	New Clinical Research Center
CRF	Case Report Form (Source Document for Clinical Studies)
CRIB	Central Institutional review Board
CRIC	Chronic Renal Insufficiency Cohort
CRIS	Clinical Research Information System
CRISP	Computer Retrieval of Information on Scientific Programs, A searchable biomedical database of federally supported proposed research conducted at universities, hospitals, institutions, etc.
CRL	Charles River Laboratories
CRM	Customer Relations Manager
CRO	Contract Research Organization
CRP	Conference Room Pilot
CRP	Conservation Reserve Program
CRS	Congressional Research Service
CRS	Clinical Research Scholar
CRS	Community Relations Service
CRTA	Cancer Research Training Award

CRTP	Clinical Research Training Program
CRVP	Clinical Research Volunteer Program
CS	Contract Specialist
CSAC	Central Services Advisory Committee
CSAP	Center for Substance Abuse Prevention
CSAT	Center for Substance Abuse Treatment
CSB	Customer Service Branch (DMAPS)
CSB	Chemical Safety and Hazard Investigation Board
CSD	Client Services Division
CSE	Office of Child Support Enforcement
CSI	Center for the Study of Intelligence
CSR	Center for Scientific Review
CSREES	Cooperative State Research, Education, and Extension Service
CT	Computed Tomography
CTA	Clinical Trial Agreement
CTAG	Clinical Translation Advisory Group
CTC	Common Toxicity Criteria
CTEP	Clinical Therapeutic Evaluation Program
CTEP	Cancer Therapy Evaluation Program
CTN	National Drug Abuse Treatment Clinical Trials Network
CTP	Community Treatment Program
CTSA	Clinical and Translational Science Awards
CTSU	Clinical Trials Support Unit
CU	Coordinating Unit
CUAP	College and University Affiliations Program

Cumulus SPMS	Cumulus Slide/Presentation Management System
CVS	Cardiovascular Sciences
CVS	Chorionic Villus Sampling
CWC	Chemical Weapons Convention
CWD	Chronic Wasting Disease
CY	Calendar Year

D

D&A	Design and Analysis Workgroup
D&B	Dun & Bradstreet Number
DAP	Division of Acquisition Programs, OLAO
DARPA	Defense Advanced Research Projects Agency
DASAM	Deputy Secretary for Administration and Management
DASPA	Division of Advanced Studies and Policy Analysis
DB	Design Branch (DMAPS)
DBASSE	Division of Behavioral and Social Sciences and Education
DBBD	Division of Biological Basis of Disease
DBDR	Division of Blood Diseases and Resources
DBPS	Division of Bioengineering and Physical Science
DBT	Division of Biomedical Technology
DCA	Division of Cost Allocation
DCAA	Defense Contract Audit Agency
DCCT	Diabetes Control and Complications Trial
DCIS	Department Contract Information System
DCLG	Director’s Consumer Liaison Group

DCM	Division of Comparative Medicine
DCMC	Defense Contract Management Command
DCMS	Division of Mail and Courier Services (ORS)
DCPS	Division of Clinical and Population Based Studies
DCR	Division of Career Resources, OHRM, NIH
DCR	Division of Clinical Research
DCRT	Division of Computer Research and Technology (now CIT)
DDC	Defense Distribution Center
DDER	Deputy Director of Extramural Research, NIH
DDIR	Deputy Director for Intramural Research
DDKR	Drug Delivery & Kinetics Resource (DBPS)
DDM	Deputy Director for Management
DDN	Division of Digestive Diseases and Nutrition, NIDDK
DDP	Diamminedichloroplatinum
DEA	Division of Extramural Activities, NIDDK
DEC	Deputy Ethics Counselor
DeCA	Defense Commissary Agency
DEIS	Division of Extramural Information Systems
DELPRO	Delegated Procurement System
DEM	Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
DEMS	Division of Events Management Services (PES or P&ES)
DEPC	Division of Emergency Preparedness & Coordination
DEPS	Division of Epidemiology and Population Studies
DERT	Division of Extramural Research and Training
DES	Division of Engineering Services

DFAS	Defense Finance and Accounting Service (sends out DHHS/NIH W2s for honorariums, etc.)
DFM	Division of Financial Management
DHHS	Department of Health and Human Services
DHRS	Division of Human Resource Systems, OHRM, NIH
DHVD	Division of Heart and Vascular Diseases
DICOM	Digital Imaging and Communications in Medicine
DINFOS	Defense Information School
DIR	Division of Intramural Research, NIDDK
DITA	Division of Information Technology Acquisition, OLAO (also known as NITAAC)
DITR	Division of International Training and Research
DLD	Division of Lung Diseases
DLS	Division of Library Services
DLS	Division of Logistics Services, OLAO
DLT	Digital linear tape
DMS	Data Management and Sharing
DMAPS	Division of Medical Arts and Printing Services
DMAS	Data Management and Analysis Subcommittee
DMCM	Division of Molecular and Cellular Mechanisms
DMCS	Division of Mail and Courier Services
DMDC	Defense Manpower Data Center
DMID	Division of Microbiology and Infectious Diseases
DMS	Division of Management Services
DNA	Deoxyribonucleic Acid
DOHS	Division of Occupational Health and Safety
DORRA	DLA Office of Operations Research and Resource Analysis

DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DPPS	Division of Personal Property Services, OLAO
DPS	Division of Physiological Systems
DPSM	Division of Physical Security Management
DRA	Division of Research Acquisition, OLAO
DRI	Division of Research Infrastructure
DRR	Division of Receipt and Referral
DRS	Division of Radiation Safety
DRSB	Diagnostic & Research Services Branch
DS	Division of Safety, Office of Research Services
DSEIS	Division of Scientific Equipment and Instrumentation Services (ORS)
DSFM	Division of Space and Facility Management
DSMB	Data and Safety Monitoring Board
DSM-IV	Diagnostic & Statistical Manual of Mental Disorders – 4th Edition
DSO	Division of Security Operations
DSS	Division of Support Services
DSSA	Division of Station Support Acquisition, OLAO
DTIC	Defense Technical Information Center
DTM	Department of Transfusion Medicine (ORS)
DTP	Developmental Therapeutics Program
DTTS	Division of Travel and Transportation Services
DUNS	Data Universal Numbering System
DVR	Division of Veterinary Resources
DW	Data Warehouse
DWD	Division of Workforce Development

E

EA	Expanded Authorities
EA	Enterprise Architecture
EAC	External Advisory Committee
EACC	External Affairs Coordinating committee
EAP	Employee Assistance Program
EBSA	Employee Benefits Security Administration
EC	Executive Committee
EC	European Commission
ECA	Executive Committee for Acquisition
ECA	Bureau of Educational and Cultural Affairs
ECAB	Employees' Compensation Appeals Board
ECB	Electronic Council Book
ECFMG	Educational Commission for Foreign Medical School Graduates
ECIE	Executive council on Integrity and Efficiency
ECL	Executive Committee on Logistics
ECOSOC	Economic and Social Council
ECP	Emergency Conservation Program
ECR-LRP	Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds
EDGAR	Electronic Data Gathering, Analysis, and Retrieval
EDI	Electronic Data Interchange
EDIC	Epidemiologic Cohort Study
Edison	Extramural Invention Information Management System
EDRG	Early Detection Research Group

EDRN	Early Detection Research Network
EEO	Equal Employment Opportunity
EEOC	Equal Employment Opportunity Commission
EES	Enterprise E-Mail System
EHP	Environmental Health Perspectives
EHRP	Enterprise Human resources and Payroll System
EIA	Energy Information Administration
EIN	Entity Identification Number
EIR	Employee Invention Report
EIS	Epidemic Intelligence Service
ELS	Earnings and Leave Statement
ELSI	Ethical, Legal and Societal Implications
EL-TRAINS	Electronic Logistics Training & Support Network
EM	Office of Environmental Management
EML	Environmental Measurement Laboratory
EMPSB	Events Management Program Support Branch (DEMS)
ENC	Eisenhower National Clearinghouse
ENR	Endocrinology and Reproductive Sciences
ENS	Early Notification System
EO	Executive Order
EOB	Editorial Operations Branch
EOC	Ethics Oversight Committee
EOD	Entrance on Duty
EOIR	Executive Office for Immigration Review
EOP	Executive Office of the President

EOUSA	Executive Office for United States Attorneys
EP	Extramural Programs
EPMC	Extramural Program Management Committee
EPN	Executive Plaza North (6130 Executive Blvd.; Rockville, MD 20852)
EPRU	Enteric Pathogens research Unit
EPS	Executive Plaza South (6120 Executive Blvd.; Rockville, MD, 20852)
EPSCoR	Experimental Program to Stimulate Competitive Research
EPSS	Electronic Performance Support Systems
eRA	Electronic Research Administration; responsible for IMPAC II
ERDA	Energy Research and Development Administration
EREN	Energy Efficiency and Renewable Energy Network
ERIC	Educational Resources Information Center
EROD	Educational Resource Organizations Directory
ERP	Extramural Research Program
ERS	Economic Research Service
ERSB	Equipment Rental & Sakes Branch (DSEIS)
ES	Executive Secretariat (NIH)
ESA	Extramural Scientist Administrator
ESA	Employment Standards Administration
ESA	Economics and Statistics Administration
ESDIM	Environmental Services Data and Information Management
ESG	Executive Staffing Group (REPS, PMB, NCI)
ESI	Early-Stage Investigator
eSNAP	Electronic Streamlined Non-competing Award Process
ETA	Employment and Training Administration

ETSO	Employee Transportation Services Office

F

F & A	Facilities and Administrative Cost
F Awards	Fellowship Awards
FACA	Federal Advisory Committee Act
FAES	Foundation for Advanced Education in the Sciences
FAI	Fair Act Inventory
FAIR Act	Federal Activities Inventory Reform Act
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FARB	Funding Advisory Review Board
FASAB	Federal Accounting Standards Advisory Board
FASEB	Federation of American Societies for Experimental Biology
FCC	Federal Communications Commission
FCOI	Financial Conflict of Interest
FCRDC	Frederick Cancer Research and Development Center
FDA	Food and Drug Administration (PHS)
FDP	Federal Demonstration Partnership
FECA	Federal Employees' Compensation Act
FEGLI	Federal Employees' Group Life Insurance
FEHBP	Federal Employees' Health Benefit Program
FEMA	Federal Emergency Management Agency
FERC	Federal Energy Regulatory Commission
FERS	Federal Employees' Retirement System

FFLA	Family Friendly Leave Act
FIC	John E. Fogarty International Center
FICA	Federal Insurance Contributions Act (Social Security)
FIRST	First Independent Research Support and Transition Award
fMRI	Functional Magnetic Resonance Imaging
FMS	Financial Management Service
FNIH	Foundation for the National Institutes of Health
FOIA	Freedom of Information Act of 1966, amended 1986
FRB	Federal Reserve Board
FRS	Federal Reserve System
FTC	Federal Trade Commission
FTE	Full Time Equivalent
FTTP	Full-Time Training Position
FWA	Federal Wide Assurance
FY	Fiscal Year (October 1 – September 30)
FYI	For Your Information

G

GAO	General Accounting Office, Congress
GBV-C	Hepatitis G (GB Virus-C)
GCRC	General Clinical Research Center
GDB	Human Genome Database
GH	Growth Hormone
GM	Grants Management
GMB	Grants Management Branch Office

GME	Graduate Medical Education
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPA	Grade Point Average
GPEA	Government Paperwork Elimination Act of 1998
GPO	Government Printing Office
GPRA	Government Performance Results Act of 1993
GPS	Global Positioning Satellite System
GRE	Graduate Record Examinations
GS	General Schedule
GSA	General Services Administration
GTA	Grants Technical Assistant
GWAC	Government-Wide Acquisition Contract

H

HAART	Highly Active Antiretroviral Therapy
HBCU	Historically Black Colleges and Universities
HBV	Hepatitis B Virus
HCV	Hepatitis C virus
HDR-LRP	Loan Repayment Program for Health Disparities Research
HEM	Hematology Study Section
hESC	Human Embryonic Stem Cells
HHMI	Howard Hughes Medical Institute
HHS	Health and Human Services (Department of)
HIPAA	Health Insurance Portability and Accountability Act of 1996

HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization
HPV	Human Papillomavirus
HQ	Headquarters
HRSA	Health Resources and Services Administration, PHS
HRT	Hormone Replacement Therapy
HSA	Health Scientist Administrator
HSRAC	Human Subjects Research Advisory Committee
HSRB	Human Subjects Review Board
HSV	Herpes Simplex Virus
HTML	Hypertext Markup Language

I

IACUC	Institutional Animal Care and Use Committee
IAG	Interagency Agreement
IAR	Internet Assisted Review
IBC	Institutional Biosafety Committee
IC	Institute and Center (NIH)
ICC	Interstate Commerce Commission
ICD	Institutes/Centers/Divisions
ICF	Informed Consent Form
ID	Identification
IDE	Investigational Device Exemption (FDA)
IDeA	Institutional Development Award Program (NCRR)
IDIQ	Indefinite Delivery Indefinite Quality Contract

IDM	Infectious Diseases and Microbiology
iEdison	NIH's Extramural Electronic Invention Reporting system
IFCN	Integrative, Functional and Cognitive Neuroscience
IG	Inspector General
IHS	Indian Health Service, PHS
IMA	Internal Monitoring Board
IMAGE	Integrated Molecular Analysis of Genomes and their Expression
IMF	International Monetary Fund
IMPAC	Integrated Management, Planning, Analysis and Coordination (Data System)
IMPAC II	Information for Management, Planning, Analysis, and Coordination (grants data system)
IMS/ADB	Information Management System/Administrative Data Base System (DELPRO)
IND	Investigational New Drug Application (FDA)
INS	Immigration and Naturalization Service (now the United States Citizenship and Immigration Services)
IO	Information Officer
IOM	Institute of Medicine, NAS
IP	Intellectual Property
IPC	Incidental Patient Contact
IPF	Institutional Profile File Number
IRA	Individual Retirement Account
IRACDA	Institutional Research and Academic Career Development Award
IRB	Institutional Review Board
IRG	Integrated Review Group, a cluster of study sections responsible for review of grant applications in scientifically related areas; sections share common intellectual and human resources.
IRM	Information Resources Management
IRP	NIH Intramural Research Program

IRPG	Interactive Research Project Grant
IRTA	Intramural Research Training Award or Agreement
ISO	International Organization for Standardization
ISSO	Information Systems Security Office
IT	Information Technology
ITAS	Integrated Time and Attendance System
ITB	Information Technology Branch
ITC	United States International Trade Commission

J

JAX	The Jackson Laboratory
JHU	Johns Hopkins University
JOFOC	Justification for Other than Full and Open Competition
Just-in-time	Grant application timeframe that requires applicants to send some information to NIH only if an award is likely. Also used for other support information, and other items, including: certification of IRB approval, Federal wide assurance, IACU certification, and letter stating key personnel have been trained in protecting human subjects

K

K Awards	Mentored and Career Development Awards
KSA	Knowledge, Skills and Ability Form
KSASF	Knowledges, Skills, Abilities Supplemental Form (NIH-2252-3)
KUH	Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

L

LABS	Laboratory Automated Bibliographic System

LAN	Local Area Network
LAO	Leave Approving Official
LAS	Laboratory Animal Sciences
LAT	Laboratory Animal Technician (AALAS Certified)
LATG	Laboratory Animal Technologist (AAALAS Certified)
LCM	Laser Capture Microdissection
LI	Lead Investigator
LOC	Library of Congress
LOCIS	Library of Congress Information System
LOE	Level of Effort
LOI	Letter of Intent
LRP	Loan Repayment Program (NIH)
LWOP	Leave Without Pay

M

MA	Master Agreement
MAC	Multiple Award Contract
MACs	Multiple Agency Contracts
MARC	Minority Access to Research Career Program
MBRS	Minority Biomedical Research Support
MC	Manual Chapter
MCDN	Molecular, Cellular and Developmental Neuroscience
MCP	NIH Management Cadre Program
MCR	Management Control Review
MCSB	Mail Customer Service Branch (DMCS)

MCRU	Metabolic Clinical Research Unit (in NIH Clinical Center)
MEDLINE/ PUBMED	National Library of Medicine's Database for Scientific Publications
MEO	Most Efficient Organization
MERIT	Method to Extend Research in Time Award
MeSH	Medical Subject Headings
MF	NIH Management Fund
MHC	Major Histocompatibility Complex
MHPF	Minority Health Professionals Foundation
MI	Minority Institutions
MIGA	Multilateral Investment Guarantee Agency
MIS	Medical Information System
ML	Military Leave
MM	Medical Monitor
MODY	Maturity Onset Diabetes of the Young
MORE	Minority Opportunities in Research
MOU	Memorandum of Understanding
MOU/MOA	Memorandum of Understanding/Memorandum of Agreement
MPA	Multiple Project Assurance
MPP	Merit Program Plan (NIH)
MPW	Medical Pathological Waste
MRA	Minimum Retirement Age
MRC	Medical Research Council (UK)
MRI	Magnetic Resonance Imaging
M-RISP	Minority-Research Infrastructure Support Program
mRNA	Messenger RNA

MRS	Magnetic Resonance Spectroscopy
MSDS	Material Safety Data Sheet
MSPB	Merit Systems Protection Board
MTA	Material Transfer Agreement
MTCT	Mother-to-Child Transmission

N

N/A	Not Applicable/Not Available
NAFTA	North American Free Trade Agreement
NAHFE	National Association of Hispanic Federal Executives
NARA	National Archives and Records Administration
NARCH	Native American Research Centers for Health
NARFE	National Association of Retired Federal employees
NAS	National Academy of Sciences (U.S.)
NBAC	National Bioethics Advisory Commission
NBII	National Biological Information Infrastructure
NBN	National Biospecimen Network
NBRSS	NIH Business and Research Support System
NBS	New Business Systems/NIH Business System
NCATS	National Center for Advancing Translational Sciences
NCBI	National Center for Biotechnology Information
NCC	National Coordinating Center for Telecommunications
NCCIH	National Center for Complementary and Integrative Health (NIH)
NCCDPHP	National Center for Chronic Disease and Prevention Health Promotion (CDC)
NCCIC	National Child Care Information Center

NCCLS	National Committee for Clinical Laboratory Standards
NCD	National Council on Disability
NCEH	National Center for Environmental Health (CDC)
NCES	National Center for Education Statistics
NCHS	National Center for Health Statistics
NCI	National Cancer Institute (NIH)
NCICAS	National Cooperative Inner-City Asthma Study
NCIPC	National Center for Injury Prevention and Control (CDC)
NCRR	National Center for Research Resources (dissolved as of December 23, 2011)
NCSDR	National Center on Sleep Disorders Research
NCTR	National Center for Toxicological Research
NCUA	National Credit Union Administration
NCVHS	National Committee on Vital and Health Statistics
NDA	New Drug Application
NDDKDAC	National Diabetes and Digestive and Kidney Diseases Advisory Council
NDIC	National Drug Intelligence Center
NDRI	National Disease Research Interchange
NED	NIH Enterprise Directory
NEI	National Eye Institute (NIH)
NFT	Notification of Foreign Travel
NGA	Notice of Grant Award (also NoGA) [see NOGA p 36/59]
NGO	Non-Government Organization
NGRI	Next Generation of Researchers Initiative
NHGRI	National Human Genome Research Institute (NIH)
NHIC	National Health Information Center

NHLBI	National Heart, Lung, and Blood Institute (NIH)
NHP	Nonhuman Primate
NHRPAC	National Human Research Protection Advisory Committee
NHSC	National Health Sciences Scholarship
NIA	National Institute on Aging (NIH)
NIAAA	National Institute on Alcohol Abuse and Alcoholism (NIH)
NIAID	National Institute of Allergy and Infectious Disease (NIH)
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Disease (NIH)
NIBIB	National Institute of Biomedical Imaging and Bioengineering (NIH)
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NIH)
NIDA	National Institute on Drug Abuse (NIH)
NIDCD	National Institute on Deafness and Other Communication Disorders (NIH)
NIDCR	National Institute of Dental and Craniofacial Research (NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
NIDRR	National Institute on Disability and Rehabilitation Research
NIEHS	National Institute of Environmental Health Sciences (NIH)
NIGMS	National Institute of General Medical Sciences (NIH)
NIH	National Institutes of Health
NIH DW	NIH Data Warehouse
NIHAC	The National Institutes of Health Animal Center (Poolesville, MD)
NIHITS	NIH Integrated Training System
NIHTC	National Institutes of Health Training Center
NIMH	National Institute of Mental Health (NIH)
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)
NINDS	National Institute of Neurological Disorders and Stroke (NIH)

NINR	National Institute of Nursing Research (NIH)
NIOSH	National Institute for Occupational Safety and Health (CDC)
NIST	National Institute of Standards and Technology
NLAES	National Longitudinal Alcohol Epidemiologic Survey
NLM	National Library of Medicine (NIH)
NLT	Not Later Than
NMA	National Medical Association
NMR	Nuclear Magnetic Resonance
NMS	Nutritional and Metabolic Sciences
NOA	Nature of Action
NOGA	Notice of Grant Award [see NoGA prior page at NGA]
Non-FTE	Non Full-time Equivalent
NOTA	National Organ Transplant Act
NPEBC	National Programs of Excellence in Biomedical Computing
NPRC	National Primate Research Center
NREN	National Research and Education Network
NREVSS	National Respiratory and Enteric Virus Surveillance System
NRFC	Not Recommended for Further Consideration
NRL	Naval Research Laboratory
NRSA	National Research Service Award (e.g., T32, F32)
NS	No Score (lower 50% of grants in study section)
NSF	National Science Foundation
NSRG	Nutritional Science Research Group
NSTC	National Science and Technology Center
NSTL	National Space Technology Laboratories

NTE	Not To Exceed
NTIA	National Telecommunications and Information Administration
NTIS	National Technical Information Service
NTP	National Toxicology Program

O

OA	Office of Administration
OACU	Office of Animal Care and Use
OAM	Office of Administrative Management (OD)
OAMP	Office of Acquisition Management and Policy, OA
OAPP	Office of Adolescent Pregnancy Programs (OASH)
OAR	Office of AIDS Research
OASDI	Old Age Survivor Disability Insurance
OASH	Office of the Assistant Secretary for Health, PHS
OASPA	Office of the Assistant Secretary for Public Affairs
OB	Office of Budget (NIH OD)
OBA	Office of Biotechnology Activities (NIH OD)
OBL	Office of Business Liaison
OBSF	Office of Business Systems & Finance (OD)
OBSSR	Office of Behavioral and Social Sciences Research (NIH OD)
OC	Office of Communications
OCAB	Office of the Assistant Secretary for Health, PHS
OCC	Operations Coordinating Committee
OCCC	Office of Clinical Center Communications
OCL	Office of Community Liaison (NIH OD)

OCPL	Office of Communications & Public Liaison
OD	Office of the Director, NIH
ODA	Official Duty Activities
ODEO	Office of the Director Executive Office (NIH OD)
ODEP	Office of Disability Employment Policy
ODP	Office of Disease Prevention (NIH OD)
ODS	Office of Dietary Supplements (NIH OD)
OE	Office of Education (NIH OD)
OEEO	Office of Equal Employment Opportunity (NIH OD)
OEO	Office of Equal Opportunity
OEODM	Office of Equality, Opportunity & Diversity Management
OEP	Office of Extramural Programs, OER, OD, NIH
OER	Office of Extramural Research, OD, NIH
OFACP	Office of Federal Advisory Committee Policy (NIH OD)
OFCCP	Office of Federal Contract Compliance Programs
OFM	Office of Financial Management
OFRM	Office of Financial Resources Management
OGC	Office of the General Counsel (NIH OD)
OGE	Office of Government Ethics
OHASIS	Office of Health and Safety Information System
OHER	Office of Health and Environmental Research
OHR	Office of Human Resources (NIH OD)
OHRM	Office of Human Resource Management (NIH OD)
OHRP	Office for Human Research Protections
OHS	Office of Healthy Start (HRSA)

OHSR	Office of Human Subjects Research
OIB	Office of Information Branch
OIG	Office of the Inspector General (USDA)
OIIA	Office of Intergovernmental and Interagency Affairs
OIR	Office of Intramural Research (NIH OD)
OIT	Office of Information Technology
OLAO	Office of Logistics and Acquisition Operations
OLAW	Office of Laboratory Animal Welfare, OER, OD, NIH
OLM	Office of Logistics Management
OLPA	Office of Legislative Policy and Analysis (NIH OD)
OLRS	Office of Loan Repayment and Scholarship (NIH OD)
OM	Office of Management (NIH OD)
OMA	Office of Management Assessment (NIH OD)
OMAR	Office of Medical Applications of Research (NIH OD)
OMB	Office of Management and Budget (White House)
OMBS	Office of Medical Board Services
OMH	Office of Minority Health (OASH)
OMS	Occupational Medical Services (DOHS)
ONC	Oncological Sciences
OPASI	Office of Portfolio Analysis and Strategic Initiatives (dissolved October 2008)
OPDIV	Operating Division (HHS)
OPEC	Office of Prevention, Education, and Control
OPERA	Office of Policy for Extramural Research Administration
OPF	Official Personnel File
OPHS	Office of Public Health and Science

OPL	Offices of Public Liaison (NIH OD)
OPM	Office of Personnel Management
OPRR	Office of Protection from Research Risks
ORA	Office of Reports and Analysis, OER, OD, NIH
ORD	Office of Rare Diseases (NIH OD)
ORI	Office of Research Integrity, HHS
ORIM	Office of Information Resources Management
ORS	Office of Research Services (NIH OD OM)
ORWH	Office of Research on Women's Health, OD, NIH
OS	Office of the Secretary
OSA	Office of Scientific Affairs, OER, OD, NIH
OSC	Office of Strategic Coordination, DPCPSI, OD, NIH
OSD	Office of the Scientific Director
OSE	Office of Science Education (NIH OD)
OSHA	Occupational Safety and Health Administration
OSHRC	Occupational Safety and Health Review Commission
OSMP	Office of Strategic Management and Planning (NIH OD)
OSP	Office of Science Policy (NIH OD)
OSPA	Office of Science Policy Analysis
OSPP	Office of Science Policy and Planning
OST	Office of Science and Technology
OSTI	Office of Scientific and Technical Information
OSTP	Office of Science and Technology Policy (White House)
OT	Overtime
OTA	Office of Technology Assessment

OTD	Office of Technology Development
OTS	Omega Travel Service (NIH Travel Agent)
OTT	Office of Technology Transfer
OUTPT	Outpatient
OWH	Office on Women's Health

P

P/TRP	Promotion/Tenure Review Panel
PA	Program Announcement
PA	Purchasing Agent
PAM	Office of Acquisition and Property Management
PAR	Program Announcement with special receipt or review
PART	Program Assessment Rating Tool (OMB)
PAS	Program Announcement with Set-aside funds
PCA	Physicians Comparability Allowance
PCBE	President's Council on Bioethics
PD	Position Description
PDF	Portable Document Format
PET	Positron Emission Tomography
PETA	People for the Ethical Treatment of Animals
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service (U.S.)
PHS OWH	U.S. Public Health Service's Office on Women's Health
PHTN	Public Health Training Network
PI	Principal Investigator

PIA	Procurement Integrity Act
PIN	Personal Identification Number
PKU	Phenylketonuria
PLC	Program Leadership Committee
PMCID	PubMed Central Identification
PMI	Presidential Management Intern
PMIS	Property Management Information System
PMO	Property Management Officer
PO	Program Official
PO	Project Officer (For a Grant or Contract)
PO	Purchase Order
Post-Doc	Post-Doctoral Fellow
PP	Pay Period
PPE	Pay Period Ending
PPP	Public Private Partnerships
PPS	Pathophysiological Sciences
PR	Public Relations
PRB	Protocol Review Board
PRC	Processing Resource Centers
Pre-Doc	Pre-Doctoral Fellow
PRG	Progress Review Groups
PRIMR	Public Responsibility in Medicine and Research
PRMC	Protocol Review and Monitoring Committee
Project EXPORT	Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training
PROTRACK	Clinical Center Protocol Tracking Database

PrP	Prion Protein
PRPL	Patient Recruitment and Public Liaison Office
PRRR	Program Review Report Record
PRS	Protocol Review Subcommittee
PSC	Program Support Center
PSC	Publications Subcommittee
PSO	Professional Service Order
PSP	Physician Special Pay (Title 38)
PTSD	Post-Traumatic Stress Disorder
PWS	Performance Work Statement

Q

Q&A	Questions and Answers
QA	Quality Assurance
QALY	Quality-Adjusted Life Years
QAP	Quality Assurance Program
QAS	Quality Assurance Subcommittee
QC	Quality Control
QRB	Quality Review Board
QSI	Quality Step Increase

R

R&D	Research & Development
R&W	Recreation and Welfare
R01	Standard NIH Research Project Grant

R34	Investigator-Initiated Clinical Trial Planning and Implementation Grants
R56	Grant allowing an interim award so principal investigator can continue while reapplying for an R01 grant. Also enables new investigators to gather preliminary data to improve their grant applications. (Bridge Award)
RA	Research Assistant
RAC	Recombinant-DNA Advisory Committee
RAID	Rapid Access to Intervention Development
RAL	Restored Annual Leave
RALAT	Registered Assistant Laboratory Animal Technician
RAO	Regulatory Affairs Officer
RCC	Research Coordination Council (Department-wide)
RCDA	Research Career Development Award (K-series awards)
RCDC	Research, Condition, and Disease Categorization
RCR	Responsible Conduct of Research
RCRII	RCMI Clinical Research Infrastructure Initiative
RCT	Randomized Controlled Trial
rDNA	Recombinant DNA
RePORT	NIH Research Portfolio Online Reporting Tools
RePORTER	RePort Expenditures and Results
RFA	Request for Application (request for grant applications for a research area)
RFC	Request For Contract
RFI	Request for Information
RFIP	Research Facilities Improvement Program
RFP	Request For Proposal (request for contract proposal for a project)
RFQ	Request for Quotation
RIF	Reduction In Force

RIMS	Robocom Inventory Management System
RISE	Research Initiative for Scientific Enhancement
RM	Roadmap, now Common Fund
RMA	Risk Management Agency
RMS	Research Management Support
RNA	Ribonucleic Acid
RNAi	RNA interference
RPC	Review Policy Committee
RPG	Research Project Grant
RPHB	Risk, Prevention, and Health Behaviors
RPPR	Research Program Performance Report
RRTC	Regional Research and Training Center
RSA	Rehabilitation Services Administration
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSOB	Radiation Safety Operations Branch (DRS)
RSUM	Research Supplements for Underrepresented Minorities

S

SAC	Simplified Acquisition Committee
SAE	Serious Adverse Event
SAMHSA	Substance Abuse and Mental Health Services Administration, HHS
SB	Small Business
SBA	U.S. Small Business Administration
SBIR	Small Business Innovation Research

SBO	Small Business Office
SBRS	Senior Biomedical Research Service
SBS	Small Business Specialist
SBSA	Small Business Set-Aside
SC	Steering Committee
SCD	Service Computation Date
SCORE	Support of Continuous Research Excellence
SCR	Special Council Review
SD	Scientific Director
SDB	Small Disadvantaged Business
SEER	Surveillance, Epidemiology, and End Results
SE	Special Emphasis
SEP	Special Emphasis Panel (an SRG convened for a single meeting)
SES	Senior Executive Service
SF	Standard Form
SF	Staff Fellow
SIG	Shared Instrumentation Grant
SIMS	Scientific Initiative Management System
SIP	Summer Internship Program in Biomedical Research
SLA	Simple Letter of Agreement
SMSA	Small Business & Minority Business Set Aside
SNAP	Streamlined Noncompeting Award Process
SNEM	Social Science, Nursing, Epidemiology, and Methods
SNMA	Student National Medical Association
SNOMED	Systemized Nomenclature of Medicine

SNOMED CT	Systemized Nomenclature of Medicine – Clinical Terms
SNPs	Single Nucleotide Polymorphisms
SO	Signing Official
SOP	Standard Operating Procedure
SOW	Statement Of Work
SPA	Single Project Assurance
SPF	Specific-pathogen free
SPIN	Shared Pathology Informatics Network
SPORE	Specialized Program of Research Excellence
SRAs	Scientific Review Administrator (an NIH scientist administrator in charge of review and advisory groups; now called SROs)
SRB	Surgery, Radiology, and Bioengineering
SRB	Scientific Review Board
SREA	Scientific Review Evaluation Awards
SRFP	Summer Research Fellowship Program
SRG	Scientific Review Group (performs initial scientific merit review of grant application & contract proposals; also called Initial Review Group (IRG) when pertaining to grant applications)
SROs	Scientific Review Officer (manages the peer review process for grant applications and contract proposals; designated Federal official responsible for the peer review meeting; major focus is on scientific rather than administrative activities; former title was SRA)
SSB	Support Services Branch (DP)
SSEB	Source Selection Evaluation Board
SSF	Senior Staff Fellow
SSF	Service and Supply Fund
SSN	Social Security Number
SSS	Special Study Section
STD	Sexually Transmitted Disease
STDCRC	Sexually transmitted Disease Cooperative Research Centers

STDCTU	Sexually Transmitted Disease Clinical Trials Unit
STEP	Staff Training in Extramural Programs
STI	Scientific and Technical Information
STTR	Small Business Technology Transfer
SV	Student, or Special Volunteer

T

T&A	Time and Attendance
TAIMS	Time and Attendance Information Management System
TEHIP	Toxicology and Environmental Health Program
TIA	Time Off Incentive Award
TIG	Time In Grade
TIN	Payer Identification Number Tax
TK	Timekeeper
TMA	Tissue Microarray
TMJ	Temporomandibular joint
TO	Task Order
TOD	Tour of Duty
TOXNET	Toxicology Data Network
TQM	Total Quality Management
TSC	Training Subcommittee
TSP	Thrift Savings Plan
TTB	Technology Transfer Branch
TX	Treatment

U

U.S.C.	United States Code
UMLS	Unified Medical Language System
URC	User Resource Center
USAID	United States Agency for International Development
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USIA	United States Information Agency
USOPM	United States Office of Personnel Management
USUHS	Uniformed Services University of Health Sciences

V

VA	Veterans Administration
VA	Department of Veterans Affairs
VF	Visiting Fellow
VLTP	Voluntary Leave Transfer Program
VRC	Vaccine Research Center
VRP	Veterinary Resources Program
VS	Visiting Scientist
VSOF	Visual Status of Funds

W

WAG	Widely Attended Gathering
WFCL	Work and Family Life Center
WG	Wage Grade

WGI	Within-Grade Increase
WHI	Women's Health Initiative
WHO	World Health Organization, United Nations
WTO	World Trade Organization
WWW	World Wide Web
WYLBUR	Interactive system providing simultaneous service to more than 825 terminals or microcomputers.

X

X-Train	Trainee Activities System

Y

YTD	Year To Date

Z

ZIP (Code)	Zone Improvement Plan

National Institute of Diabetes and Digestive and Kidney Diseases Mission, Overview, and History

Until May 19, 1972, the National Institute of Arthritis and Metabolic Diseases; until June 23, 1981, the National Institute of Arthritis, Metabolism, and Digestive Diseases; and until April 8, 1986, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Mission

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.

Overview

The NIDDK supports a wide range of medical research through grants to universities and other medical research institutions across the country. The Institute also supports government scientists who conduct basic, translational, and clinical research across a broad spectrum of research topics and serious, chronic diseases and conditions related to the Institute's mission. In addition, the NIDDK supports research training for students and scientists at various stages of their careers and a range of education and outreach programs to bring science-based information to patients and their families, health care professionals, and the public.

External research funded by the NIDDK is organized into three scientific program divisions:

- Diabetes, Endocrinology, and Metabolic Diseases
- Digestive Diseases and Nutrition
- Kidney, Urologic, and Hematologic Diseases

The NIDDK's overarching principles in moving research forward include:

- maintaining a vigorous, investigator-initiated research portfolio that supports cross-cutting science that can be broadly applied to many disease-specific research areas
- supporting pivotal clinical studies and trials, with a focus on substantial participation of groups at highest risk.
- preserving a stable pool of talented new investigators
- fostering exceptional research training and mentoring opportunities
- ensuring that science-based health information reaches patients, their families, health care providers and the public through communications and outreach activities

Important Events in NIDDK History

August 15, 1950—President Harry S. Truman signed the Omnibus Medical Research Act into law, establishing the National Institute of Arthritis and Metabolic Diseases (NIAMD) in the U.S. Public Health Service. The new Institute incorporated the laboratories of the Experimental Biology and Medicine Institute, and expanded to include clinical investigation in rheumatic diseases, diabetes, and a number of metabolic, endocrine, and gastrointestinal diseases.

November 15, 1950—The National Advisory Arthritis and Metabolic Diseases Council held its first meeting and recommended approval of NIAMD's first grants.

1959—Dr. Arthur Kornberg, former chief of the Institute's enzyme and metabolism section, won the Nobel Prize for synthesizing nucleic acid.

1961—Laboratory-equipped mobile trailer units began an epidemiological study of arthritis among the Blackfeet and Pima Indians in Montana and Arizona, respectively.

October 16, 1968—The Nobel Prize was awarded to Dr. Marshall W. Nirenberg of the National Heart Institute, who reported his celebrated partial cracking of the genetic code while an NIAMD scientist.

November 1970—The Institute celebrated its 20th anniversary. U.S. Secretary of Defense Melvin R. Laird addressed leaders in the department, representatives from voluntary health agencies and professional biomedical associations, and past and present Institute National Advisory Council members.

May 19, 1972—The Institute's name was changed to the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD).

October 1972— Dr. Christian B. Anfinsen, chief of the Institute's Laboratory of Chemical Biology, shared a Nobel Prize with two other American scientists for demonstrating one of the most important simplifying concepts of molecular biology: that the three-dimensional conformation of a native protein is determined by the chemistry of its amino acid sequence. A significant part of the research cited by the award was performed while Anfinsen was with the NIH.

September 1973—The creation of the first Diabetes-Endocrinology Research Centers marked the beginning of the Institute’s Diabetes Centers Program.

November 1975—After nine months of investigation into the epidemiology and nature of diabetes mellitus and public hearings throughout the United States, the National Commission on Diabetes delivered its report, the *Long-Range Plan to Combat Diabetes*, to Congress. Recommendations included expanding and coordinating diabetes and related research programs; creating a diabetes research and training centers program; accelerating diabetes health care, education, and control programs; and establishing a National Diabetes Advisory Board.

April 1976—The National Commission on Arthritis and Related Musculoskeletal Diseases issued *The Arthritis Plan*. This report to Congress called for increased arthritis research and training programs, multipurpose arthritis centers, epidemiologic studies and data systems in arthritis, a National Arthritis Information Service, and a National Arthritis Advisory Board.

October 1976—Dr. Baruch Blumberg was awarded the Nobel Prize in Physiology or Medicine for research on the hepatitis B virus protein, the "Australia antigen," which he discovered in 1963 while at the Institute. This advance has proven to be a scientific and clinical landmark in detecting and controlling viral hepatitis and led to the development of preventive measures against hepatitis and liver cancer.

April 19, 1977—The NIH director established a trans-NIH program for diabetes, with the NIAMDD taking lead responsibility.

September 1977—More than $5 million in grants was awarded to 5 institutions to establish Diabetes Research and Training Centers.

October 1977—In response to the recommendation of the National Commission on Diabetes, the National Diabetes Data Group was established within the Institute to collect, analyze, and disseminate diabetes data to scientific and public health policy and planning associations.

December 1977—Institute grantees Drs. Roger C.L. Guillemin and Andrew V. Shally shared the Nobel Prize in Physiology or Medicine with a third scientist. Guillemin's and Shally's prizes were for discoveries related to the brain's production of peptide hormones.

1978—In response to congressional language, the NIDDK created the National Diabetes Information Clearinghouse to increase knowledge and understanding about diabetes among people with these conditions and their families, health professionals, and the public.

January 1979—The National Commission on Digestive Diseases issued the report, The *National Long-Range Plan to Combat Digestive Diseases*. Recommendations to Congress included establishing a National Digestive Diseases advisory board and information clearinghouse and emphasizing digestive diseases educational programs more in medical schools.

June 1980—In response to congressional language, the NIDDK created the National Digestive Diseases Information Clearinghouse to increase knowledge and understanding about digestive diseases among people with these conditions and their families, health professionals, and the public.

September 1980—Dr. Joseph E. Rall, director of NIAMDD intramural research, became the first person at the NIH to be named to the distinguished executive rank in the Senior Executive Service. President Jimmy Carter presented the award in ceremonies at the White House on September 9.

October 15, 1980—NIAMDD celebrated its 30th anniversary with a symposium, "DNA, the Cell Nucleus, and Genetic Disease." Dr. Donald W. Seldin, chairman of the department of internal medicine, University of Texas Southwestern Medical School, Dallas, was guest speaker.

1981—A report entitled *An Evaluation of Research Needs in Endocrinology and Metabolic Diseases* was prepared by an external group of scientific experts and was submitted to the NIH and the Senate Committee on Appropriations.

June 23, 1981—The Institute was renamed the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

April 1982—U.S. Department of Health and Human Services (HHS) Secretary Richard S. Schweiker elevated the NIADDK's programs to division status, creating five extramural divisions and the Division of Intramural Research.

November 1982—Dr. Elizabeth Neufeld, chief of the NIADDK's genetics and biochemistry branch, received a Lasker Foundation Award. She was cited, along with Dr. Roscoe E. Brady of the then-named National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), for "significant and unique contributions to the fundamental understanding and diagnosis of a group of inherited diseases called mucopolysaccharide storage disorders (MPS)."

November 1984—Grants totaling more than $4 million were awarded to six institutions to establish the Silvio O. Conte Digestive Diseases Research Centers. The research centers investigate the underlying causes, diagnoses, treatments, and prevention of digestive diseases.

April 8, 1986—The Institute's Division of Arthritis, Musculoskeletal and Skin Diseases became the core of the new National Institute of Arthritis and Musculoskeletal and Skin Diseases. The NIADDK was renamed the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

June 3, 1986—The National Kidney and Urologic Diseases Advisory Board was established to formulate the long-range plan to combat kidney and urologic diseases.

1987—The NIDDK created the National Kidney and Urologic Diseases Information Clearinghouse to increase knowledge and understanding about diseases of the kidneys and urologic system among people with these conditions and their families, health care professionals, and the general public.

August 1, 1987—Six institutions were funded to establish the George M. O'Brien Kidney and Urological Research Centers.

December 1987—In response to congressional language on the fiscal year (FY) 1988 appropriation for the NIDDK, the Institute established a program of cystic fibrosis research centers.

March 1990—The National Kidney and Urologic Diseases Advisory Board issued its "Long-Range Plan: Window on the 21st Century," which recommended uniting the public and private sectors in the quest to prevent these diseases; improve methods for early detection, treatment, and rehabilitation; and ultimately find cures.

September 16, 1990—The NIDDK celebrated its 40th anniversary. Dr. Daniel E. Koshland, Jr., editor of *Science*, was guest speaker.

June 1991—The NIDDK Advisory Council established the National Task Force on the Prevention and Treatment of Obesity to synthesize current science on preventing and treating obesity and to develop statements about topics of clinical importance based on critical analyses of the scientific literature.

September 30, 1992—Three Obesity/Nutrition Research Centers were established, along with an extramural animal models core to breed genetically obese rats for obesity and diabetes research.

October 12, 1992—Drs. Edwin G. Krebs and Edmond H. Fischer were awarded the Nobel Prize in Physiology or Medicine for their work on "reversible protein phosphorylation." At the time of the award, the scientists had been receiving continuous NIDDK grant support since 1951 and 1956, respectively.

October 30, 1992—In response to congressional language on the Institute's FY 1993 appropriation, the NIDDK initiated a program to establish gene therapy research centers with emphasis on cystic fibrosis.

November 1, 1993—The functions of the NIH Division of Nutrition Research Coordination, including those of the NIH Nutrition Coordinating Committee, were transferred to the NIDDK.

October 10, 1994—Drs. Martin Rodbell and Alfred G. Gilman received the Nobel Prize in Physiology or Medicine for discovering G-proteins, a key component in the signaling system that regulates cellular activity. Dr. Rodbell discovered the signal transmission function of GTP while a researcher at the then-named NIAMD.

June 22, 1997—Led by the NIDDK, the NIH and the U.S. Centers for Disease Control and Prevention (CDC) announced the creation of the National Diabetes Education Program (NDEP). The NDEP's goals are to reduce the rising prevalence of diabetes, the morbidity and mortality of the disease, and its complications.

July 18, 2000—The NIDDK created the National Kidney Disease Education Program to raise awareness among the public of kidney disease and its risk factors, and make resources available to consumers and health care providers.

June 2000—To reduce the disproportionate burden of many diseases in minority populations, the NIDDK initiated an Office of Minority Health Research Coordination.

November 16, 2000—The NIDDK celebrated its 50th anniversary. Professional societies in eight U.S. locations and Canada sponsored scientific symposia and hosted an NIDDK exhibit. NIDDK published *A New Century of Science*: *A New Era of Hope* was published to highlight NIDDK-supported research and jointly hosted a scientific symposium at the Society for Cell Biology's 40th anniversary meeting.

November 2002—NIDDK created the Network of Minority Health Research Investigators to help increase the number of minority health researchers who compete for NIH research support in the fields of interest to NIDDK.

October 8, 2003—NIDDK grantee Dr. Peter Agre shared the Nobel Prize in Chemistry with another scientist for studies of channels in cell membranes. Agre discovered aquaporins, proteins that move water molecules through the cell membrane.

October 4, 2004—Dr. Richard Axel, once an intramural research fellow under Dr. Gary Felsenfeld at the NIDDK, shared the Nobel Prize in Physiology or Medicine with another scientist for discovering a large family of receptors selectively expressed in cells that detect specific odors.

October 6, 2004—Long-time grantees Drs. Irwin A. Rose and Avram Hershko shared the Nobel Prize in Chemistry with another scientist for discovering ubiquitin-mediated protein degradation inside the cell.

October 2007—Institute grantee Dr. Oliver Smithies shared the Nobel Prize in Physiology or Medicine with two other scientists for discovering principles for introducing specific gene modifications in mice by using embryonic stem cells.

2010—The NIDDK celebrated its 60th anniversary. Special events included the September 21 scientific symposium "Unlocking the Secrets of Science: Building the Foundation for Future Advances" and the publication of the commemorative report *NIDDK: 60 Years of Advancing Research to Improve Health.*

September 2010—NIDDK grantee Dr. Jeffrey Friedman and former grantee Dr. Douglas Coleman won the 2010 Albert Lasker Basic Medical Research Award for discovering the hormone leptin, which plays a key role in regulating energy intake and energy expenditure.

October 3, 2011—NIDDK grantee Dr. Bruce Beutler shared the 2011 Nobel Prize in Physiology or Medicine with NIH grantee Dr. Jules Hoffman for their discoveries concerning the activation of innate immunity. NIH grantee Dr. Ralph Steinman also shared the award posthumously for his discovery of the dendritic cell and its role in adaptive immunity.

December 2011—The journal *Science* named an HIV-prevention research study led by NIDDK grantee Dr. Myron Cohen the 2011 Breakthrough of the Year. The study found that people infected with HIV reduced the risk of transmitting the virus to their sexual partners by taking oral antiretroviral medicines when their immune systems were relatively healthy.

April 29, 2012—The Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) study results appeared in the New England Journal of Medicine, marking the first major comparative effectiveness trial for the treatment of type 2 diabetes in young people. The NIDDK-funded study found that combined therapy with metformin and rosiglitazone was superior to metformin alone. The rate of treatment failure with metformin alone suggested that most youth with type 2 diabetes will require combination treatment or insulin within a few years after diagnosis.

September 21, 2012—Dr. Thomas E. Starzl, a longtime NIDDK grantee, received the 2012 Lasker-DeBakey Clinical Medical Research Award – shared with Dr. Roy Calne — for his work developing liver transplantation, an intervention that has restored normal life to thousands of people with end-stage liver disease.

October 2012—Dr. Robert J. Lefkowitz, who trained at NIDDK from 1968-1970 as a clinical associate in the Clinical Endocrinology Branch, won the 2012 Nobel in chemistry for studies of protein receptors that let body cells sense and respond to outside signals.

October 2013—Dr. James Rothman, an NIDDK grantee, received the 2013 Nobel Prize in physiology or medicine, shared with fellow NIH grantees Drs. Randy W. Schekman and Thomas C. Südhof "for their discoveries of machinery regulating vesicle traffic, a major transport system in our cells," according to the Nobel organization. The researchers' work revealed how cells use small sacs, called vesicles, to import and export materials to and from cells. This transport system is a fundamental process in how cells work.

August 1, 2015—NIDDK established the Office of Nutrition Research, replacing the NIH Division of Nutrition Research Coordination. The Office is within the NIDDK Office of the Director and will assist in leading a trans-NIH group to strategically plan new initiatives for NIH nutrition research.

September 2016—NIDDK grantee, Dr. Gregg L. Semenza was awarded the 2016 Albert Lasker Basic Medical Research Award, shared with Dr. William G. Kaelin Jr. and Dr. Peter J. Ratcliffe for their "discovery of the pathway by which cells from humans and most animals sense and adapt to changes in oxygen availability- a process essential for survival," according to the organization.

2020—The NIDDK celebrated its 70th anniversary.

January 2021—The NIDDK Office of Nutrition is relocated to the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the NIH Office of the Director.

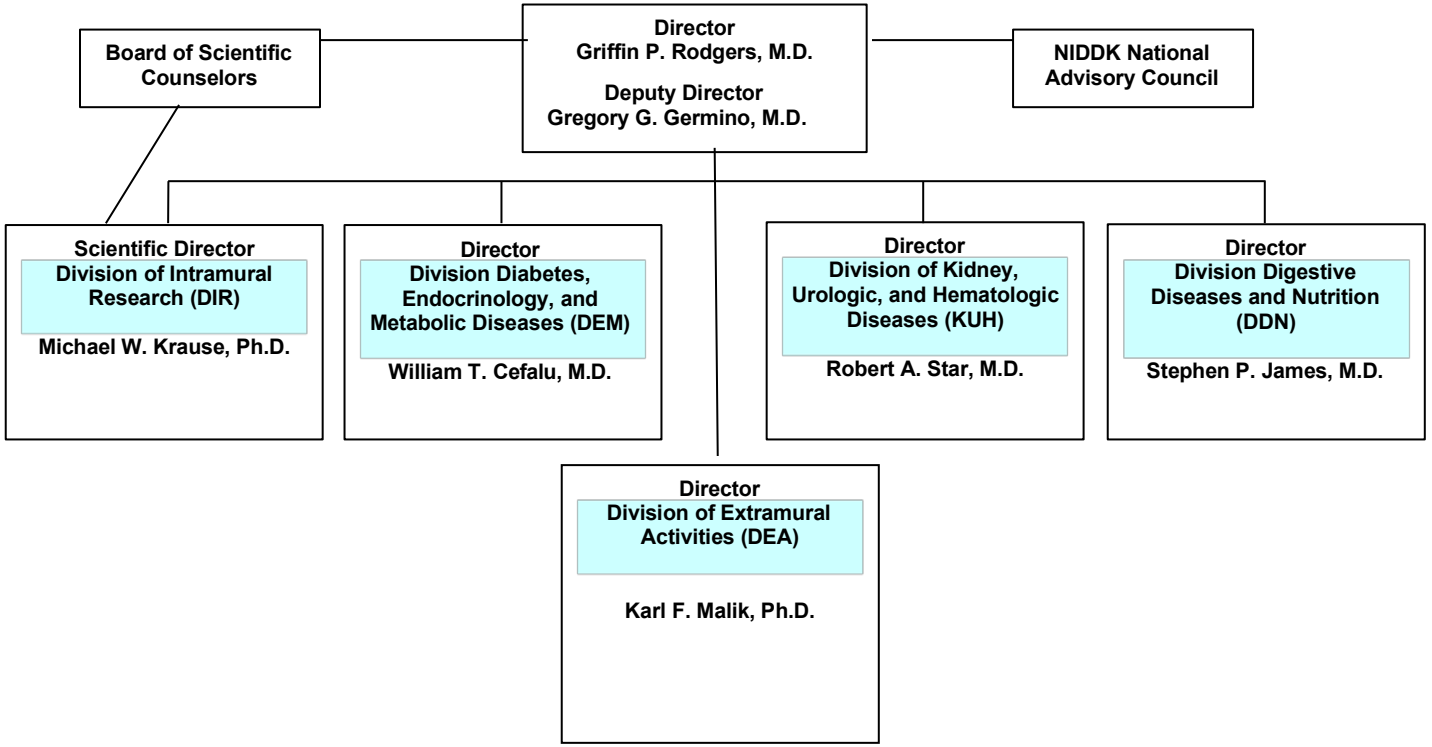
September 2024—The NIDDK Office of Minority Health Research Coordination (OMHRC) is reorganized to the NIDDK Office of Health Equity Research (OHER).

2025—The NIDDK will celebrate its 75th anniversary.

NIDDK Directors

Name	In Office from	To
William Henry Sebrell, Jr.	August 15, 1950	October 1, 1950
Russell M. Wilder	March 6, 1951	June 30, 1953
Floyd S. Daft	October 1, 1953	May 3, 1962
G. Donald Whedon	November 23, 1962	September 30, 1981
Lester B. Salans	June 17, 1982	June 30, 1984
Mortimer B. Lipsett	January 7, 1985	September 4, 1986
Phillip Gorden	September 5, 1986	November 14, 1999
Allen M. Spiegel	November 15, 1999	March 3, 2006
Griffin P. Rodgers	April 1, 2007	present

NIDDK Organizational Chart



Overview of the Office of the Director

The Office of the Director includes the following offices:

- Biostatistics Program
- Executive Office, including administrative components:
  - Administrative Management Branches
  - Computer Technology Branch
  - Ethics Office
  - Office of Financial Management and Analysis
  - Office of Workforce and Strategic Planning
  - Purchasing Office
- NIDDK Central Repository
- Office of Clinical Research Support
- Office of Communications and Public Liaison
- Office of Obesity Research
- Office of Health Equity Research
- Office of Scientific Program and Policy Analysis
- Regulatory Support Program
- Technology Advancement Office

Within the Office of the Director are the following research coordination offices.

The ***Office of Health Equity Research*** *(OHER)* addresses the burden of diseases and disorders that disproportionately impact the health of minority populations. OHER helps to implement the Institute's strategic plan for health disparities and build on the strong partnership with the National Institute of Minority Health and Health Disparities at the NIH. Dr. Pamela Thornton is the acting director of OHER.

The NIDDK ***Office of Obesity Research*** (OOR) is responsible for coordination of obesity-related research within NIDDK and carries out its functions through the NIDDK Obesity Research Working Group. Drs. Maren Laughlin (DEM) and Susan Yanovski (DDN) are the co-directors of OOR. The Office is located organizationally under the auspices of the Office of the Director, NIDDK, and its co-directors represent the two divisions with primary responsibility for obesity-related extramural research, the Division of Digestive Diseases and Nutrition (DDN) and the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM). The Obesity Research Working Group consists of representatives of DDN, DEM, the Division of Kidney, Urologic, and Hematologic Diseases (KUH), the NIDDK Review Branch and the Office of Scientific Program and Policy Analysis (OSPPA). The responsibilities of the NIDDK Obesity Research Working Group are: (1) to provide a forum for sharing and coordination of trans- NIDDK and trans-NIH obesity research activities; (2) to assist the Director, NIDDK in identifying research opportunities, initiatives, and advances; (3) to identify and plan appropriate workshops and conferences; and (4) to assist in the preparation of obesity-related reports and inquiries.

Overview of the Division of Intramural Research

The Division of Intramural Research conducts biomedical research and training related to diabetes mellitus; endocrine, bone, and metabolic diseases; digestive diseases, including liver diseases and nutritional disorders; and kidney, urologic, and hematologic diseases. The research conducted in the Intramural Research Program (IRP) spans the breadth of modern biomedical investigation, from basic science to clinical studies.

A sampling of areas under study includes:

- **biophysics** – studies of protein folding, development of optical and vibrational imaging, and theory of protein dynamics
- **cell biology** – studies of nuclear import/export, intracellular protein and lipid trafficking, cellular migration and prions
- **chemical biology and medicinal chemistry** – synthesis and characterization of novel compounds and discovery of biologically active natural products
- **developmental biology** – studies using model systems ranging from single-cell organisms to vertebrates to human cells
- **genetics, pathogenesis and novel therapies of disease** – studies of diabetes types 1 and 2, hepatitis, endocrine disorders, nephritis/nephropathy, obesity, sickle cell anemia, and gastrointestinal disorders
- **molecular biology** – studies of chromatin structure and function, transcriptional regulation and DNA recombination
- **signal transduction** – basic and human disease-oriented studies of GTP-binding proteins and GTP-binding protein-coupled receptors, tyrosine kinase receptors and nuclear hormone receptors
- **structural biology** – studies using x-ray crystallography and NMR spectroscopy

The hallmarks of the NIDDK IRP are excellence and diversity. Many of the scientists within the IRP have achieved international recognition as highly productive and innovative researchers. The program continues a tradition of excellence reflected in the several Nobel prizes and other prestigious awards that have resulted from its work. Many scientists trained in the IRP are now prominent faculty members at leading universities throughout the world.

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-intramural-research

Overview of the Division of Extramural Activities

The Division of Extramural Activities (DEA) is responsible for:

1. Coordinating the receipt, referral, and scientific review of extramural research before funding
2. The publication of Notices of Funding Opportunities in the NIH Guide for Grants and Contracts
3. The processing of awards for grants, cooperative agreements, and contracts
4. Performing quantitative and qualitative data analyses and evaluations on behalf of NIDDK's scientific program divisions and the NIDDK Office of the Director
5. Providing leadership and advice in developing, implementing, and coordinating extramural programs and policies within the NIDDK
6. Coordinating the Institute's committee management activities and meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council

Components of the DEA

- **Receipt and Referral** – logs, assigns, and internally distributes all applications received by the NIDDK
- **Grant Review Branch** – conducts scientific and technical peer review of applications
- **Grants Management Branch** – manages awards for research project grants, program project and center grants, research training and development grants, cooperative agreements, and research contracts
- **Committee Management Office** – coordinates the administrative details of all of NIDDK's meetings that operate under the Federal Advisory Committee Act. These meetings include peer review meetings to review grant applications, meetings of the NIDDK Advisory Council, and meetings of the NIDDK Board of Scientific Counselors to review components of the Intramural Research Program. Additionally, the office functions as a Service Center, overseeing all committee management tasks for the National Institute on Aging (NIA), *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD), and Fogarty International Center (FIC).
- **Office of Research Evaluation and Operations** – oversees and coordinates disease coding and reporting for the NIDDK extramural program, manages the NIH Guide publication process associated with publishing Notices of Funding Opportunities, and supports NIDDK Advisory Council activities. The office also facilitates harmonization of activities among NIDDK's four extramural divisions, and coordinates and performs special projects at the request of the NIDDK leadership.

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-extramural-activities

Overview of the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM)

The Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM) provides research funding and support for basic and clinical research in the areas of type 1 and type 2 diabetes and other metabolic disorders, including cystic fibrosis; endocrinology and endocrine disorders; obesity, neuroendocrinology, and energy balance; and development, metabolism, and basic biology of liver, fat, and endocrine tissues. DEM also provides funding for the training and career development of individuals committed to academic and clinical research careers in these areas.

The Division of Diabetes, Endocrinology, and Metabolic Diseases supports research in:

Diabetes Research Programs

- Bioengineering, Biotechnology, and Imaging
- Clinical Research in Type 1 Diabetes
- Clinical Research in Type 2 Diabetes
- Clinical, Behavioral, and Epidemiological Obesity Research
- Diabetes and Metabolism HIV/AIDS
- Diabetes Centers
- Diabetes Genetics and Genomics
- Diabetes, Endocrine, and Metabolic Disease Translational Research
- Diabetes: Treatment, Prevention, and Complications
- Diabetic Kidney Disease
- Diabetic Urologic Disease
- Endocrine Pancreas
- Endocrinology and Hormone Signaling
- Genetic Metabolic Disease
- Kidney Genetics and Genomics
- Metabolic Pathways
- Obesity, Pregnancy, and the Intrauterine Environment
- Pathophysiology of Diabetes and Metabolic Disease

Endocrine and Metabolic Diseases Research Programs

- Bioengineering, Biotechnology, and Imaging as applied to Diabetes, Metabolic and Endocrine Diseases
- Chronic Kidney Disease
- Clinical, Behavioral, and Epidemiological Obesity Research
- Cystic Fibrosis
- Cystic Fibrosis Research and Translational Centers
- Diabetes and Metabolism HIV/AIDS
- Diabetes, Endocrine, and Metabolic Disease Translational Research
- Endocrine Pancreas
- Endocrine Tumors of the Pancreas
- Endocrinology and Hormone Signaling
- Genetic Metabolic Disease
- Metabolic Pathways
- Metabolism, Energy Balance, and Obesity

- Nutrient Metabolism, Status, and Assessment
- Obesity, Pregnancy, and the Intrauterine Environment
- Pathophysiology of Diabetes and Metabolic Disease

Research Training and Career Development

Small Business Programs

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-diabetes-endocrinology-metabolic-diseases

Overview of the Division of Digestive Diseases and Nutrition (DDN)

The Division of Digestive Diseases and Nutrition (DDN) supports research related to digestive diseases, including the alimentary tract, liver and pancreas, nutrition and obesity. The programs include basic, translational and clinical research, research training, and career development. DDN also promotes public awareness and education about digestive diseases and related conditions and oversees several national public awareness campaigns.

The Division of Digestive Diseases and Nutrition supports basic, translational and clinical research in:

Digestive Diseases Research Programs

- Digestive Diseases Clinical Research and Epidemiology
- Digestive Diseases Genetics and Genomics
- Digestive Diseases Research Core Centers
- Gastrointestinal Immunology, Inflammation, and Inflammatory Diseases
- Gastrointestinal Microbiology and Infectious Diseases
- Gastrointestinal Neuroendocrinology
- Gastrointestinal Physiology, Development, and Epithelial Biology
- Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS
- Motility and Functional Gastrointestinal Disorders
- Nutrient Metabolism, Status, and Assessment

Liver Disease Research Programs

- Digestive Diseases Research Core Centers
- Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS
- Iron and Heme Metabolism, Iron Chelation
- Liver Clinical Research and Epidemiology
- Liver Diseases Genetics and Genomics
- Translational and Basic Liver Disease Research

Nutrition Research Programs

- Clinical and Epidemiological Nutrition Research
- Clinical, Behavioral, and Epidemiological Obesity Research
- Endocrinology and Hormone Signaling
- Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS
- Metabolic Pathways
- Metabolism, Energy Balance, and Obesity
- Nutrient Metabolism, Status, and Assessment
- Nutrition and Obesity Genetics and Genomics
- Nutrition Obesity Research Centers
- Obesity Treatment and Prevention
- Obesity, Pregnancy, and the Intrauterine Environment

Obesity Research Programs

- Chronic Kidney Disease
- Clinical, Behavioral, and Epidemiological Obesity Research
- Endocrinology and Hormone Signaling

- Metabolic Pathways
- Metabolism, Energy Balance, and Obesity
- Neurobiology of Obesity
- Nutrient Metabolism, Status, and Assessment
- Nutrition and Obesity Genetics and Genomics
- Nutrition Obesity Research Centers
- Obesity Treatment and Prevention
- Obesity, Pregnancy, and the Intrauterine Environment

Pancreatic Disease Research Programs

- Acute and Chronic Pancreatitis
- Endocrine Pancreas
- Endocrine Tumors of the Pancreas
- Hereditary and Pediatric Disorders of the Pancreas
- Pancreas Basic Research and Development
- Pancreas Clinical Research and Epidemiology

Research Training and Career Development

Small Business Programs

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-digestive-diseases-nutrition

Overview of the Division of Kidney, Urologic, and Hematologic Diseases (KUH)

The Division of Kidney, Urologic, and Hematologic (KUH) Diseases provides research funding and support for basic, translational, and clinical research studies of the kidney, urinary tract, and disorders of the blood and blood-forming organs. Areas of research include:

Kidney
Chronic kidney disease, end-stage renal disease, diabetic nephrology, polycystic kidney disease, hypertensive nephrosclerosis, acute kidney injury, kidney donation, congenital kidney disorders, IgA nephrology, hemolytic uremic syndrome, fluid and electrolyte disorders, kidney repair and regeneration, and normal and abnormal kidney development and physiology.

Urology
Benign prostatic hyperplasia, urinary incontinence, urinary tract infections, stones, erectile dysfunction, urologic chronic pelvic pain syndromes (including interstitial cystitis and chronic prostatitis), congenital urologic disorders, repair and regeneration of lower urinary tract organs, and normal and abnormal lower urinary tract development and physiology.

Hematology
Blood and blood-forming organs, hematopoiesis, hemoglobin disorders, iron metabolism, sickle cell disease, bone marrow failure, iron deficiency, Cooley's anemia (thalassemia), and hemochromatosis.

The KUH also provides funding for training and career development of persons committed to academic and clinical research in these areas.

Kidney Disease Research Programs

- Acute Kidney Injury
- Chronic Kidney Disease
- Diabetic Kidney Disease
- End-Stage Renal Disease
- Genetic Metabolic Disease
- Kidney Basic Research
- Kidney Bioengineering, Biotechnology, and Imaging
- Kidney Clinical Research and Epidemiology
- Kidney Developmental Biology and Aging
- Kidney Disease Centers
- Kidney Genetic and Genomics
- Kidney HIV/AIDS
- Kidney Inflammation and Inflammatory Diseases
- Kidney Precision Medicine Project
- Pediatric Kidney Disease
- Polycystic Kidney Disease

Urologic Disease Research Programs

- Diabetic Urologic Disease
- Genetic Metabolic Disease
- Pediatric Urology
- Urologic Disease Centers
- Urology Basic Research
- Urology Bioengineering, Biotechnology, and Imaging
- Urology Clinical Research and Epidemiology
- Urology Developmental Biology and Aging
- Urology Genetics and Genomics
- Urology HIV/AIDS
- Women's Urology

Hematologic Disease Research Programs

- Erythropoiesis and Hemoglobin
- Genetic Metabolic Disease
- Hematology HIV/AIDS
- Hematopoiesis and Hematopoietic Stem Cell Biology
- Iron and Heme Metabolism, Iron Chelation
- Molecular Hematology Centers

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-kidney-urologic-hematologic-diseases

Funding Mechanisms (and Activity Codes) Supported by NIDDK

Brief Overview

While there are some specialized exceptions (e.g., prizes/challenges), NIH/NIDDK primarily uses three funding mechanisms (grants, cooperative agreements, and contracts).

Activities identifiy major funding categories or programs within a mechanism. General categories include:

- F – fellowships
- K – career development awards
- N – research contracts
- P – program project and research center grants
- R – research project grants
- S – research-related programs
- T – training grants
- U – cooperative agreements
- Y – interagency agreements

An activity code is a three-digit code assigned by NIH to distinguish variations in the ways that funding mechanisms are used (e.g. F32, K12, P01, R01, T32, etc.). See the NIH Funding Categories page (http://grants.nih.gov/grants/funding/funding_program.htm) for more information about the the NIH funding landscape or the comprehensive list of extramural grant and cooperative agreement activity codes for descriptions of all activites/codes.

With grants (i.e., activities with letters other than "N" or "U"), investigators are responsible for developing the concepts, methods, and approach for a research project. With contracts (i.e., "N" series), the DHHS awarding unit is responsible for establishing the detailed requirements. With cooperative agreements (i.e., "U" series), both the awarding unit and the recipient have substantial involvement.

Special NIH-Wide Programs

DP1 **NIH Director's Pioneer Award** (NDPA) (Roadmap program)
To support individual scientists of exceptional creativity, who propose pioneering – and possibly transforming approaches – to major challenges in biomedical and behavioral research.

DP2 **NIH Director's New Innovator Awards** (Roadmap program)
To support highly innovative research projects by new investigators in all areas of biomedical and behavioral research.

DP3 **Type 1 Diabetes Targeted Research Award**
To support research tackling major challenges in type 1 diabetes and promoting new approaches to these challenges by scientific teams.

DP5 **Early Independence Award**
To support the independent research project of a recent doctoral degree recipient.

Fellowship Programs

F30 **Individual Predoctoral National Research Service Award (NRSA) for M.D./Ph.D Fellowship**
To support students enrolled in MD/PhD, or equivalent combined degree programs, once they have identified a dissertation project.

F31 **Individual Predoctoral National Research Service Award (NRSA)**
To support students enrolled in a doctoral degree program (usually PhD) once they have identified a mentor and have chosen a dissertation research project.

F32 **Individual Postdoctoral National Research Service Award (NRSA)**
To support postdoctoral fellows to pursue mentored research training prior to applying for a faculty position.

F99 **Individual Predoctoral to Postdoctoral Fellow Transition Award**
K00 To encourage and retain outstanding graduate students who have demonstrated potential and interest in pursuing careers as independent researchers. Facilitates the transition of talented graduate students into successful research postdoctoral appointment.

Research Career Programs

K01 **Research Scientist Development Award - Research & Training**
To support basic scientists (non-clinicians) as they transition to independence and develop their careers with the support of a mentor.

K05 **Research Scientist Award**
To support a research scientist qualified to pursue independent research which would extend the research program of the sponsoring institution, or to direct an essential part of this research program.

K08 **Clinical Investigator Award (CIA)**
To support early clinician scientists who are transitioning to independence in a junior faculty position while pursuing a basic or clinical research project and developing their career.

K12 **Physician Scientist Award (Program) (PSA)**
Award to an institution to support several individuals as they transition from fellowship to faculty while pursuing a research project with the help of a mentor(s).

K23 **Mentored Patient-Oriented Research Career Development Award**
To provide support for the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. Supports early clinician scientists who are transitioning to independence in a junior faculty position and developing their career while pursuing a clinical research project that involves direct patient contact and the support of a mentor(s).

K24 **Midcareer Investigator Award in Patient-Oriented Research**
Supports established clinician scientists to enable them to pursue their patient-oriented research while mentoring the next generation of patient-oriented researchers.

K25 **Mentored Quantitative Research Career Development Award**
To support highly productive postdoctoral fellows pursuing mentored research projects while looking for faculty appointments.

K99 **NIH Pathway to Independence Award (PI)**
R00 Supports the initial phase of a Career/Research Transition award program that provides 1-2 years of mentored support for highly motivated, advanced postdoctoral research scientists.

Extramural Loan Repayment Program

L30 **Loan Repayment Program for Clinical Researchers**
NIH may repay up to $50,000 of your qualified student loan debt per year, including most undergraduate, graduate, and medical school loans if you are actively engaged in clinical research.

L40 **Loan Repayment Program for Pediatric Research**
NIH may repay up to $50,000 of your qualified student loan debt per year, including most undergraduate, graduate, and medical school loans if you are actively engaged in research related to pediatric disease or disease model.

L50 **Loan Repayment Program for Contraception and Infertility Research**
NIH may repay up to $50,000 of your qualified student loan debt per year, including most undergraduate, graduate, and medical school loans if you are actively engaged in research related to contraception and/or fertility.

L60 **Loan Repayment Program for Health Disparities Research**
NIH may repay up to $50,000 of your qualified student loan debt per year, including most undergraduate, graduate, and medical school loans if you are actively engaged in research related to health disparities.

L70 **Loan Repayment Program for Research in Emerging Areas Critical to Human Health**
NIH may repay up to $50,000 of your qualified student loan debt per year, including most undergraduate, graduate, and medical school loans if you are actively engaged in research Emerging Areas Critical to Human Health.

Research and Development-Related Contracts

N01 **Research and Development Contracts**
To develop and/or apply new knowledge or to test, screen, or evaluate a product, material, device, or component for use by the scientific community.

N02 **Resource and Support Contracts - Awarded in the ICD**
To support intramural and extramural station support needs. This activity also includes the provision of resources to intramural research programs.

N41 **Small Business Technology Transfer (STTR) Contracts - Phase I**
To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

N42 **Small Business Technology Transfer (STTR) Contracts - Phase II**
To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

N43 **Small Business Innovation Research (SBIR) Contracts- Phase I**

To support project, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s). These contracts may be made only with small businesses.

N44 **Small Business Innovation Research (SBIR) Contracts - Phase II**
To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. These contracts may be made only to small businesses.

Research Program Projects and Centers

P01 **Research Program Projects**
For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

P20 **Center Exploratory Grants**
To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

P30 **Center Core Grants**
To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. The core grant is integrated with the center's component projects or program projects, though funded independently from them. This support, by providing more accessible resources, is expected to assure a greater productivity than from the separate projects and program projects.

P50 **Specialized Center**
To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes.

Research Projects

R01 **Research Project Grant**
To support a discrete, specified, circumscribed project to be performed by the named

investigator(s) in an area representing his specific interest and competencies.

R03 **Small Research Grants**
Supports research projects that can be completed in a 2-yr time frame. NIDDK does not participate in the parent NOFOs for R03s, but issues NOFOs for specific audiences, e.g. NIDDK- supported K01, K08, and K23 awardees.

R13 **Research Conference Grant**
To support recipient sponsored and directed international, national or regional meetings, conferences and workshops.

R15 **Academic Research Enhancement Awards (AREA)**
To support small-scale research projects conducted by faculty in primarily baccalaureate degree-granting domestic institutions. Awards are for up to $375,000 for direct costs (plus applicable indirect costs) for periods not to exceed 3 years.

R18 **Research Demonstration and Dissemination Projects**
To provide support designed to develop, test, and evaluate health service activities, and to foster the application of existing knowledge for the control of categorical diseases.

R21 **Exploratory/Developmental Grants**
Supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

R24 **Resource-Related Research Projects**
To support research projects that will enhance the capability of resources to serve biomedical research.

R25 **Education Projects**
For support to develop and/or implement a program as it relates to a category in one or more of the areas of education, information, training, technical assistance, coordination, or evaluation.

R34 **Clinical Trial Planning Grant**
To provide support for the initial development of a clinical trial, including the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

R41 **Small Business Technology Transfer (STTR) Grants - Phase I**
R42 To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

R43 **Small Business Innovation Research (SBIR) Grants - Phase I**
R44 To support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s).

RC2 **High Impact, Interdisciplinary Science in NIDDK Research Areas**
To support high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/

resource designed to accelerate scientific progress in the future.

Research-Related Programs

S06 **Native American Research Centers for Health (NARCH)**
Supports partnerships between American Indian/Alaska Native (AI/AN) tribes or tribally-based organizations and institutions that conduct intensive academic-level biomedical, behavioral and health services research.

SC1 **Research Enhancement Award**
Individual investigator-imitated research projects aimed at developing researchers at minority-serving institutions (MSIs) to a stage where they can transition successfully to other extramural support (R01 or equivalent).

SC2 **Pilot Research Project**
Individual investigator-initiated pilot research projects for faculty at MSIs to generate preliminary data for a more ambitious research project.

Training Programs

T32 **Institutional National Research Service Award (NRSA)**
To enable institutions to make National Research Service Awards to individuals selected by the institution, in either short-term, predoctoral, and/or postdoctoral research training in specified shortage areas.

T32 **Diversity NRSA Diversity Supplement Award**
Additional slot awarded to an existing training grant for either a specific medical student wishing to take a year off from school to pursue research training or for a pre- or post-doctoral trainee from a group underrepresented in biomedical research, when no slot is available on the training grant.

T32 **MSRT Medical Student Research Training Supplement**
Additional slot awarded to an existing training grant for either a specific medical students wishing to take a year off from school to pursue research training or for a pre- or post-doctoral trainee from a group underrepresented in biomedical research, when no slot is available on the training grant.

T35 **NRSA Short-Term Research Training**
Provides 2-3 months of support for medical students, selected by the institution, to pursue research training during off-quarters or summer periods.

Cooperative Agreements

Note: For all funding mechanisms within this section, substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.

U01 **Research Project Cooperative Agreement**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

U13 **Research Conference Cooperative Agreement**
To support international, national, or regional meetings, conferences and workshops where substantial programmatic involvement is planned to assist the recipient.

U24 **Resource – Related Research Projects – Cooperative Agreement**
Supports research projects contributing to improvement of the capability of resources to serve biomedical research.

U34 **Multi-Center Clinical Study Implementation Planning Grants**
Supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

U54 **Specialized Center – Cooperative Agreement**
To support any part of the full range of research and development from very basic to clinical; may involve ancillary, supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These differ from program project in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes, with funding component staff helping to identify appropriate priority needs.

UC4 **High-Impact Research and Research Infrastructure Cooperative Agreements**
To support multi-year funded cooperative agreement research with high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future. It is the cooperative agreement companion to the RCA. It is also the multi-year funded companion to the existing UC2; thus ICs need OER prior approval to use the UC 4.

UG3 **Phase 1 Exploratory/Developmental Cooperative Agreement**
As part of a bi-phasic approach to funding exploratory and/or developmental research, the UG3 provides support for the first phase of the award. This activity code is used in lieu of the UH2 activity code when larger budgets and/or project periods are required to establish feasibility for the project.

UH2 **Exploratory/Developmental Cooperative Agreement Phase II**
UH3 To provide a second phase for the support for innovative exploratory and development research activities initiated under the UH2 mechanism. Although only UH2 awardees are generally eligible to apply for UH3 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under UH2.

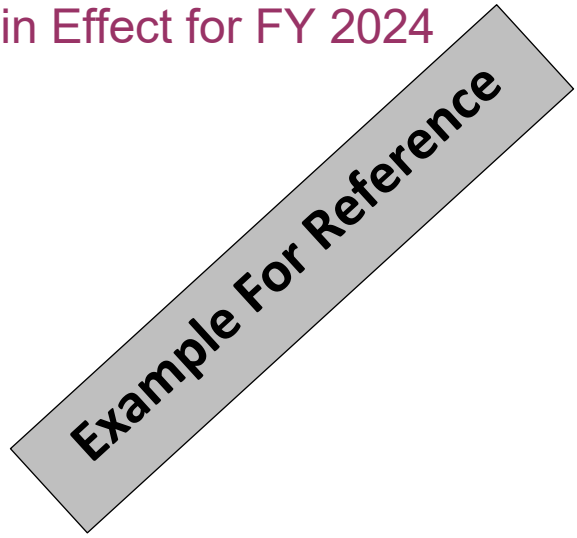
U2C **Resource-Related Research Multi-Component Projects and Centers Cooperative**
TL1 **Agreements –Linked Training Award**
To support multi-component research resource projects and centers that will enhance the capability of resources to serve biomedical research. To support research training experiences for pre- and post-doctoral trainees who are interested in pursuing research careers in multi-disciplinary clinical and translational science.

X01 **Resource Access Program**
To invite eligible institutions to seek access to NIH research resources. This includes programs where institutions will request access to submit to the resource, e.g., high throughput screening assays. It also includes programs where access to a specific NIH research resource is needed to

conduct certain research.

X02 **Preapplication**
A program to invite eligible institutions to submit a pre-application (also known as a "white paper" to "precis") to facilitate certain approaches or economies, such as reducing burden on the applicant community, for a funding opportunity.

Notice of Fiscal Policies in Effect for FY 2024



Notice Number:

NOT-OD-24-109

Key Dates

Release Date:

March 30, 2024

Related Announcements

- **April 30, 2024** - Notice of Legislative Mandates in Effect for FY 2024. See Notice NOT-OD-24-110.
- **April 23, 2024** - Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2024. See Notice NOT-OD-24-104.
- **January 29, 2024** - Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2024. See Notice NOT-OD-24-057.
- **February 3, 2023** - Notice of Fiscal Policies in Effect for FY 2023. See Notice NOT-OD-23-071.

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

This Notice provides guidance about the NIH Fiscal Operations for Fiscal Year 2024 and implements the *Further Consolidated Appropriations Act, 2024* (Public Law 118-47), signed into law on March 23, 2024.

FY 2024 Funding Levels: Non-competing continuation awards made in FY 2024 will generally be issued at the commitment level indicated on the Notice of Award with exceptions posted on the NIH Funding Strategies webpage. Subsequent budget periods are funded based on the availability of appropriations, satisfactory performance, compliance with the terms and conditions of the award, and the continued best interest of the Federal government. The NIH awarding Institutes/Centers (ICs) will develop and post their fiscal policies consistent with overall NIH goals and available FY 2024 funds.

Ruth L. Kirschstein National Research Service Awards (NRSA): Consistent with the recommendations of the Advisory Committee to the Director regarding the Biomedical Research Workforce, the NIH will increase NRSA stipends by approximately four percent for predocs and eight percent for postdocs. The full range of stipend adjustments for FY 2024 is described in NIH Guide Notice NOT-OD-24-104.

Salary Limits: Section 202 of PL 118-47 restricts the amount of direct salary to Executive Level II of the Federal Executive pay scale. Effective January 1, 2024, the salary limitation for Executive Level II is $221,900. Further information is described in NIH Guide Notice NOT-OD-24-057.

Additional Information: Additional details on Fiscal Operations, including specific funding strategies for ICs, will be posted on the NIH Funding Strategies webpage.

Inquiries

Please direct all inquiries to:

National Institutes of Health
Office of Policy for Extramural Research Administration (OPERA)
Division of Grants Policy
GrantsPolicy@nih.gov

2024 Award Funding Policy

The National Institute of Diabetes and Digestive a ses (NIDDK) conducts and supports basic and clinical research on man ious diseases affecting public health.

NIDDK extramural research is organize matic divisions: 1) Diabetes, Endocrinology, and Metabolic Disea Diseases and Nutrition; and 3) Kidney, Urologic, and Hematologi

The Institute supports basic arch through investigator-initiated grants, program project and cent rative agreements, career development and training awards, and co

The NIDDK has developed an ued a Strategic Plan to accelerate research into the causes, treatment, and prevention of diseases and conditions under the Institute's mission. This overarching 5-year trans-NIDDK Strategic Plan complements our disease-specific planning efforts. The Plan highlights NIDDK's commitment to empowering a multidisciplinary research community; engaging diverse stakeholders; and leveraging discoveries of connections among diseases across NIDDK's mission to improve prevention, treatment, and health equity—pursuing pathways to health for all. NIDDK will make funding decisions, as consistent with applicable law, in alignment with values established in the Strategic Plan.

Budget Data

Current Appropriation

NIH is operating at a program level of $47.081 billion in FY 2024, a decrease of approximately $378 million over the FY 2023 final budget allocations. NIDDK's discretionary appropriation for FY 2024 is $2.311 billion. This is an increase of about 0.43% from NIDDK's appropriation in FY 2023. This figure does not include the Special Type 1 Diabetes appropriation of $160 million that NIDDK oversees on behalf of the Department of Health and Human Services.

Funding Strategy

NIDDK is committed to supporting as many meritorious competing research grant applications as possible. Consistent with NIH policy (see NIH Guide Notice NOT-OD-24-109) and the Next Generation Research Initiative (see NOT-OD-17-101) NIDDK will manage its portfolio in biomedical research investments in a manner that includes recognizing applications from and providing special consideration for early career investigators.

To maximize our available resources, all grant awards will continue to be subject to programmatic adjustments from the National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council approved levels. These adjustments take into consideration the

overall scientific and technical merit of the grant application, the cost of the proposed research, and other resources available for related research projects.

Funding Guidelines

Competing Awards

NIDDK established an initial FY2024 R01 general pay line of the 15th percentile, for both New and Competing applications, which was effective for October 2023 and January 2024 Council. However, due to the availability of funds, R01 applications reviewed for May 2024 Council will have a general payline at the 13th percentile. Most R01 applications submitted to Notices of Funding Opportunity that 1) do not have set-aside funds, 2) have a primary assignment to NIDDK, 3) request less than $500,000 direct costs per year, and 3) score at or better than the payline established (per the above) will receive an award. Applications that have NIDDK as a secondary assignment do not benefit from this payline.

R01 applications that do not include therapeutic clinical trials as the primary focus of the research plan requesting $500,000 or more in direct costs for any year will be held to a more stringent pay line. The more stringent pay line is 5% below the prevailing general payline threshold in effect at the time for both Type 1 and 2 R01 applications which do not have therapeutic clinical trial as the primary focus of the research plan.

Therapeutic Clinical Trial R01 Applications

Per NOT-DK-18-012, NIDDK will not apply the more stringent pay line to R01 applications that include therapeutic clinical trials if the total direct costs (exclusive of F&A on subcontracts) for five years do not exceed $2.5 million (or $2 million for four years), even if the direct costs equal or exceed $500,000 in some years. As indicated above, the more stringent pay line will continue to be applied for all other R01 applications (i.e., all applications that do not have a therapeutic clinical trial as the primary focus of the research plan).

R01 Applications Received in Response to PARs

Consistent with NIDDK policy first established in FY 2016, R01 applications received in response to Notices of Funding Opportunity (NOFOs) that are PARs will not automatically be considered for funding based on payline/percentile ranking. Scores and additional programmatic factors will be weighed when considering applications received under R01 PAR NOFOs for funding.

General Considerations Regarding Competing Awards

Please note the following regarding competing awards:

- NIDDK will exercise discretion and consider portfolio balance, programmatic importance, and other factors in determining precisely which applications are awarded.
- All grant awards will continue to be subject to programmatic adjustments from the NDDK Advisory Council approved levels.
- These funding guidelines are applicable for applications to be paid in FY 2024. Many applications submitted in FY 2024 (e.g., those submitted in January/February/March for September/October Advisory Council consideration) will usually not be eligible for funding consideration until FY 2025. The funding levels for FY 2025 cannot now be reliably predicted.

Early-Stage Investigators (ESIs)

Fostering the success of investigators establishing careers in biomedical research is a high priority of the NIDDK and NIH (see Policy Supporting the Next Generation Researchers Initiative). In FY 2024 NIDDK will place special emphasis on supporting ESIs (new investigators within 10-years of their terminal research degree or medical residency who have not yet been awarded a substantial, competing NIH research grant; see ESI FAQs and NIDDK's New and Early Stage Investigators page) by establishing a nominal payline for R01 applications submitted by ESIs at the 25th percentile. In addition, when possible and appropriate the full period of support recommended will be awarded.

R01 applications submitted by New Investigators who are not also ESIs will have a nominal payline at the 15th or 13th percentile (same as the general pay line per the above).

First Competitive Renewal Applications of R01 Grants Awarded to NIDDK ESIs

Consistent with the NIH Next Generation Researchers Initiative , NIDDK seeks to encourage the stable integration of early career researchers into the scientific research workforce. In support of this, the nominal payline for first competitive renewal applications for R01 awards to researchers who were ESIs when they competed for the initial NIDDK Type 1 R01 award scoring between 16th and 18th percentile except for the May Council which is between the 14th and 16th may be considered for funding in FY 2024. Only one award per eligible investigator may be considered for this special payline. If a special payline award is made to an eligible investigator any other eligible applications from that investigator will be considered for funding based on the standard nominal payline.

Bridge Support

In cases where a competing renewal application falls near but beyond the nominal payline, NIDDK will continue to consider interim support on a case-by-case basis and provide limited support in selected cases. The goal is to preserve essential research resources pending the re-review of a revised application. NIDDK can choose to award a

one- or two-year R56 grant to an R01 application scored outside the payline. These awards provide support for investigators to collect preliminary data and use these data to revise and improve their R01 applications.

Administrative Supplements

NIDDK has prioritized its budget to maintain funding of investigator-initiated grants at the highest possible level. Therefore, the institute has little flexibility to support administrative supplements. Given this prioritization, the number of successful administrative supplement applications will be extremely low and generally limited to rare, unforeseen circumstances (e.g., requests to replace key pieces of equipment following a natural disaster). In FY2024, NIDDK does not have any special NOFOs or Notices soliciting administration supplements to replace old equipment or to purchase shared equipment or to expand the scope of a project by adding funds or restoring an administratively cut year.

Duration of Grant Support

Competing awards are adjusted to achieve a 4-year average duration for research project grants. Nevertheless, applications from ESIs, program project grants, and clinical trial grants are generally awarded for the full length of their recommended project period.

Salaries

The Consolidated Appropriations Act, 2024 prohibits payments for salaries under grants and other extramural mechanisms in excess of Executive Level II currently set at $221,900.

Non-competing (Continuation) Awards

Consistent with the Notice of Fiscal Policies in Effect for FY 2024 (see NOT-OD-24-109) non-competing (Type 5) continuation grants (research and non-research) issued in FY 2024 will generally be issued at 96% of the commitment level indicated on the Notice of Award. This includes U24 non-competing awards and excludes Type 1 Diabetes funding. Out-year commitments for continuation awards in FY 2024 and beyond remain unchanged.

Program Project (P01), High Impact, Interdisciplinary Science in NIDDK Research Areas (RC2), and Other Applications with Budgets Greater than $500K

NIDDK has adopted a more stringent funding practice for awarding program project (P01) grants, High Impact, Interdisciplinary Science in NIDDK Research Areas (RC2), and other investigator-initiated grant applications with budgets of $500,000 or more requested direct costs in any one year. Prior approval is required before submitting an application for review that requests $500,000 or more in direct costs in any one year. The request to submit such applications should be received at least three months prior to the proposed submission date. Prior approval is required for renewal and revised applications as well as new applications. Please consult with the appropriate NIDDK program staff and visit the following site for information on research areas supported by NIDDK: http://www.niddk.nih.gov/research-funding/research-programs/. Renewal (competing continuation [Type 2]) program project (P01) applications may request a maximum of $6.25 million in direct costs over five years, excluding the Facilities & Administrative (F&A) costs for subcontracts. In addition to the caps on the amount requested, P01 awards are subject to administrative adjustment from the NIDDK Advisory Council approved levels. Also, please note that any P01 grant receiving a competing award in FY 2011 or later will be limited to one subsequent renewal.

HIV/AIDS Research

HIV/AIDS related applications will receive additional consideration in the context of NIH's HIV/AIDS research priorities (see NOT-OD-20-018) as well as programmatic relevance to the NIDDK mission.

Resources for New and Early Stage Investigators

A New Investigator (NI) is an NIH research grant applicant who has not yet competed successfully for a substantial, competing NIH research grant. For a complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator, see the NIH Definition of New Investigator.

An Early Stage Investigator (ESI) is a new investigator who has completed his or her terminal research degree or medical residency – whichever date is later – within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant.

How Are New Investigators (NIs) and Early Stage Investigators (ESIs) Identified?

Software within the eRA Commons will check first for New Investigator (NI) status based on the individual's previous award history. For individuals identified as NIs, the software will calculate the ten-year window of Early Stage Investigator (ESI) status based on the date of the terminal research degree or the residency end date entered in the investigator's Profile. To ensure that NIH recognizes your ESI status, you must update your eRA Commons profile to reflect the date of completion of your terminal research degree of the end of your residency.

Note: NIH will consider a request to extend the period of your ESI status if there has been a lapse in your post-degree training (see Form for Requesting an Extension in the Early Stage Investigator (ESI) Period).

What Benefits Are Conveyed With New Investigator (NI) or Early Stage Investigator (ESI) Status?

Peer Review – For both New Investigator (NI) and Early Stage Investigator (ESI) applications, peer reviewers are instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by established investigators. Institute staff members pay special attention to applications from NI and ESI investigators as well.

Differential payline (for ESIs) – Each year, the NIDDK sets a percentile "payline" for R01 applications based on available funds and the volume of applications. The payline for ESI applications is typically more generous than the regular payline for established investigators (see NIDDK Funding Policy). While NIDDK often makes administrative reductions in grant duration, applications from ESIs that fall within the payline are usually awarded the full requested duration.

Consideration for NIH High Priority, Short-Term Project Award (R56) – Although you cannot apply for this grant activity, NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These provide support for an investigator to collect key preliminary data in order to submit an improved revised R01 application, but you should understand that NIDDK has only enough funds to make very few of these awards.

Mentoring Workshops – NIDDK regularly holds workshops for recently funded new investigators. In addition, when NIs or ESIs receive their first grant they are encouraged to maintain contact with their Program Official who can be an excellent resource during this critical stage of your research career.

First Competitive Renewal of R01 Applications From Former NIDDK ESIs – NIDDK seeks to encourage the stable integration of early career researchers into the scientific research workforce. In support of this, the nominal payline for first competitive renewal applications for R01 awards to researchers who were ESIs when they competed for the initial NIDDK Type 1 R01 award is typically more generous than the regular payline for established investigators (see NIDDK Funding Policy). Only one award per eligible investigator may be considered for this special payline. If a special payline award is made to an eligible investigator any other eligible applications from that investigator will be considered for funding based on the standard nominal payline.

For Information

Visit the NIH New and Early Stage Investigator Policies page, or view NIDDK Research Programs and Contacts for your scientific area of interest.

Role of NIDDK Advisory Council

Established by law and charter, the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKDAC) meets three times annually to advise the NIDDK about its research portfolio. The Council typically undertakes broad issues of science policy. An important role of the Council is to provide second-level peer review of grant applications that have been scored by scientific review groups. The Council members are an important liaison between the research communities they represent and NIDDK, which supports each community's research efforts.

Who are the Council members?

Members of the Advisory Council are drawn from the scientific and lay communities, are appointed for 4-year terms, and represent all areas within the Institute's research mission. The Council membership consists of 18 voting members, including 12 health or science experts and 6 public members.

Six nonvoting, *ex officio* members provide liaison with higher level agencies or organizations having missions consistent with that of NIDDK, including the Secretary, Department of Health and Human Services (DHHS), and representatives from the Department of Defense, Department of Agriculture, and Department of Veterans' Affairs.

Council's health or science experts contribute technical expertise and an understanding of the needs of the research communities of academia and industry. Council's public representatives impart a perspective of people affected by diseases in NIDDK's research mission.

Each Council member also belongs to one of the three Council subcommittees – Digestive Diseases and Nutrition; Diabetes, Endocrinology, and Metabolic Diseases; and, Kidney, Urologic and Hematologic Diseases, corresponding to NIDDK's extramural programmatic divisions.

A copy of the current Council roster is included in the next section on Advisory Council Logistical documents and online https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/members.

What does the Council do? (For an abbreviated version see: "RESPONSIBILITIES OF NIDDK ADVISORY COUNCIL MEMBER" at the end of this document.)

As required by law, chartered advisory committees, including the councils, are part of every NIH institute. NIDDK's Council performs the following four key roles:

- Conducts second-level peer review of grant applications scored by scientific review groups
- Advises NIDDK on broad issues of science policy
- Reviews NIDDK programs
- Clears concepts for grant Notices of Funding Opportunities (NOFOs) and contract Requests for Proposals (RFPs).

The subcommittees conduct most of the NIDDK Division-specific business, including the closed-session discussion of grant applications. Note that other public venues may clear concepts.

What is second-level review?

Second-level review is the assessment of the quality of the initial review of grant applications. The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote.

Expedited Concurrence of En Bloc Actions. For grant and cooperative agreement applications that have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution), excluding those from foreign organizations, a process of expedited concurrence is available. The purpose is to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive, and responsible manner. In this process, the power to review applications is delegated by the Chairman of the Advisory Council to specifically designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee consists of the Council Executive Secretary and six members of the NDDKDAC. Two members are selected from each subcommittee of the NDDKDAC. Electronic or written concurrence by a minimum of two members with no votes for nonconcurrence within 7 days of notification of posting is required for expedited concurrence approval.

Expedited review enables NIDDK to fund grants a few weeks after the initial peer review meeting.

The NIDDK Director makes final funding decisions based on staff and Advisory Council/Board advice.

What happens at Council meetings?

Council meets in September or October, January or February, and May or June. Its activities are driven partly by the budget and appropriation cycle. For example, discussions in September reflect the beginning of the fiscal year (which begins on October 1st).

Council meetings are scheduled for two days, but typically are scheduled for a single day, depending on the agenda. Council meetings may be conducted: 1) in-person on the NIH Campus in Bethesda, MD; 2) virtually using meeting software (Zoom); or 3) using a combination of in-person and virtual formats (i.e., hybrid format). For the foreseeable future, NIDDK's Council meetings will be held in hybrid format. We ask, whenever possible, that Council members attend Council meetings in-person

Typically, on the morning of the first day of the Council meeting, the full Council (Council in the Whole) meets in open session to hear updates from the Director, NIDDK, and to discuss items that cut across NIDDK Divisional lines. This may include scientific and administrative topics for discussion, often presented by staff or outside speakers. ***Note: Open sessions are open to the public and members of the press may be present.***

Typically, sometime after the open session of the full Council (either in the same day or on the following day) the three subcommittees meet individually to review applications needing special consideration, discuss selective pay nominations, and discuss any appeals and/or the funding any applications submitted by foreign institutions. Then, the Director, NIDDK, convenes the full Council for a short, closed meeting to discuss and formally concur with subcommittee recommendations for funding grants and concur with initial peer review regarding all remaining applications under consideration.

Note: A sample Council meeting agenda is included among the Advisory Council Logistical documents. Council meeting agendas are posted several weeks before the meetings and are available from the Council's home page (https://www.niddk.nih.gov/about-niddk/advisory-coordinating-

committees/national-diabetes-digestive-kidney-diseases-advisory-council). Minutes are also posted and available from the home page.

What is Council's role in concept clearance?

NIDDK seeks Council's advice regarding its plans for the development of Notices of Funding Opportunities (NOFOs). The final decision to move forward with an initiative and publish a NOFO is made by NIDDK, based on scientific and programmatic priorities and on the availability of funds.

Definitions of Special Issues Presented to Council

The following types of special issues are typically presented to Council.

1. **Reinstatement of Research Aims**. Applications for which the division is requesting to reinstate specific aims or research not recommended for support by the study section.

2. **Non-Peer-Reviewed Applications**. Used in some circumstances. Council performs both initial peer review and second-level review functions.

3. **Deferred Applications**. All Council-deferred applications independent of review results.

4. **Unresolved Appeals.** When program staff working with a scientific review officer have been unable to resolve the applicant's concerns regarding the review process (based on at least one of the four criteria for an appeal including: bias, conflict of interest, inappropriate expertise, and/or, the DEA director reviews the appeal, and staff present it to Council.

5. **Foreign Applications**. Foreign applications (applications submitted by a foreign institution) that a division proposes to award.

6. **Human Subjects**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of human subjects.

7. **Biohazards**. Applications proposed for award with unresolved concerns about biohazards.

8. **Use of Animals in Research**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of animals in research.

9. **Minority Recruitment Plans in Institutional Training Grant Applications**. Fundable, meritorious National Research Service Award applications with inadequate plans for minority recruitment. When the study section deems a plan inadequate, options are (1) no special action, pay by priority score; (2) defer payment pending submission and staff approval of a recruitment plan; or (3) defer for study section re-review pending receipt of an acceptable plan.

10. **Inclusion of Women and Minorities as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

11. **Inclusion of Children as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

12. **Special Council Review**. Review of research applications from a Principal Investigator with more than $2,000,000 in total costs in annual NIH support.

CHARTER

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

COMMITTEE'S OFFICAL DESIGNATION

National Diabetes and Digestive and Kidney Diseases Advisory Council

AUTHORITY

Required by 42 U.S.C. 284a, sections 406 of the Public Health Service (PHS) Act, as amended, The National Diabetes and Digestive and Kidney Diseases Advisory Council (Council) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary) and the Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK, also referred to as Institute) on matters related to the activities carried out by and through the Institute and the policies respecting these activities.

DESCRIPTION OF DUTIES

The Council may recommend to the Secretary, in accordance with section 231 of the PHS Act, as amended, acceptance of conditional gifts for basic and clinical study, investigation, or research on diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Institute.

The Council may review applications for grants and cooperative agreements for research and training and recommend approval of applications for projects which show promise of making valuable contributions to human knowledge; may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute; may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Institute was established and, with the approval of the Director of NIDDK, make available such information through appropriate publications for the benefit of public and private health entities, health professions personnel and scientists, and for the information of the general public.

The Council will prepare triennial reports describing the manner in which the Institute has complied with section 429B of the PHS Act, which sets forth requirements addressing the inclusion of women and members of minority groups as subjects in clinical research conducted or supported by NIH. Each report shall be submitted to the Director, NIDDK, for inclusion in the triennial report submitted to Congress by the

Director, NIH, pursuant to section 403 of the PHS Act. Each triennial report prepared by the Council shall include each of the following:

1. The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

2. The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories od research area, condition, or disease and accounting for single-race and single-ethnicity studies.

3. For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—
   (a) Have been completed during such reporting period; and
   (b) Are being carried out during such reporting period and have not been completed.

4. The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with section 492B(c)(2)(A) of the PHS Act.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Council will advise the Secretary and the Director, NIDDK.

SUPPORT

Management and support services will be provided by the Office of the Director, NIDDK.

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is $102,073. The estimated annual person-years of staff support required is 0.5, at an estimated annual cost of $196,912.

DESIGNATED FEDERAL OFFICER

The Director, NIDDK, will assign a full-time or permanent part-time NIDDK employee to serve as the Designated Federal Officer (DFO) of the Council. In the event that the DFO cannot fulfill the assigned duties of the Council, one or more full-time or permanent part-time NIDDK employees will be assigned as DFO and carryout these duties on a temporary basis.

The DFO will approve all of the Council's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Council and subcommittee meetings, adjourn any

meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH, or Director, NIDDK.

The Director, NIDDK shall designate a member of the staff of the institute to serve as the executive secretary of the Council. The DFO will also serve as the executive secretary for the Council.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Council will be held at the call of the Chair (with the DFO's approval) or upon request of the Director, NIDDK, not less than three times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b to Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Council's functions, dates and places of meetings, and a summary of the Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Continuing.

TERMINATION

Unless renewed by appropriate action, prior to its expiration, the Charter for the National Diabetes and Digestive and Kidney Diseases Advisory Council will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Council will consist of not more than 18 members appointed by the Secretary (appointed members) and 6 nonvoting ex officio members. The nonvoting ex officio members will include the Secretary; the Director, NIH; the Director, NIDDK; the Under Secretary for Health of the Department of Veterans; the Assistant Secretary of Defense for Health Affairs; the Assistant Secretary for Science and Education, United States Department of Agriculture (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its functions. Of the appointed members, two-thirds will be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the NIDDK, particularly representatives of the health and scientific disciplines in the areas of diabetes mellitus, endocrinology, metabolism, digestive diseases, nutrition, nephrology, urology, hematology and public health. One-third of the appointed members will be appointed by the Secretary from the general public and will include leaders in the fields of public policy, law, health policy, economics, and management. All appointed members must be eligible to serve as Special Government Employees (SGEs) and will serve as SGEs. A quorum for the conduct of business by the full Council will consist of a majority of currently appointed members.

Appointed members will be invited to serve for overlapping four-year terms, except that any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term. The Secretary shall make appointments in such a manner as to ensure that the terms of the appointed members do not all expire in the same year. A member may serve 180 days after the expiration of that member's term if a successor has not taken office. A member who has been appointed for a term of four years may not be reappointed to this Council before two years from the date of expiration of that member's term of office.

The Chair of the Council will be selected by the Secretary from among the appointed members, except that the Secretary may select the Director, NIDDK, to be the Chair. The term of office of the Chair will be two years.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Council's jurisdiction. The advice/recommendations of a subcommittee /working group must be deliberated by the parent advisory committee. A subcommittee/working group may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. A quorum for a subcommittee will be three members. Ad hoc consultants are not members, do not count towards the quorum and may not vote. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the Council and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Council and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE

October 31, 2023

APPROVED

Lawrence A. Tabak -S
Digitally signed by Lawrence A. Tabak -S
Date: 2022.10.12 04:38:35 -04'00'

Performing the Duties of the NIH Director

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

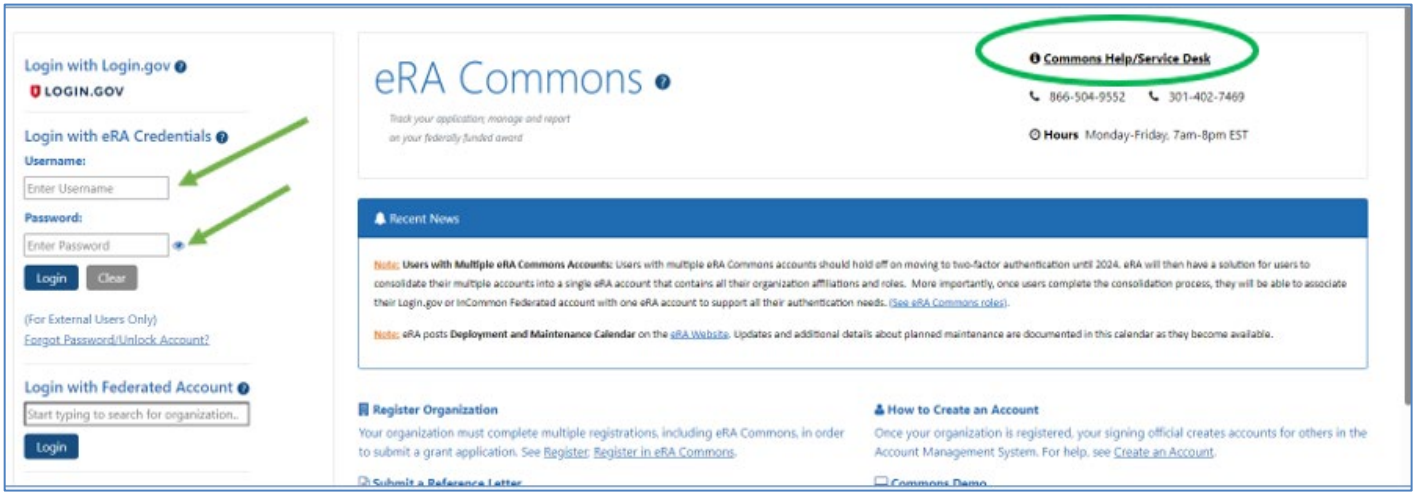
What is the NIH Electronic Council Book?

The Electronic Council Book (ECB) is an online system that provides a variety of services in support of the second level of review of grant applications by a review group (hereafter referred to as the Advisory Council) at the funding agency.

- ***The data in the ECB, and the passwords that you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it open while unattended. Use it and then disconnect. If you are logged-in to the system but inactive (approximately one hour) the system will automatically disconnect, and you will have to log-in again.***

How do I get started?
Logging in to the new Electronic Council Book (ECB):

1. Council Members should receive an email from NIH eRA that is inviting them to access the eRA Commons Homepage. Click on the link within that email (If needed, check your spam folder). Alternatively, the ECB can be accessed at https://public.era.nih.gov/ecb.
2. Use your eRA Commons username and password. If you do not know your login information, click the Forgot Password/Unlock Account, or contact the Commons Help/Service Desk to re-establish your credentials.
    - The new council member electronically agrees to necessary acknowledgments, such as responsibilities in protecting peer review, confidentiality, and conflict of interest forms, whereupon they land on the council information screen in ECB.



Please note: If you have problems, please email NIDDKAdvisoryCouncil@nih.gov or call the NIDDK DEA Office of the Director (301.594.8843). If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

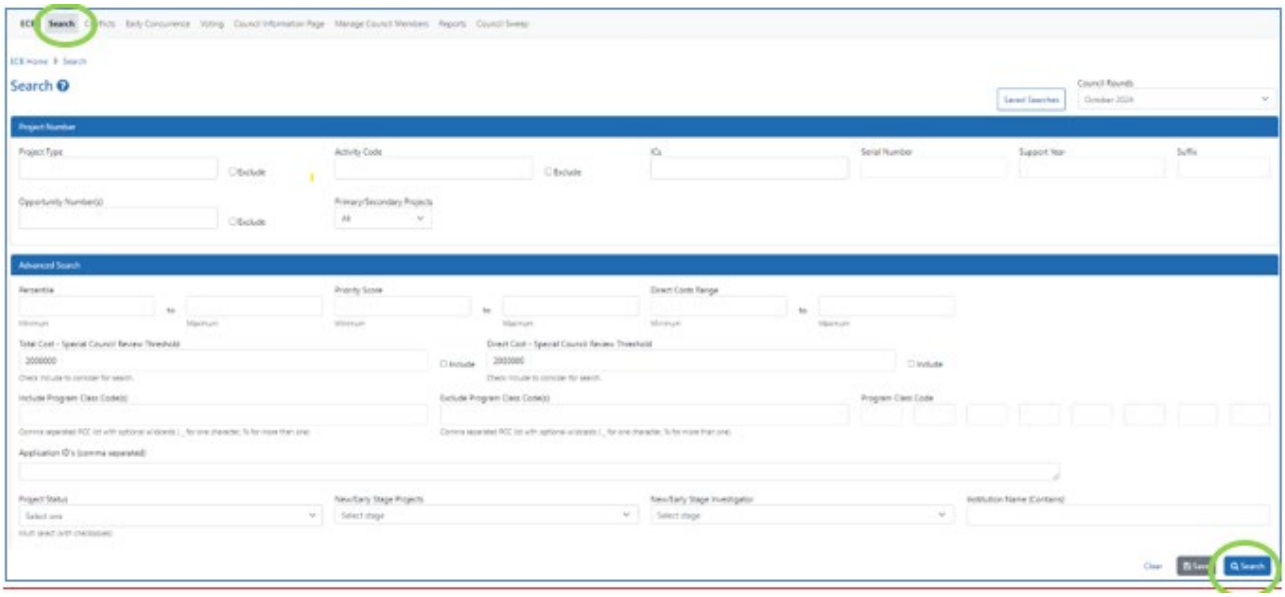
How Do I Use the System?

The ECB Council Information screen is the landing page for council members. Each council round, a new Council Information page is set up; these pages can consist of tabs, sections, subsections, text, links, and documents.

How do I initiate a search?

ECB allows you to search for applications for the current council round using several criteria on the Application Search screen.

1. Click the Search tab in the ECB menu at the top of the screen. The Application Search screen is displayed.



Selecting search criteria

Selecting search criteria

Project Type searches for one or more project types. Enter a type, then select it from the drop-down list of potential matches. Note that you can select the Exclude checkbox to include all project types except the specified type(s).

Activity Code searches for one or more activity codes. Enter a code, then select it from the drop-down list of potential matches. Note that you can select the Exclude checkbox to include all activity codes except the specified code(s).

ICs searches for one or more ICs. Enter the IC abbreviation, then select it from the dropdown list of potential matches. Note that you can select the Exclude checkbox to include all ICs except the specified one(s). Electronic Council Book (ECB) for Council Members User Guide Electronic Council Book (ECB)

Serial Number searches for the six-digit number assigned within an IC.

Support Year searches for the two-digit number indicating the segment or budget period of a project. Suffix searches for the suffix appended to an application (e.g., A1 is a resubmission).

PI First Name searches for applications based on the PI's first name.

PI Last Name searches for applications based on the PI's last name.

Institution Name searches for applications where the primary investigator is affiliated with the specified institution. Note that this performs a contains search and wildcards are not necessary.

Project Title searches for applications based on the project title. Note that although you may use wildcards, you must enter three characters before a wildcard can be entered.

PO Name searches for applications based on the PO. Click the drop-down and select the PO you wish to search for.

Percentile allows you to set a minimum value, maximum value, or both for the Percentile score in council review. Note that if an application does not have a Percentile score, it will be filtered out if any criteria are entered here.

Priority Score allows you to set a minimum value, maximum value, or both for the Priority score in council review. Note that if an application does not have a Priority score, it will be filtered out if any criteria are entered here.

Study Sections fields search for the specified criteria.

Program Class Code searches for applications that include the specified class code(s). Use an underscore (_) for a wildcard representing one character and a percent sign (%) for a wildcard representing multiple characters. If you wish to include multiple criteria, separate them with a comma (,). For more information on program class codes, visit https://partners.niehs.nih.gov/program.

Running a search

Once you have selected the appropriate criteria, you are ready to run the search.

1. Click the Search button in the lower-right left corner of the screen to run the search with the selected criteria. The Project Search Result screen is displayed.

Modifying a search

If your search did not find the expected results, you may need to modify your search criteria.

1. Click the Go back link in the upper-right corner of the screen. You are returned to the Search screen and your search criteria are still selected.
2. Modify the search criteria as desired.
3. Click the Search button to rerun the search.

The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

  1 New
  2 Competing Continuation
  3 Supplement
  4 Extension
  5 Noncompeting Continuation
  6 Change of Institute or Division
  7 Change of Grantee or Training Institution
  8 Change of Institute or Division (noncompeting continuation)
  9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).

- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.

- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.

- **Suffixes:** A field composed of the following components:

  Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

  Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

  Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

  Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND, OR*, *NOT*) from the drop-down menu between the two text boxes.

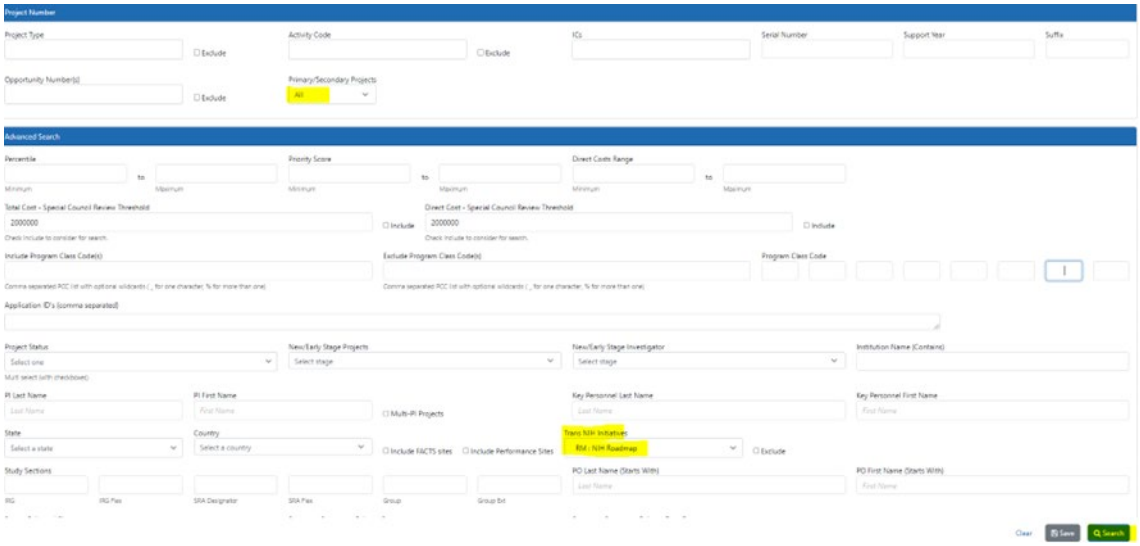
  Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the “Clear Scores” button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2021, the entry would be 01/15/2021 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

For Common Fund (Roadmap) Search:



Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting "Greater Than or Equal To" from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box 'Foreign Grants' to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note**

that there is a default score range of 0 to 30 PERCENTILE and 10 to 30 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer's email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note**: Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available.

Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a "Zip" file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:
Email: NIDDKAdvisoryCouncil@nih.gov; phone: 301.594.8843 (NIDDK DEA Office of the Director)

National Diabetes and Digestive and Kidney Diseases Advisory Council: Advisory Council Operating Procedures

A. Purpose

This documents operating procedures established annually by the N al Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKDAC) for use of co ated authorities. These authorities establish program management and council revie the Institute's extramural programs and establish authorities for management actio

In general, the Council makes three types of recom nd level review of scientific review group (SRG) actions: (1) the Council ca que; (2) it can suggest a different budget and/or a different length of t an advise deferral of an application for re-review. Specific proced ch of these types of actions. These procedures are meant to ensure a level bility across the Council's three subcommittees, which are aligned w matic divisions. Those subcommittees of Council are free to develop and s with the understanding that they be consistent with the operating procedure

B. Background

The National Institute of Diabetes a estive and Kidney Diseases (NIDDK) and other National Institutes of Health (NIH) awarding I itutes are required by policy to establish procedures for interactions between Advisory Councils and the staff responsible for the day-to-day management of extramural portfolios. These procedures, referred to as Council-delegated authorities, govern staff and NDDKDAC responsibilities with regard to grant portfolio management.

C. Definitions

1) **Council Delegated Authorities**: Those actions negotiated between the NDDKDAC and the Director, NIDDK that govern management of the Institute's extramural program portfolio.

2) ***En Bloc* Action**: An action taken by Council on a group of applications under review rather than on specific individual applications being presented to NDDKDAC for review.

3) **Staff Actions**: Actions that, based on policy and procedures, do not require a specific action on the part of the NDDKDAC. These actions include, but may not necessarily be limited to: (a) change of grantee institution, (b) change of principal investigator, (c) administrative supplements, (d) no-cost extensions, and (e) phase-out or interim support.

4) **Communication Letter**: A communication between an applicant and Institute staff that is included for NDDKDAC information purposes. Communication letters may or may not be acted upon by Council and need not be brought up for special discussion.

D. Policy and Implementation Procedures

The NDDKDAC by approval has delegated authority to the NIDDK Director for staff to negotiate adjustments in dollars and/or the terms and conditions of grant and cooperative agreement awards

recommended by the Council. In general, these operational guidelines for administrative actions are developed to provide a day-to-day framework for the smooth and effective operations necessary after review of grant applications by the Council. They are principally intended to enhance the administration of the federal assistance portfolio by the NIDDK.

NIDDK program and grants management staff analyze and review applications, i.e., noncompeting continuation applications and competing applications (new, resubmission (amended) renewal, or revision (supplemental)) before issuing a grant award. NIDDK staff negotiates appropriate adjustments, when applicable, for such changes as the base used for recovery of facilities and administrative costs and/or legislatively imposed salary or other limits. Also, staff can make adjustments to reconcile inconsistencies between SRG recommended budgets and approved activities.

Expedited *En* Bloc Concurrence

NIH, to improve the efficiency of making awards, authorized the use of an expedited *en bloc* concurrence Council review process. NIDDK makes use of an expedited concurrence of *en bloc* actions to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive and responsible manner.

All grant and cooperative agreement applications, excluding those from foreign organizations, which have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution) or need SCR, will follow a process of expedited concurrence whereby the review of applications is delegated by the Chairman of the Advisory Council to designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee shall consist of the Council Executive Secretary (non-voting) and six members of the NDDK Advisory Council. Two members will be selected from each subcommittee of the NDDKDAC.

The Executive Secretary will alert the concurrence committee members with responsibility for expedited concurrence when review outcomes for eligible applications are available in the Electronic Council Book. The Electronic Council Book enables members to access: Application Number, Principal Investigator, Project Title and Percentile/Priority Score. Typically, this will occur once each Council round, several weeks before the scheduled NDDKDAC meeting, however circumstances may arise that will require an additional, earlier expedited concurrence review to allow a set of applications to be funded in a timely manner to optimize the initiation or continuation of the proposed research. In the event of an earlier expedited concurrence review the same procedures described below will be followed including the involvement of the full NDDKDAC.

Electronic or written concurrence by a minimum of two members with no votes for non-concurrence within seven days of notification of posting is required for expedited concurrence approval. Any member may bring an application to full NDDKDAC consideration without the need for justification. Any single vote for non-concurrence within the allotted time period will result in that application going for regular consideration to the NDDKDAC under its normal procedures for concurrence. Members not acting upon an application within the allotted time period after posting will be considered to have abstained from a vote on that application. Expedited listings lacking enough votes for final action will be presented to the regular NDDKDAC meeting for review.

The full NDDKDAC will be provided with a list of all applications eligible for expedited concurrence, as well as the outcome of the vote by the concurrence committee members on those applications.

Special Council Review

Each Council round the NDDKDAC will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under NIH policy. For each application on the list that may be funded, NIDDK staff will provide information about that other funding for the PI that brings their total cost total to the $2 million threshold and a justification for considering funding. Council members will review these cases and indicate whether or not they have concerns.

Specification of Council Action Requirements

Actions requiring NDDKDAC review or advice and ***not*** eligible for expedited *en bloc* concurrence are: SCR, applications from foreign institutions, and extensions, and unresolved appeals of initial peer review.

Actions not requiring NDDKDAC review or advice are: (1) change of grantee institution, (2) change of principal investigator, (3) administrative supplements to provide additional support either to meet the increased cost of maintaining the level of research previously recommended, to otherwise accommodate research activities or to meet needs judged by staff to be within the scope of the previously peer reviewed project, or (4) phase-out or interim support.

The Council will be provided with notice of general solicitations for administrative supplements if they apply to an entire class of applications. Administrative requests for increases in direct costs, which are the result of marked expansion or significant change in scientific content after formal peer review, will be referred to the Council for advice and recommendation. The NIDDK Director will determine whether the urgency is sufficient to warrant interim consultation with the Council by mail, e-mail, videoconference or telephone, instead of delaying action until the next Council meeting, or by mutual agreement, in rare instances the NIDDK Director may act on behalf of the Council as a whole.

NIDDK staff may restore requested time and support which were deleted by the initial review group when the principal investigator has provided written justification, and the restoration is in the best interest of the Institute and the project is of high programmatic relevance. Staff will record the action taken and its justification in a memo to the file. In addition, restorations will be summarized for Council information at the next regular scheduled meeting.

The NDDKDAC may also advise the Institute on: The adequacy of the initial review process; and, funding of applications out of order (i.e., “Reaches”) and/or with Special Emphasis dollars.

Finally, the NDDKDAC will receive a report annually on the activities of the NIDDK Board of Scientific Counselors.

E. Exceptional Situations

As circumstances require, based on programmatic considerations, the Director, NIDDK, generally after consultation with Council, may make exceptions to these guidelines.

Exceptions to these procedures should be extremely rare because there needs to be consistent application of these procedures across extramural divisions. Nonetheless, circumstances may require the deviation from the prescribed procedure in order to achieve the mission of the NIDDK. By NDDKDAC delegated procedures, the Director, NIDDK has authority to act upon unusual or extenuating circumstances. These actions are usually discussed by a subset of Council members selected by the Director and Executive

Secretary of NDDKDAC. Any actions of this exceptional nature must be appropriately documented as necessary for the official record and should be reported to Council at its next scheduled meeting.

F. References

1) Public Health Service Act as amended, 42 USC 52h, 42 USC 241, 42 USC 284a

2) PHS Policy on Humane Care and Use of Laboratory Animals
(http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf)

3) OER Policy & Guidance: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects – Policy Implementation Page
(http://grants.nih.gov/grants/funding/women_min/women_min.htm)

4) OER Policy & Guidance: Inclusion of Children Policy Implementation
(http://grants.nih.gov/grants/funding/children/children.htm)

5) NOT-OD-22-049: Notice of Change to NIH's Policy on Special Council Review of Research Applications
(https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-049.html

10/31/2024

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL
(All terms end December 31)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Department of Health and Human Services

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NIDDK Advisory Council Meetings Dates: 2025 - 2026

2025

January 29 (Wednesday)

- Building 31, C-Wing 6th Floor Conference Center, Conference Rooms A&B, C, D, and F&G

May 14-15 (Wednesday and Thursday)

- Building 31, C-Wing 6th Floor Conference Center, Conference Rooms A&B, C, D, and F&G

September 17-18 (Wednesday and Thursday)

- Building 31, C-Wing 6th Floor Conference Center, Conference Rooms A&B, C, D, and F&G

2026

January 28-29 (Wednesday and Thursday)

- Building 31, C-Wing 6th Floor Conference Center, Conference Rooms A&B, C, D, and F&G

May 13-14 (Wednesday and Thursday)

- Building 31, C-Wing 6th Floor Conference Center, Conference Rooms A&B, C, D, and F&G

September 9-10 (Wednesday and Thursday)

- Building 31, C-Wing 6th Floor Conference Center, Conference Rooms A&B, C, D, and F&G

226th Meeting of the
NATIONAL DIABETES and DIGESTIVE and KIDNEY DISEASES
ADVISORY COUNCIL

- Hybrid Meeting -
Held in-person NIH Main Campus (Bethesda, MD),
Building 45, Natcher Conference Center
and virtually using web-based collaboration/meeting tools

Wednesday, September 11, 2024

OPEN SESSION of the COUNCIL 8:30 a.m. to noon EDT - *Conference Room E1&E2*

I. CALL to ORDER and ANNOUNCEMENTS **Dr. Griffin Rodgers**

II. CONSIDERATION of SUMMARY MINUTES **Dr. Rodgers**
225th COUNCIL MEETING

III. FUTURE COUNCIL DATES **Dr. Rodgers**

2025

January 29-30 (Wednesday and Thursday)
Building 31, C-Wing 6th Floor Conference Center
Conference Rooms A&B, C, D, and F&G

May 14-15 (Wednesday and Thursday)
Building 31, C-Wing 6th Floor Conference Center
Conference Rooms A&B, C, D, and F&G

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2026

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May 13-14 (Wednesday and Thursday)
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Conference Rooms A&B, C, D, and F&G

September 9-10 (Wednesday and Thursday)
Building 31, C-Wing 6th Floor Conference Center
Conference Rooms A&B, C, D, and F&G

IV. ANNOUNCEMENTS **Dr. Karl Malik**
Confidentiality/Conflict of Interest

V. REPORT from the NIDDK DIRECTOR **Dr. Rodgers**

VI. THE NIDDK OFFICE of OBESITY RESEARCH **Dr. Susan Yanovski**
Dr. Maren Laughlin

VII. UPDATE: NIH DIVISION of PROGRAM COORDINATION, PLANNING and STRATEGIC INITIATIVES (DPCPSI) **Dr. Tara Schwetz**

***<<BREAK** 10:30 a.m. -- 10:45 a.m. EDT>>*

VIII. UPDATE from the DIRECTOR, NATIONAL EYE INSTITUTE **Dr. Michael Chiang**

IX. CONCEPT CLEARANCE **NIDDK Staff**

***<<BREAK** noon – 1:00 p.m. EDT>>*

X. SUBCOMMITTEE MEETINGS

Open Sessions

- **Diabetes, Endocrinology, and Metabolic Diseases** *(1:00 p.m. – 2:15 p.m. EDT)*
  - *Conference Room E1&E2*
- **Digestive Diseases and Nutrition** *(1:00 p.m. – 2:15 p.m. EDT)*
  - *Conference Room D*
- **Kidney, Urologic, and Hematologic Diseases** *(1:00 p.m. – 2:15 p.m. EDT)*
  - *Conference Room F1&F2*

Closed Sessions

- **Diabetes, Endocrinology, and Metabolic Diseases** *(2:15 p.m. – 3:30 p.m. EDT)*
  - *Conference Room E1&E2*
- **Digestive Diseases and Nutrition** *(2:15 p.m. – 3:30 p.m. EDT)*
  - *Conference Room D*
- **Kidney, Urologic, and Hematologic Diseases** *(2:15 p.m. – 3:30 p.m. EDT)*
  - *Conference Room F1&F2*

***<<BREAK –** 3:30 p.m. – 3:45 p.m. EDT>>*

CLOSED SESSION of the COUNCIL 3:45 p.m. to 4:00 p.m. EDT - *Conference Room E1&E2*

XI. REPORTS of SUBCOMMITTEES: Dr. Malik
CONSIDERATION of APPLICATIONS

- Digestive Diseases and Nutrition
- Diabetes, Endocrinology, and Metabolic Diseases
- Kidney, Urologic, and Hematologic Diseases

EXECUTIVE CLOSED SESSION of the COUNCIL 4:00 p.m. to 4:30 p.m. EDT - *Conference Room E1&E2*

XII. ANNUAL INTRAMURAL RESEARCH PROGRAM UPDATE Dr. Michael Krause

XIII. ADJOURNMENT Dr. Rodgers

225th Meeting of the
National Diabetes and Digestive and Kidney Diseases Advisory Council

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Department of Health and Human Services

CALL to ORDER and Opening Remarks
Dr. Griffin Rodgers

Dr. Rodgers, Director, National Institute of [illegible] and Kidney Diseases (NIDDK), called to order the 225th meeting of the [illegible]cil at 8:30 a.m. EDT on May 8, 2024, via a hybrid meeting (in-person [illegible]rence). The meeting was conducted using a two-tiered webinar format [illegible]ed NIDDK Advisory Council members and NIDDK staff members wh[illegible]eeting. The audience tier was available via a live stream to the public and [illegible]nd listen to the meeting.

ATTENDANCE – C[illegible] PRESENT

Dr. De[illegible]
Ms. Davi[illegible]
Dr. Jacquely[illegible]
Dr. Mark Nelso[illegible]
Dr. Keith Norris
Ms. Ceciel Rooker
Dr. Kathleen Sakamoto
Dr. Philipp Scherer
Dr. Elizabeth Seaquist

Subject Matter Experts:
Dr. Jamy Ard
Dr. Richard Blumberg
Ms. Neicey Johnson
Dr. Aylin Rodan
Dr. Claire Yang

Ex-officio Members:
Dr. David D'Alessio
Dr. Ian Stewart

Also Present:
Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council
Dr. Karl Malik, Executive Secretary, NIDDK Advisory Council
Dr. Gregory Germino, Deputy Director, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK
Dr. Stephen James, Director, Division of Digestive Diseases and Nutrition, NIDDK
Dr. Robert Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

Panelists and Speakers:

Dr. Talitha Washington
Dr. Atul Butte

Dr. Rodgers noted that NIDDK plans to hold hybrid Council meetings, which accommodate virtual and in-person participation, for the foreseeable future. Council members and staff were encouraged to attend Council meetings in-person whenever possible. The in-person experience fosters more engaging and productive conversations and facilitates more impactful discussions that can profoundly impact the Institute's future. The Council website will have further details in the future.

Recognition of Subject Matter Experts

Dr. Rodgers welcomed five subject matter experts attending the meeting and thanked them for their time and participation in the Council process.

- **Dr. Jamy Ard** is a Professor of Epidemiology and Prevention at Wake Forest University. Dr. Ard will participate on the Division of Digestive Diseases and Nutrition (DDN) Subcommittee.
- **Dr. Richard Blumberg** is Professor of Medicine at Harvard Medical School, and Chief of the Division of Gastroenterology, Hepatology, and Endoscopy and Senior Physician in Medicine and Gastroenterology at Brigham and Women's Hospital. Dr. Blumberg will participate on the DDN Subcommittee.
- **Ms. Neicey Johnson** is the Senior Director for the Association of Black Cardiologists, Inc. Ms. Johnson will participate on the Division of Diabetes, Endocrinology, and Metabolic (DEM) Diseases Subcommittee.
- **Dr. Aylin Rodan** is an Associate Professor of Internal Medicine at the University of Utah School of Medicine. Dr. Rodan will participate on the Division of Kidney, Urology, and Hematologic (KUH) Diseases Subcommittee.
- **Dr. Claire Yang** is a Professor and Chief of Service at the University of Washington Medicine Department of Urology. Dr. Yang will participate on the KUH Subcommittee.

Council Member News

Dr. Rodgers recognized four Council members that agreed, once again, to extend their Council service and participate in the meeting: **Debra Haire-Joshu, Mark Nelson, Ceciel Rooker, and Kathleen Sakamoto**. **David Penson** also extended his membership and attended the January Council meeting but was not able to attend the May meeting. Dr. Rodgers thanked them for continuing their service on the Council because of the delayed processing of membership slates. Dr. Rodgers then presented certificates of appreciation to the retiring members.

In Memoriam

Dr. Rodgers noted recent losses for the NIDDK research community:

- **Dr. William Heinrich** was a former NIDDK Advisory Council Member and Professor of Medicine at the University of Texas Southwestern School of Medicine (UTSW) and was the inaugural holder of the John P. Howe, III, MD, Distinguished Chair in Health Policy. For the past 15 years Dr. Henrich served as President of UTSW. During this period, he transformed the UT Health Science Center at San Antonio into a top-ranked academic health center with world-class programs in cancer, obesity and diabetes, dementia, and aging. Dr. Henrich was a leader in nephrology and served as President of the American Society of Nephrology. Over

his career, Dr. Heinrich authored over 300 original articles and chapters and was the founding editor of the popular dialysis textbook, "Henrich's Principles and Practice of Dialysis." Dr. Heinrich will be remembered for his creativity, good humor, wise council, and generous mentorship of students, residents, and young physicians.

- **Dr. Jerry Palmer** served for a decade on NIDDK Council as the Veteran's Administration representative and was Professor Emeritus at the University of Washington in Seattle and his research was supported by NIDDK for many years. Dr. Palmer was professor within the Division of Metabolism, Endocrinology, and Nutrition at the University of Washington's Department of Medicine for 45 years. He was also Chief of endocrinology at the VA Puget Sound Health Care System in Seattle for 35 years. Dr. Palmer's many scientific achievements included significant contributions to NIDDK-supported clinical trials that revolutionized diabetes care. For example, he served on the Steering Committee for the Diabetes Control and Complications Trial from 1982 to 1993. He also played a central role in the Epidemiology of Diabetes Intervention and Complications Trial and was involved in both the Diabetes Prevention Trial of Type 1 Diabetes and TrialNet. Dr. Palmer also established the UW Diabetes Care Center, which he directed for 12 years.
- **Dr. Philip Cryer**, whose illustrious career at the Washington University School of Medicine in St. Louis spanned more than four decades. Dr. Cryer led the university's General Clinical Research Center for more than 30 years. He also served as the longtime Director of the Division of Endocrinology, Metabolism & Lipid Research as well as a Professor of Endocrinology and Metabolism. Dr. Cryer received research support from NIH and NIDDK for more than three decades, including an NIH Merit Award, which provides extended grant support to investigators with outstanding records of scientific achievement. Dr. Cryer was internationally known for his research on hypoglycemia, including the physiology behind glucose counter-regulation, which are the mechanisms that prevent or correct hypoglycemia. This research led to the development of approaches to identify, prevent, and treat hypoglycemia in people with diabetes.
- **Dr. Gary Felsenfeld**, an intramural distinguished scientist, who was with NIDDK for more than 60 years and was a founding member of NIDDK's Laboratory of Molecular Biology, serving as the lab's Chief from the late 1990s until he retired in 2023. He studied physical chemistry with world-renowned chemist Linus Pauling before joining the Public Health Service in 1956 to work at the National Institute of Mental Health on polynucleotides. There, he played a role in discovering the first triple-stranded nucleic acid molecule. From 1961, when Dr. Felsenfeld joined NIDDK, he shared in the discovery of the first erythroid-specific transcription factor and began investigating chromatin boundary regions, eventually identifying the protein CTCF as a major genomic boundary protein. This discovery led to research on long-range interactions in the nucleus that affect insulin regulation in human pancreatic cells. Dr. Felsenfeld's legacy encompasses the many trainees he mentored, including 25 currently active leaders of research groups worldwide. He published more than 250 primary research papers and garnered many awards. Dr. Felsenfeld was not just a great scientist, mentor, and leader, he was also a beloved colleague and friend with a great sense of humor and a warm, generous nature.

NIDDK Staffing News

Dr. Rodgers announced recognition earned by several NIDDK Intramural Research Program Investigators:

Dr. Jenny Hinshaw, Senior Investigator in NIDDK's Laboratory of Cell & Molecular Biology,

received the Biophysical Society's 2024 Sir Bernard Katz Award in recognition of her outstanding scientific career in understanding the role of dynamins in membrane fission and fusion.
Dr. Susan Buchanan, Deputy Scientific Director in the Division of Intramural Research and Chief of the Laboratory of Molecular Biology, received the Biophysical Society's 2024 Anatrace Membrane Protein Award. The award recognizes her impactful contributions to the understanding of outer membrane protein folding and insertion, and for structural insights into small and large molecule active transport across the outer membrane.
Dr. Jurgen Wess, Chief of Molecular Signaling in NIDDK's Laboratory of Bioorganic Chemistry, was elected as a 2023 AAAS Fellow for his distinguished contributions to molecular and translational pharmacology.

Dr. Rodgers announced new extramural staff:

Dr. Minnjuan W. Flournoy Floyd joined DEM as a program officer in January 2024. In her position, she will provide oversight to DEM's growing program in Health Disparities and Health Equity and specifically will oversee programs addressing health equity research in adults with type 2 diabetes (T2D) at the individual level. Dr. Floyd received her Ph.D. in Health Services, Policy, and Management at the Norman J. Arnold School of Public Health, University of South Carolina, and a Master of Business Administration (MBA) in Healthcare Administration from William Howard Taft University, Denver, CO. Prior to joining NIDDK, she served as a Social and Behavioral Sciences Administrator at the National Institutes of Drug Abuse.
Dr. Jia Nie also joined DEM in December 2023 as a Data and Technology Advancement (DATA) National Service Scholar, through a program run by the NIH Office of Data Science Strategy (ODSS). Dr. Nie is working on developing a dynamic, searchable metadata and meta-standards catalogue of NIDDK data science resources, including both basic science data types and clinical and observational data types. Dr. Nie will also organize a NIDDK data science workshop to gather community input.

Dr. Rodgers announced a retiring NIDDK staff member and congratulated her on her public service and remarkable career.

Ms. Van Nguyen retired after 30 years of federal service at NIH, including 14 years at NIDDK. As NIDDK's Budget Officer, Ms. Nguyen served as senior advisor to Institute leadership for all NIDDK's financial activities. These activities included grants, research and development contracts, research management and support activities, Cooperative Research and Development Agreements (CRADAs), gift funds, and royalties. Prior to her time at NIDDK, Ms. Nguyen worked at the National Institute of Mental Health and the National Institute on Aging.

Finally, Dr. Rodgers recalled Dr. Noni Byrnes' presentation at the January Council meeting and mentioned the implementation of the Simplified Review Framework for most research project grants. As a reminder, NIH is implementing a simplified framework for the peer review of most competing research project grant applications, beginning with submissions with due dates of January 25, 2025. To keep up with the information and guidance he suggested that attendees visit the "Simplifying Review of Research Project Grant Applications" webpage. Either by navigating to this website or performing a web search on "NIH Simplified Review Framework."

CONSIDERATION OF SUMMARY MINUTES
Dr. Griffin Rodgers

The Council approved, by electronic poll, the Summary Minutes of the 224th Council meeting,

which had been sent to members in advance for review.

FUTURE COUNCIL DATES
Dr. Griffin Rodgers

As noted previously, Dr. Rodgers told Council that future meetings will be held using a hybrid format to accommodate both virtual and in-person attendance. The next meeting of the NIDDK Advisory Council is scheduled for September 11-12, 2024. Although the plan is to meet September 11, the Council was asked to hold both days open to maintain flexibility. Dr. Rodgers noted that the September Council meeting will be held in the Natcher Conference Center (Building 45). Updates about future meetings will be posted on the Council website.

ANNOUNCEMENTS
Dr. Karl Malik

Confidentiality

Dr. Malik said that material furnished for review purposes and discussion during the closed portion of this meeting is considered confidential. The content of discussions taking place during the closed session may be disclosed only by the staff and only under appropriate circumstances. Any communication from investigators to Council members regarding actions on an application must be referred to the Institute. Any attempts by Council members to handle questions from applicants could create difficult or embarrassing situations for the members, the Institute, and/or the investigators.

Conflict-of-Interest

Dr. Malik reminded Advisors and consultants serving as members of public advisory committees, such as this Council, may not participate in situations in which any violation of conflict-of-interest laws and regulations may occur. Responsible NIDDK staff shall assist Council members to help ensure that the member does not participate in and is not present during review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, partner (including close professional associates), or an organization with which the member is connected. To ensure that a member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file.

Prior to today's meeting, Council members were sent a statement regarding conflict-of-interest in their review of applications (members who here in-person today have the statement in their table folder). Dr. Malik directed each Council member to a statement in their meeting folder regarding conflict-of-interest in review of applications. He asked each Council member to read it carefully, sign it, and return the signed hard copy or file before the end of the day.

At Council meetings when applications are reviewed in groups without discussion, that is, by "en bloc" action, all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict.

Regarding multi-campus institutions of higher education, Dr. Malik said that an employee may participate in any particular matter affecting one campus of a multi-campus institution of higher

education, if the employee's financial interest is solely employment in a position at a separate campus of the same multi-campus institution, and the employee has no multi-campus responsibilities.

COUNCIL FORUM: DATA SCIENCE & DATA MANAGEMENT
Dr. Gregory Germino, Dr. Talitha Washington, and Dr. Atul Butte

Dr. Germino reminded attendees that at the January meeting, Dr. Susan Gregurick provided an overview of the NIH Strategic Plan for Data Science. She reviewed progress made on the 2018-2022 plan and then introduced the updated 2023-2028 draft that was open for public comment at the time. In her presentation, Dr. Gregurick laid out the vision for how NIH will facilitate and support development of policy, programs, technologies, and infrastructure to continue to develop data-driven discovery across the agency. Dr. Germino introduced the Data Science Forum Series, intended to continue the discussion between Council members and two invited speakers with perspectives on how data sharing, data harmonization and integration, and emerging technologies, such as generative artificial intelligence (AI) and other machine learning models, will facilitate knowledge generation and advance health across NIDDK science. Additionally, the forum was to include discussion of ways that researchers can ensure equity in the development and application of these novel methods, and ways that we can encourage equal participation and representation of all populations in such research and data.

Dr. Germino then introduced the two speakers. Dr. Talitha Washington is the Director of the Atlanta University Center Data Science Initiative; a tenured professor of mathematics at Clark Atlanta University; and an affiliate faculty at Morehouse College, Morehouse School of Medicine, and Spelman College. She is the lead Principal Investigator of the National Data Science Alliance, a national network of academic, industry, and government partnerships that will grow the capacity of Historically Black Colleges and Universities to transform data science discoveries into tangible societal benefits that advance equity for all. She is also the President of the Association for Women in Mathematics. Dr. Washington studied mathematics at Spellman College and earned her master's and Ph.D. from the University of Connecticut, where she also received an honorary Doctorate. She is a fellow of the African Scientific Institute, the American Mathematical Society, and the American Association for the Advancement of Science.

He then introduced the second speaker, Dr. Atul Butte, who is the Priscilla Chan and Mark Zuckerberg Distinguished Professor and inaugural Director of the Bakar Computational Health Sciences Institute at the University of California, San Francisco. He is also the Chief Data Scientist for the entire University of California Health System, the tenth largest by revenue in the United States. Dr. Butte trained in Computer Science at Brown University, worked as a software engineer at Apple and Microsoft, received his MD at Brown University, trained in Pediatrics and Pediatric Endocrinology at Children's Hospital Boston, then received his Ph.D. from Harvard Medical School and the Massachusetts Institute of Technology. Dr. Butte has been continually funded by NIH for 20 years, is an inventor on 24 patents, and has authored nearly 300 publications. He was elected to the National Academy of Medicine in 2015 and in 2013, he was recognized by the Obama Administration as a White House Champion of Change in Open Science, promoting science through publicly available data.

Dr. Washington discussed considerations for building data science networks that will address societal and health challenges. Dr. Washington presented data from Association for Women in Mathematics, noting that the percentage of women progressing from undergraduate members to full professors decreases with each step. Dr. Washington also stated that while African American

individuals make up 12% of the US population, they make up only 3% of data and analytics processionals. The importance of having a data-skilled workforce is aligned with the NIH-Wide Strategic Plan, which calls for advances in data science, technology, and tools that will aid decision-making by patients and providers to improve disease prevention and health promotion. Dr. Washington provided the example of a health insurance company that maps electronic health records against models using AI and machine learning (ML) to determine treatment protocols, noting a lack of checks on these models to ensure their accuracy. Dr. Washington suggested that there are existing systems and protocols in place, like the IRB, that can help bring transparency to AI/ML processes.

Dr. Washington explained that data science serves as a measuring tool to identify and examine health disparities and lead to more questions and insights that spur additional programming and improved outcomes. She then turned to the AUC Data Science Initiative, created by the Atlanta Universities Center (AUC), which is working to expand data science capacity across all Historically Black Colleges and Universities (HBCUs). Key highlights of the initiative include: building faculty expertise to create an ecosystem where students can thrive; emphasizing the importance of industry partnerships; introducing a data science minor with six learning outcomes that includes a course on data in the African diaspora community; and building up the 10 key technology areas included in the Chips and Science Act through workshops, courses, internships, research, symposia, and other opportunities.

Dr. Washington provided examples of the work carried out by the Data Science Initiative. She mentioned the AIM-AHEAD program at Morehouse School of Medicine that aims to build AI/ML capacity at minority serving institutions, increase underrepresented minority AI/ML scientists, and cultivate community trust to build diverse datasets. Additionally, a symposium on the Power of Data Behind Black Health held in June 2023 explored how to advance AI/ML approaches that improve health outcomes and address health disparities for Black communities. The resulting ideas from that symposium generated numerous project ideas that have been implemented. A generative AI faculty training session at Spelman College explored developing generative AI policies to minimize risk, how generative AI is advancing innovations in research, how generative AI will impact teaching and learning in undergraduate education, and how to prepare students to join the AI workforce.

Future programs include a Pre-Freshman Experience weeklong virtual program open to all HBCUs on data for social impact, scheduled for summer 2024. There is also a mini-grant program funded by Microsoft that is open to faculty and staff at HBCUs to support and strengthen HBCU faculty and staff researchers to enhance participation in and contributions to data science research and curriculum development. An upcoming symposium on Envisioning AI Education Across Disciplines will be held in June 2024 to develop strategies to infuse AI into courses from across disciplines. Dr. Washington also mentioned that there is a Seminar Series, also available on YouTube, which explored topics such as AI and Black health, mobilizing healthier communities through data, and why cultural competence matters.

The National Data Science Alliance (NDSA) is funded by the National Science Foundation (NSF) program to establish a national network of HBCUs to advocate for the building of institutional data science capacity. The vision is to increase the number of Black people who earn data science credentials by 20,000 and create equitable data science techniques and models. At this stage, the program is holding faculty workshops, curriculum development workgroups, and research affinity cohorts. Listening sessions held during the development of the NDSA program led to several themes including representation (need for demographic inclusivity, participation in decision making, addressing bias, and ensuring accurate representation in data), interdisciplinarity (highlighted the

applicability of data science across disciplines), resources (encompassing issues such as insufficient support, financial limitations, software/hardware availability, buy in, and the need for professional development), and hands-on learning (role of data science in bridging classroom knowledge with real-world industry application). Workgroups were formed to develop curriculum for the creation of data science majors and minors. In June 2024, a research affinity cohort will meet for a two-week intensive workshop to discuss and problem solve issues in data science such as algorithmic impacts on Black communities, credit card fraud, evaluating equitable energy access, machine learning approaches to exploring the relationship between adverse childhood experiences and adolescent opioid usage, and unveiling disparities in African-American health experiences.

Dr. Washington concluded by encouraging governmental agencies to cooperate with other agencies to solve data sciences challenges. There may be too much partition between research funded by NSF and NIH, and the challenges of data science could be solved by working together.

Dr. Atul Butte discussed treating diabetes using health data to guide evaluation and treatment of patients. The United States spends billions on Electronic Health Records (EHR), but too few use this data in the practice of medicine. The University of California system has 10 campuses, 3 national labs, 227,000 employees, and 280,000 students per year; there are 6 medical schools and 14 other health professional schools. The system has a large operating budget and receives ample NIH funding. The University of California created a 10-year partnership with UnitedHealth Group to form a new accountable care organization and clinically integrated network. This involves combining healthcare data from across 6 University of California medical schools and systems. The same central database is used for operations and research. All six sites utilize Epic as their EHR. There are approximately 9.5 million patients in that database spanning approximately 13 years, as well as nearly half a billion encounters. 1.2 billion procedures, and 1.6 medication orders. Once the data are deidentified, ample demographic and census information is available.

Dr. Butte provided examples of how this database could be used to monitor and optimize population health for patients with diabetes. A data analysis using the University of California Health Systems database found extremely diverse treatment trajectories for patients with T2D. A dashboard allows for visualization of how all care is delivered across all five included academic medical centers. One model shows that the introduction of cardioprotective medications in eligible patients with diabetes showed significant improvements over 3 years. Data did not cause the change; rather, the visualization of data in the dashboard led to a discussion about sharing best practices. Type 2 diabetes treatment guidelines are very complicated, but by tracking only the first four medication changes for 97,231 patients, there were 12,134 different treatment trajectories with 8,988 unique to only one patient each. Using 10 years of UC Health Systems data, Dr. Butte's group made comparisons across treatment plans controlled with the propensity score of action to find that real world evidence can match the results of a trial like GRADE. Lastly, large language models can assess treatment plans developed by endocrinologists, and recent versions of Chat GPT can create care plans that match the recommendations of doctors for a given case. These tools might be useful to help standardize treatment outside of large academic medical centers.

Council Questions and Discussion
Dr. Germino, moderator

Dr. Germino asked a series of questions that were provided to the Council and Speakers ahead of time.

Given the rapid pace of advances in generative AI capabilities, what strategies can we employ to

prepare future generations to utilize AI in addressing the research priorities of NIDDK?

Dr. Butte replied that more generative AI strategies will be used for clinical notes and physicians must prepare for the use of this technology with regards to physician notes and patient replies.

Dr. Washington agreed that generative AI is already widely accessible and will be increasingly used in new and interesting ways.

What skills, expertise, experiences, and training are needed in the workforce to keep up with emerging technologies and ensure ethical and inclusive research that will benefit all populations?

Dr. Butte said that quantitative science fundamentals, like skilled screening, will become increasingly important, and this is currently not taught in the traditional physician scientist training curriculum.

Dr. Washington added that undergraduates in the health sciences do not have a data science background and these programs should increase knowledge in digital literacy to prepare them for the jobs of the future. Dr. Washington sees training opportunities as an open-ended question and an opportunity to better understand and plan for ideas like digital literacy, incentivizing adoption, and more.

How are institutions integrating data management, harmonization, and sharing into your daily workflows? What incentives (carrots and sticks) will be needed to speed adoption of these values in the research community?

Dr. Butte envisioned future networks across the country of noncompeting institutions sharing data for businesses purposes, treatment, payment, operations, and research.

Dr. Washington mentioned that funding is often allocated to large well-resourced universities. Incentives for a variety of institutions to participate in data sharing need to be created and these incentives may be different from those used in the past for large institutions. She emphasized the need to consider the magnitude of different institutions to ensure varied needs are met.

What technologies do you see on the horizon, and what is needed to prepare for them now?

Dr. Washington said that technologies like cloud computing are important, but so are functional devices like laptops that enable appropriate access. She also highlighted the importance of ensuring equitable access and training. Technology development should take the end user into account.

The speakers also answered direct questions from Council members.

Comment from Council*: How can academia and industry interact in the interest of embracing change? Can you leverage expertise within industry to help train the next generation of leaders and ensure that there is diversity in thinking?*

Dr. Washington noted that curriculum development and training are happening in industry, and efforts are underway to bridge the divide between the education that industry and academia are offering. Providing opportunities for crosstalk through presentations and workshops allows for better discussion about and understanding of data science. Government leaders can also collaborate in building these relationships. A sustainable, collaborative relationship involved working together

to develop technology, develop the talent pipeline, and make further connections.

***Comment from Council**: What opportunities are there to encourage learning and engagement with students much earlier in life in order to increase the onramp for diversity in the workforce?*

Dr. Washington responded that the AUC has a K-12 working group that aims to bring programs to schools and support legislation in this area. There are also programs that train teachers in data science to give them the background they need to bring data science to their students. Morehouse School of Medicine provides health programming to K-12 students and has a data-driven summer program for high school. Other universities and AUC have resources for younger age groups as well. She also mentioned that, while expanding the pipeline in earlier years is important, bias still exists at all levels of academia, and a focus on removing barriers for researchers producing peer-reviewed science is important as well.

Dr. Butte added that diversity in data sets is still needed. Models should not be trained on small, regional data sets and need to reflect the populations that they will be used in.

***Comment from Council**: What kinds of internships are available through the AUC? How can health systems connect with trainees that they could retain as part of the workforce?*

Dr. Washington answered that there is a disconnect between job ads and the skills that industry is seeking. More work is needed to ensure that the workforce is well-trained for industry needs, and that industry is representing those needs well. There are internships available at some HBCUs, but not all. The next step is developing internships at all HBCUs. There also need to be incentives for faculty to participate in these internships with industry.

Dr. Germino concluded that the NIDDK data science working group is currently developing a workshop on data and metadata standards for NIDDK mission diseases and conditions. Development and use of agreed upon data standards, standardized terminologies, and common data elements will be key to the success of data interoperability.

REPORT FROM THE NIDDK DIRECTOR
Dr. Griffin Rodgers

Budget Update

Dr. Rodgers updated the Council on recent budget events.

Congress had to pass four short-term continuing resolutions (CRs) to keep the government funded at the fiscal year (FY) 2023 funding level while they worked to reach an agreement on the FY 2024 budget. The fourth CR used a laddered approach of two separate deadlines: March 8 for a package of six appropriations bills and March 22 for the remaining six appropriations bills, including the Labor, Health and Human Services, and Education bill. On March 8, the President signed the first package of six appropriations bills into law, providing full-year appropriations for FY 2024 for many departments across the federal government. This package also extended authorization for the Special Diabetes Program (SDP) through December 31, 2024, and included a new annual authorization level of $160 million for the program, an increase of $10 million and the first increase in that program since FY 2004. On March 23, hours after the expiration of the fourth CR, the President signed the second appropriations package into Law, funding all the agencies included in the remaining six bills, including NIH.

NIH received $47.08 billion, a decrease of $378 million over the FY 2023 enacted level. This overall decrease (0.8%) in total NIH funding is due to a decrease in this year's 21st Century Cures funding for All of Us and the BRAIN Initiative. Despite a tough budget climate this year, NIH received a number of targeted funding increases, including an increase of $100 million for Alzheimer's and related dementias research and an increase of $120 million for cancer research at the National Cancer Institute (NCI). NIDDK received $2.31 billion, which is a $10 million increase over FY23. This additional $10 million was provided by Congress to support diabetes-related research.

On March 11, President Biden also released the FY 2025 President's Budget Request that proposed funding NIH at $48.3 billion, which is a 2.7% increase over the 2024 enacted budget. It also requests $2.31 billion for NIDDK, maintaining FY 2024 funding levels. The increases in the NIH budget request primarily target specific areas, such as the Cancer Moonshot, maternal and women's health, mental health initiatives, health disparities and health equity research, and more. The President's Budget also requests funding for the SDP through FY 2026 and includes $1.5 billion for ARPA-H, the Advanced Research Projects Agency for Health.

HHS Secretary Becerra testified at Senate and House Hearings in April to discuss the FY 2025 budget request. Members asked about a wide range of topics, including research on maternal health, opioid use disorder, youth mental health, cancer, and health disparities, as well as ARPA-H, and insulin pricing.

As the SDP received reauthorization and a funding increase, Dr. Rodgers provided an overview of the program's history. The SDP started in FY 1998 at a funding level of $30 million per year, which increased to $100 million per year starting in FY 2001 and increased again to $150 million per year in FY 2004 and remained at that level through FY 2023. The recent reauthorization in the FY 2024 bill increased funding to $160 million, which is the first funding increase for the Program since FY 2004. The increase will provide support for additional research to move faster towards more effective treatment and prevention of type 1 diabetes (T1D). The SDP is now authorized through December 2024.

Congressional and Constituency Activities

Dr. Rodgers highlighted the welcome reception hosted by American Cancer Society and Research!America at the end of January to celebrate the new NIH Director, Dr. Monica Bertagnolli. Dr. Germino attended on behalf of NIDDK and many Members of Congress also attended.

Dr. Rodgers then highlighted several meetings that NIDDK participated in with Congressional staff and partner groups. On January 22, staff from Senator Bernie Sanders' Office and the Senate HELP Committee met with Dr. Kevin Hall, one of NIDDK's intramural principal investigators to discuss Dr. Hall's research on ultraprocessed foods as part of the Committee's ongoing work to understand the relationship between food and health outcomes.

On February 22, NIDDK hosted the annual Friends of NIDDK meeting, during which discussions centered on the Institute's latest accomplishments and upcoming goals with the patient, physician, research, and disease advocacy organizations in attendance.

On March 5, Drs. Robert Star, Debbie Gipson, and Rodgers briefed Senator Debbie Stabenow of Michigan on recurrent focal segmental glomerulosclerosis and kidney disease research.

Upcoming Meetings

NIDDK's 75th Anniversary is coming up next year, and there will be many opportunities in 2025 to highlight the anniversary, celebrate accomplishments, and look ahead to the future.

CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance by Council, a step required before Institutes and Centers (ICs) can publish notices of funding opportunities. To streamline this process, summaries of the concept were supplied to Council members for their review prior to the meeting. Cleared concepts will be made publicly available on the NIDDK website.

Division of Digestive Diseases and Nutrition (DDN) Concepts

Various staff members presented concepts on behalf of the division.

The Role of Neuroimmune Interactions in Gastrointestinal Health and Disease

Dr. Terez Shea-Donohue

For gastrointestinal (GI) disorders such as inflammatory bowel disease (IBD), disorders of the gut-brain interactions (DGBI), metabolic diseases, and others, the correlation between disease pathology and symptoms is often imprecise, and there is a lack of disease or response biomarkers that assess treatment efficacy. In addition, current available therapies for these chronic debilitating GI diseases are limited, and traditionally have targeted either the nervous or immune system. A barrier to the development of new treatments is that these diseases are complex, multifactorial, exacerbated by stress, and may affect one gender more than another. In June 2023, NIDDK hosted a workshop highlighting neuroimmune crosstalk in the gut in health and disease as a focal point for research areas of interest to NIDDK including enteric neurodevelopment, neurogenesis, gut sensation, and gut-brain communication. The workshop recognized that dysfunctional neuroimmune communications contribute to the symptoms, severity, and chronicity of GI disorders. Moreover, remodeling of neuroimmune interactions may underlie the persistence of symptoms in disease remission in IBD or in the absence of overt disease pathology in DGBI. To advance research around neuroimmune interactions related to GI diseases, it is necessary to incentivize collaboration between siloed investigators in immunology and neurogastroenterology and facilitate sharing of state-of-the-art resources specific to each area.

Continuation of the Liver Cirrhosis Network

Dr. Jay Hoofnagle

The Liver Cirrhosis Network (LCN) was established in August 2021 by the NIDDK through Request for Applications (DK-20-003 and 004) with subsequent integrated support by the National Institute on Alcohol Abuse and Alcoholism (NIAAA), and the NCI. The LCN was charged to address several pressing clinical issues about cirrhosis that are encompassed in the development of two studies: a refined longitudinal natural history cohort (LCN Cohort Study) and a randomized, double-blind trial of statins for their effect in altering the natural history of liver cirrhosis (Rosuvastatin Efficacy and Safety for Cirrhosis in the United States (RESCU): A Double-Blind Randomized, Placebo-Controlled Phase 2 Study). Cirrhosis and chronic liver disease are listed as the 3rd most common disease-related cause of death in US adults below the age of 75 and its prevalence is rising. Cirrhosis of the liver is the outcome of many chronic liver diseases and once established, the irreversible nature places the patient at risk for significant clinical consequences

such as portal hypertension, ascites, variceal hemorrhage, hepatic encephalopathy, severe hepatic dysfunction and, most ominously, liver cancer. Liver transplantation is the only viable avenue for reversing end-stage liver disease but is a medically and resource intensive intervention not available to many persons with cirrhosis. The LCN Cohort Study and RESCU were initiated within 1 and 2 years respectively from the establishment of the LCN and both are actively enrolling.

Continuation of the Nutrition Obesity Research Center (NORC) Program
Dr. Mary Evans

The NORC program has been an ongoing program for over 40 years with support for 11 NORCs across the US. The NORCs promote new discoveries and enhance scientific progress through support of cutting-edge basic, clinical, and translational research related to nutrition science and/or obesity. The goal of the NORCs is to serve as a key component of the overall NIH/NIDDK plan to advance the fields of nutrition science and obesity and improve health of Americans across the lifespan. NORCs are intended to improve the quality and multidisciplinary nature of research on nutrition and obesity by providing shared access to specialized and technical resources and expertise. NORCs facilitate progress in research with the goal of developing new methods to evaluate, prevent, and treat obesity and to support basic and clinical nutrition science and dietary interventions. The NORCs are part of an integrated program of nutrition and obesity research at extramural research institutions that have established an existing base of high-quality, nutrition and obesity-related research. NORCs provide increased, cost-effective collaboration among multidisciplinary groups of investigators at institutions with an established, comprehensive research base in nutrition and obesity.

Silvio O. Conte Digestive Diseases Research Core Centers
Dr. Peter Perrin

The Silvio O. Conte Digestive Diseases Research Core Centers (DDRCC) program seeks to promote synergy between established investigators at domestic institutions who are engaged in digestive and/or liver diseases research. Each DDRCC supports a cohesive research base consisting of basic and clinical investigators actively conducting research related to an organizing theme that primarily aligns with NIDDK's mission as opposed to digestive and/or liver diseases research areas for which other NIH Institutes or Centers are considered the primary source of NIH funding. Both the theme and the structure should promote impactful multidisciplinary collaboration. This is facilitated by biomedical research cores that offer shared resources in a cost-effective manner, a pilot and feasibility program, and an enrichment program.

Dr. Rodgers then invited Council members to ask any questions related to the DDN concepts.

Council Questions and Comments
Comment from Council: *Regarding both the NORCs and DDRCCs, is there an expectation that the number of centers receiving funding will change?*

Dr. Evans responded that there are no opportunities to expand the number of centers.

Division of Division of Diabetes, Endocrinology, and Metabolic (DEM) Diseases Concepts
Members of the DEM staff presented concepts on behalf of the division.

Pilot/Opportunity Support for Generative Pretrained Transformers (GPT) to Accelerate Diabetes Research

Dr. Xujing Wang

One major challenge in T2D is the enormous heterogeneity associated with the disease. To address this challenge, the research field has generated a large amount of data and has accumulated a vast amount of prior knowledge about the disease. The data and prior knowledge contain critical, but mostly hidden, information relevant to solving this challenge, however, cross-cutting gaps exist in integrating them and extracting predictive signals. One of the major problems is the lack of data science expertise in the T2D research field, and the lack of T2D-specific data science expert systems, models, and tools. This initiative proposes to address this problem by establishing a pilot funding program that leverages the emerging opportunities from recent data science advances. It will recruit multidisciplinary teams that include both T2D and data science experts to (1) develop AI foundation models for T2D; (2) validate the models with top research questions in T2D heterogeneity; (3) disseminate the models and engage the community for further development, validation and application; and (4) develop use cases that demonstrate the models' potential in accelerating the tempo of research. The expected outcomes will include new and diverse AI experts that have joined the T2D research workforce, new AI models that other T2D researchers can use, and informative use cases of the new models.

Nutrient-Stimulated Hormones and Neural Plasticity
Dr. Bradley Cooke

Two primary unanswered questions underlie the current obesity epidemic. The first is how the modern western food environment provokes unhealthy overconsumption and fat deposition despite multiple homeostatic regulatory systems that evolved to maintain a stable body weight. The second concerns what appear to be non-genetic transmission of maternal obesity and overconsumption to offspring, supporting a sudden exponential rise of metabolic disease throughout the population. New incretin receptor agonists are poised to revolutionize diabetes and obesity care through their effects on eating behavior, and thereby also provide powerful tools that give us a new window on how the brain is highjacked by the food environment, and how it particularly affects the developing brain and leads to unhealthy behaviors and metabolic responses. Given that incretin analog drugs are highly effective for a growing number of chronic metabolic, psychiatric, addiction, and neurodegenerative diseases, it is very likely that a large segment of our population will soon be treated with them. This emphasizes both the importance for incretins, and the imperative to work now to ultimately uncover the mechanisms of their effects on human development and biology. As an important first step, we will solicit investigator-initiated R01 proposals that focus on molecular, cellular, network, and behavioral neuroscience to address the roles of incretin and related hormones on these two critically important questions.

Collaborative Awards to Support Microphysiological System Pilot Studies in Diabetes Research
Dr. Albert Hwa

Advances in biomaterials, microfluidics, and tissue engineering have resulted in microphysiological systems (MPSs) that allow for greater control of three-dimensional cell cultures containing multiple cell types and constituting more physiological tissue organization. The use of patient samples and human induced pluripotent stem cell–derived cells coupled with MPSs will enable patient-on-a-chip or clinical-trial-on-a-chip studies of T2D development and treatment that is currently not possible. The utility of these systems lends themselves to powerful in vitro modeling of metabolic tissue crosstalk, study of basic mechanisms of human T2D, and the testing of prevention and treatment strategies. MPSs are especially useful for investigating the heterogeneity of human T2D biology and

clinical responses. However, adoption of such systems as a complementary research tool by traditional basic biology laboratories requires additional MPS expertise and resources. Opportunities exist for NIDDK to incentivize collaborative studies to encourage pairings of engineering and biology labs. The current initiative will support small pilot studies to conceptualize aspects of T2D biology for modeling with MPSs, to support feasibility studies, and to generate preliminary data. It is anticipated that these pilot awards may pave the way to enhance the success of future R01 submissions and broaden the use of MPSs in human T2D research.

Advancing Research on the Application of Digital Health Technology to the Management of Type 2 Diabetes

Dr. Henry Burch

The application of digital health technology to the management of T2D is at an inflection point and comes at a time where a paradigm shift in the approach to T2D is urgently needed. The global diabetes epidemic is rapidly outpacing the ability of current health care systems to provide optimal care and ensure patients achieve basic standards of diabetes care. The increasing availability of US Food and Drug Administration (FDA)-cleared digital health technology (DHT) for T2D management holds great promise for addressing current barriers to acceptable care by ensuring improved patient access to the health care system, enhanced patient engagement and sense of empowerment, improved glycemia and other diabetes-related metabolic outcomes, reduced clinical inertial and provider dissatisfaction, and provision of favorable economics at the health care system (HCS) level. While integrated multimodality digital health approaches, referred to as virtual diabetes clinics (VDC) hold great promise and are actively marketed by industry to employers, insurers, and HCSs, the scientific rigor of studies supporting this approach lags behind their promotion, and industry has little motivation for funding large randomized controlled trials to examine the efficacy of the digital VDC approach. This initiative is intended to advance research on the application of currently available DHT in a multimodality VDC model to examine the clinical efficacy of an urgently needed paradigm shift in the population health approach to T2D.

Shared Decision Making to Improve Diabetes Prevention and Care

Dr. Maureen Monaghan Center

Shared decision making is a collaborative process that enables and encourages people to play a significant role in the decisions that impact their health. Shared decision making is central to facilitating personalized, person-centered diabetes care. However, despite inclusion of shared decision making in evidence-based standards of care, current clinical practice is not optimized for effective shared decision making. Additionally, there is a paucity of research to guide the conduct and implementation of shared decision making in diabetes care, particularly studies evaluating application of shared decision making in real-world settings, with diverse populations, and with rigorous evaluation of cost and cost effectiveness. This proposed initiative addresses the critical need to build the evidence base linking shared decision making and health outcomes in patients with diabetes, with particular attention to facilitators and barriers to shared decision making in populations of patients traditionally underserved and/or underrepresented in clinical trials and sustainability in clinical care settings.

Dr. Cefalu then invited Council members to ask any questions related to the DEM concepts.

Council Questions and Comments

Comment from Council: *For the proposal on nutrient-stimulated hormones and neural plasticity, given that many diseases of the brain involve blood vessels, will there be any research looking at*

neural modulation of plasticity and the effects first on blood vessels in the brain, such as endothelial cells or capillaries?

Dr. Cooke agreed that this is a good suggestion, and that interesting work is underway examining the role of endothelial cells in transporting nutrient-stimulated hormones across blood vessels.

Next, Dr. William Cefalu presented four DEM renewal concepts:

Centers for Diabetes Translation Research (CDTR)

The CDTR program was established in 2011 to improve translation of research findings related to diabetes prevention, treatment, and health equity by supporting research across the translational research spectrum (i.e., bedside to clinical practice and community settings, dissemination and implementation research). CDTRs provide local, regional, and national research resources to advance the field of diabetes translation, address diabetes-related health disparities, and develop the scientific workforce. The goal of CDTRs (http://www.diabetes-translation.org/) is to improve prevention/treatment of diabetes by promoting research that supports rapid dissemination, implementation, and sustained use of effective interventions/approaches, particularly in high-risk populations. CDTRs have documented evidence of progress from their current project period, which is the second renewal with seven funded grantees. To date, their scientific research base consists of over 790 members, over 4,000 consultation services across 24 local, regional, and national research service cores, and awarded 94 P&F projects. The objective of this renewal is to ensure uninterrupted support to the CDTR program after the current project period ending 6/30/2026. This will be a competitive renewal open to existing and new Center applications.

Accelerating Medicines Partnership in Type 2 Diabetes (AMPT2D) - Renewal

The Accelerating Medicines Partnership (AMP), is a pre-competitive collaboration among government, academia, and industry to improve the ongoing efforts to develop new therapies for complex, heterogeneous diseases (http://www.nih.gov/science/amp/). The overarching goal of AMP-Common Metabolic Diseases (CMD) is to use human genetics as a powerful approach to obtain human-data derived disease understanding and biomarker/therapeutic opportunities. This is being accomplished through systematic aggregation of existing genotype-phenotype data for CMD, related traits, and its complications as well as the generation of a large amount of new -omic data which are being deposited in the portal. The goal of the NIDDK-funded component of the consortium will be to continue to build on the current capabilities of the Common Metabolic Diseases Knowledge Portal and harmonize with other NIDDK resources.

National Health Interview Survey (NHIS) - Diabetes Components

We are requesting renewal of Initiative #1065 “Renewal of the NHIS - Diabetes Components” for the purpose of continuing the diabetes-related questions among this US nationally representative cohort that will be included in NHIS from FY2026-2030. Scientists from NIDDK/DEM and Centers for Disease Control and Prevention (CDC)/Division of Diabetes Translation will jointly review the current diabetes-related content in NHIS to ensure that we are obtaining robust data related to diabetes. We have modified the questions in the National Health and Nutrition Examination Survey (NHANES), renewed for FY25-29 last year, to harmonize the questions with NHIS whenever possible to strengthen our diabetes content in these two national surveys. The NHIS data are public use and have been used extensively by researchers in the United States and beyond as well as by NIDDK and CDC scientific staff and other federal agencies to inform public health and policy

decision related to diabetes.

Renewal of the NIDDK Catalyst Award

NIH high-risk/high-reward grant programs supported by the NIH Office of the Director (NIH-OD), including the Pioneer and New Innovator programs, have been highly successful at diversifying and strengthening grant portfolios across NIH. The NIH-OD programs are designed to prioritize research that spans the interests of multiple NIH institutes, and as a result, HRHR proposals that focus on NIDDK's mission areas are underrepresented. The NIDDK Catalyst initiative is patterned after key elements of the OD Pioneer Award, including requirements for an essay-based proposal focused on goals that are bold and innovative. Accordingly, the DDN joined with the DEM to offer this Catalyst program for FY2021 that funded such high-risk/high-reward proposals within the missions of DDN/DEM. Another request for applications (RFA) for Catalyst applications was published in FY2023 and applications are currently awaiting review in early 2024. Based on the robust responses to these prior funding opportunities, there remains a need to continue to support this unique and important part of DDN's/DEM's grant portfolios and provide a consistent avenue to support high-risk/high-reward research to tackle intractable problems within NIDDK's mission.

Dr. Cefalu also presented two SDP renewal concepts:

Integrated Islet Distribution Program (IIDP)

This request is to continue support of the IIDP. IIDP facilitates the distribution of human islets and associated samples including plasma, serum, peripancreatic lymph nodes as well as acinar, ductal, and duodenal tissues to biomedical researchers by establishing partnerships with qualified islet isolation facilities to prepare and distribute these samples. It also solicits requests for samples from new principal investigators and researchers new to the field of human islet research. IIDP efforts in the last project period are now supporting nearly 200 investigator-initiated projects, resulting in 168 publications in the first four years of the previous cycle. Human islets and associated tissues are essential resources for diabetes research to advance our understanding of human islet cell biology, and to promote the development of new therapies for the prevention and treatment of diabetes.

The Environmental Determinants of Diabetes in the Young (TEDDY) Data Coordinating Center

T1D is a serious and burdensome chronic disease that usually affects children and young adults. The rate of T1D incidence is rising worldwide, especially in the very young. These findings suggest that environmental triggers are responsible for increased and accelerated rates of disease in genetically susceptible individuals. TEDDY was established to identify environmental triggers of T1D, such as infectious agents, dietary factors and/or psychosocial factors, in genetically susceptible individuals that trigger or protect against the development of islet autoimmunity and T1D. TEDDY's overarching goal is to elucidate the etiology and pathogenesis of T1D and to inform new strategies to prevent or delay the disease. To date, TEDDY has shed light on the heterogeneity of the disease process. TEDDY completed recruitment of the subjects in 2010; retention and data accrual rates are meeting study projections. The study was designed to follow subjects for 15 years to accrue approximately 800 subjects who develop autoantibodies and 400 subjects who develop diabetes. The NIDDK recommends renewal of the TEDDY program to continue to conduct data analysis and prepare manuscripts, manage and perform quality control of NCC2 datasets and to prepare data sets for deposit in the NIDDK repository and other specialized repositories and finally closeout the study.

Division of Kidney, Urologic, and Hematologic (KUH) Diseases Concepts
Various KUH staff members presented concepts on behalf of the division.

Post-Dialysis Fatigue and Patient Science
Dr. Kevin Chan

Most people on chronic dialysis develop debilitating fatigue after their dialysis treatment. The scientific literature of post-dialysis fatigue is sparse, and we lack basic diagnostic criteria, an outcome measure, and pathophysiological explanation for this disease. This cooperative research initiative proposes to engage people with post-dialysis fatigue with qualitative scientists to establish a robust case definition, a diagnostic instrument, an outcome measure, and quality metrics for post-dialysis fatigue. The epidemiology and biology of the disease will be defined. This foundational science will form an anchor for subsequent therapy development and clinical trials.

Matching for Kidney Precision Therapeutics (MAP-IT)
Dr. Debbie Gipson

Patients with kidney disease are frustrated by the generic standard of care management that includes a series of treatments with low likelihood of kidney preservation and significant risk for toxicity. The Kidney Precision Medicine Project was implemented to advance the characterization of kidney disease mechanistic subgroups, associated biomarkers, and treatment targets with a goal to improve the subsequent opportunities for precision therapies. This new initiative is being designed to prepare the next step in the translational pipeline and will be informed by a March 18-19, 2024, NIDDK workshop entitled Preparing for Kidney Precision Medicine Trials. Currently identified gaps include a need for broader expertise in translating mechanism discovery to interventional trials, the translational gap from biomarker discovery to high reliability assays with defined cut-points for target population identification and trial endpoints, and efficient screening of kidney patient disease mechanisms to inform precision clinical trial enrollment. The creation of a national matching for kidney precision therapeutics program (MAP-IT) is designed to address these gaps. In this first phase, initial objectives will be accomplished by 1) establishing a transdisciplinary, multi-institutional consultative team to assess and advise on kidney precision medicine trial proposals, 2) refine and deploy assays fit for use in human trials, and 3) implement clinical trials platform demonstration projects.

Management of Asymptomatic Renal Stones (MARS)
Dr. Ziya Kirkali

An asymptomatic renal stone in the kidney is like a time bomb! Patients are anxious not knowing what will happen to them and when, as symptomatic stone events are unpredictable and can vary in intensity. Philosophically, all symptomatic stones were once asymptomatic; and clinically, a planned intervention is always better than an unplanned one. Since there are no definitive trials, management of asymptomatic stones is controversial. A patient-centered approach will be taken to identify what matters most to the person who harbors an incidental or a residual asymptomatic stone after surgery. First, a workshop is planned to get patient input, bring in the urologic community and flesh out the idea. Then a Notice of Funding Opportunity will be developed to support a Clinical Research Consortium. The study will ask to consent all patients with an asymptomatic renal stone who do not want to be randomized (patient choice) and collect data. Patients with incidental or residual asymptomatic stones smaller than 15 mm in largest diameter consenting to the study to be randomized to either active surveillance or intervention (ureteroscopy/Shock Wave Lithotripsy)

(patient/surgeon choice). The primary outcome will be stone-related surgery or Emergency Department visit, with multiple secondary outcomes. Machine learning will be used to; a) identify best management options for individuals with different characteristics, and b) identify optimal follow-up strategies for active surveillance.

Revisiting Development at KUH: Initiating New Directions, Launching Early-stage Investigators (ESIs)

Dr. Eric Brunskill

The Revisiting Development at KUH: Initiating New Directions, Launching ESIs (ReKINDLE) is an opportunity to rejuvenate the developmental biology field, address core fundamental scientific questions critical to the mission of KUH, while also attracting new investigators to the NIDDK. ReKINDLE aims to invigorate developmental biology by supporting researchers and ESIs with the resources to pursue groundbreaking research. By highlighting the importance of development, this program not only enriches our comprehension of fundamental developmental mechanisms but continues to lay a foundation for ongoing advancements in developmental biology, but also continue to foster growth in regenerative medicine, stem cell research, and the study of congenital anomalies.

Next, Dr. Robert Star presented 9 KUH renewal concepts:

Understanding Chronic Kidney Diseases of Uncertain Etiology in Agricultural Communities

Chronic Kidney Disease of Uncertain Etiology (CKDu) is recognized to cause end-stage kidney failure in rural areas of many Low- and Middle-Income Countries, resulting in a large death toll among the relatively young working age population. Environmental factors and extreme heat exposure are suspected, but there is a lack of compelling evidence for any agent, while family and geographic clustering raise the possibility of an unrecognized genetic susceptibility. Since 2021 NIDDK and National Institute of Environmental and Health Sciences (NIEHS) have jointly funded a consortium to find causes and potential interventions for CKDu. The consortium comprises of a Scientific Data Coordinating Center, Field Epidemiology Sites, and a Renal Science Core. It benefits from the active collaboration of Human Health Exposure Analysis Resource laboratories (funded by NIEHS).

Interventions to Improve Outcomes After AKI (COPE-AKI)

Acute kidney injury (AKI) is associated with high morbidity, including increased risk of chronic kidney disease (CKD), end-stage kidney disease (ESKD), cardiovascular disease, and mortality. There is limited evidence to inform recommendations for processes of care interventions targeting progression of kidney disease and the associated morbidity and mortality in AKI survivors. Since 2021, NIDDK has funded the Caring for OutPatiEnts after Acute Kidney Injury (COPE-AKI) Consortium, composed of three Clinical Centers and a Scientific and Data Research Center, to develop and test a process of care intervention that aims to reduce rehospitalizations, morbidity, and patient reported outcomes compared with usual care in patients after hospitalization with Stage 2 and 3 AKI. A 5-year extension of the COPE-AKI clinical trial is proposed to fully meet the enrollment targets, ensure appropriate representation of underrepresented minorities, complete participant follow-up, and allow for resources for data analysis and dissemination of study findings. There is currently no standard of care for patients after hospitalization with AKI. Successful completion of the COPE-AKI study will provide key insights that are expected to directly inform improved clinical management strategies and the development of standard of care for Stage 2 and 3 AKI survivors.

Phosphate Binders in Children with CKD (FIT4KID)

CKD-mineral bone disorder (CKD-MBD) is closely linked to the progression of CKD and the development of cardiovascular disease in children and adults. Management of CKD-MBD is unquestionably suboptimal and the current investigators have proposed a novel treatment paradigm. They have undertaken a clinical trial to test the paradigm. This initiative is intended to permit successful completion of the FIT4KiD multisite clinical trial by providing extended funding to the Data Coordinating Center as the clinical enrolling sites continue to accrue patients.

A Trial of Transplanting Hepatitis C-viremic Kidneys into Hepatitis C-Negative Kidney Recipients (THINKER-NEXT)

THINKER-NEXT is an ongoing multi-center trial with an overarching goal to determine if kidneys from hepatitis C-viremic (HCV) donors can safely be transplanted into HCV negative patients with end-stage renal disease. Enrollment of trial participants, kidney transplantation, and one year follow-up of the cohort is anticipated to occur at the end of the current funding period. This initiative proposes an additional one year of funding to complete analysis of the data from the THINKER-NEXT trial.

George M. O'Brien Urology Cooperative Research Centers and the Urology Centers Interactions Core

This concept seeks support for continuation of the NIDDK George M. O'Brien Urology Cooperative Research Centers (U54) and the Urology Centers Interactions Core (U24). The Urology Cooperative Research Centers foster impactful, multidisciplinary research through diverse collaborations within and outside the Centers and serve as a national resource for the urology research community. The Interactions Core supports these efforts through coordinating the Urology Cooperative Research Centers, the urology P20 Centers, and urology Institutional Career Development (K12) Programs, as well as the broader urology community, all under the umbrella of the Collaborating for the Advancement of Interdisciplinary Research in Benign Urology (CAIRIBU) effort. In addition, the Interactions Core will serve as the hub for a CAIRIBU Opportunity Pool Program and additional travel, and research awards designed to support emerging scientists, including NIH defined ESIs and investigators new to the field of urology. All efforts will address the overall goal of improving prevention and clinical management of benign (non-cancer) genitourinary disorders through research excellence, enhanced sharing of resources and access to core services, and establishment of a robust research community trained to address the Nation's biomedical research needs for urologic disorders within the NIDDK's mission.

Re-competition of Institutional Career Development for Epidemiology of Urologic Diseases (UroEpi)

The goal of this renewal proposal is to provide institutional support to mentor and develop a cohort of investigators proficient and self-sustaining who can conduct epidemiologic research in urologic diseases within our mission, serving as a parallel resource to existing projects for chronic and ESKD within KUH, and for diabetes and digestive diseases within NIDDK.

KUH Predoctoral to Postdoctoral Fellow Transition Award (F99/K00)

The purpose of the Kidney, Urology and Hematology Predoctoral to Postdoctoral Fellow Transition

Awards (F99/K00) is to recruit exceptional graduate students from diverse research disciplines and backgrounds to pursue postdoctoral training focused on Kidney, Urology or Hematology research. Talented graduate students from disciplines including, but not limited to, engineering, statistics, data science, imaging, biochemistry, and genetics are invited to apply to this opportunity. This program is committed to promoting and supporting diversity (both scientific and demographic) through training the next generation of kidney, urology, and hematology researchers.

Coordinating Unit to Support the Kidney, Urology and Hematology Innovative Science Accelerator Program Coordinating Unit (ISAC-CU)

Truly innovative, breakthrough discoveries often come from disruptive, risky research. Such innovative research must be supported by an equally innovative and nimble funding program. In 2021, KUH established the Innovative Science Accelerator (ISAC) Program, administered through the ISAC-CU, with the goals to provide: 1) seed funding, through a highly flexible funding process, for projects targeting discovery (hypothesis-generating) and exceptionally innovative, disruptive high-risk/high-reward research relevant to KUH research communities; and 2) a platform for researchers funded through the program to exchange ideas and resources to enable collaboration and accelerate innovation. We propose to continue to enable cutting-edge research and accelerate true innovation through the ISAC program.

Development of Catalytic Tools and Technologies for Kidney, Urologic, and Hematologic Diseases

The purpose of this initiative is to promote the development of innovative, enabling tools and technologies in the areas of KUH diseases. The initiative supports technology development projects that will catalyze new scientific endeavors or full-scale development efforts. This is a renewal of a concept approved in 2021, which has been successful in attracting investigators from other fields to KUH research and funding meritorious projects.

Office of Minority Health Research Coordination Concept
Dr. Rob Rivers presented a concept on behalf of the office.

Expansion of the Short-Term Research Experience Program to Unlock Potential (STEP-UP)

Historically, opportunities in this country have been mired by lack of resources based on a person's zip code. To address the myriad of health problems facing the country and the world, it is imperative that the full diversity of the United States is engaged in the biomedical research workforce. Moreover, from research, we know that more diverse teams tend to be more innovative than homogenous groups. To ensure that the biomedical research workforce encompasses talent with no boundaries on opportunity for talent, the NIDDK Short-Term Research Experience to Unlock Potential (STEP-UP) program was launched to provide hands-on research experiences to both high school and undergraduate students. For more than 20 years, this program has engaged students from throughout the country and US territories to work with researchers on the cutting edge of discovery. In this renewal, we seek to expand the program in partnership with the National Heart, Lung, and Blood Institute to have more high school centers located throughout the country. No changes are sought in the undergraduate program as the modifications made in the last round.

Office of Obesity Research
Dr. Voula Osganian presented a concept on behalf of the office.

Optimal Treatment Strategies for use of Anti-Obesity Medications in Children and Adolescents

Obesity in youth remains prevalent and a major public health problem. Since 2020, three anti-obesity medications have been approved by the FDA in youth ages 12 years and older with non-syndromic obesity. Studies of anti-obesity medications (AOMs) demonstrate significant improvements in body mass index (BMI) and cardiometabolic risk factors. However, a strong evidence base is lacking to guide treatment decisions for youth, in which physical and psychosocial growth and development need to be considered, including optimal developmental stage for AOM initiation; drug class and dosage; behavioral, nutritional and physical activity interventions to support growth and development and preservation of lean body mass; type and intensity of lifestyle interventions needed to support optimal weight and psychosocial outcomes; and potential strategies to enable discontinuation of AOMs and avoid lifetime use while preserving health benefits. This initiative will support investigator-initiated research to test AOM treatment strategies for youth with obesity that could be implemented in clinical care settings to maximize benefits and minimize risks of AOM use. Given the rapidly changing landscape and knowledge gaps in treatment strategies and safety with AOM use, well-designed studies are needed to support the appropriate, effective, and safe use of AOMs in diverse populations of children and adolescents. Findings will inform optimal medical management of children and adolescents with obesity.

Health Equity Concepts
Dr. Germino introduced this new set of concepts, which stem from NIDDK's report *Pathways to Health for* All, developed via Working Group with input from some members of the Advisory Council. The Working Group has been meeting monthly to discuss ways to implement the five major recommendations in the Report. The concepts presented are a notable step in the implementation process. Various staff members presented concepts.

Planning Grants for NIDDK Community-Engaged Research
Dr. Miranda Broadney

Understanding the critical importance of including rigorous community engagement in health research, NIDDK seeks to deepen the use of robust community-engaged methods across the spectrum of the Institute's research. This initiative proposes to solicit planning grant applications to assemble & strengthen community partnerships, assess feasibility and determine best practices to conduct community-engaged research focused on NIDDK mission diseases and populations that experience health disparities. If successful, these planning grants would support, enable, and lay the groundwork for future clinical studies or trials which have been co-created with community investigators. This initiative will also establish research activities that include the priorities of communities who are affected by and could benefit from rigorous pragmatic planning around devising research questions, describing community assets, and developing intervention approaches to better understand and/or improve the prevention and treatment of NIDDK diseases and conditions. Subsequently, these new multidisciplinary teams should be prepared and equipped to execute their co-created research study.

Program for Implementation Science and Health Equity Scholars (PrISHES)
Dr. Pamela Thornton

The PrISHES will train a cadre of investigators with advanced research skills in dissemination and implementation science and health equity in NIDDK-related disease prevention and management. Speedy translation of efficacious and expensive medical research into practice is essential to improve the health of all people. However, lags in getting research into practice persist (roughly 17 years); and only 1 in 5 evidence-based interventions make it into routine clinical practice. As cited in NIDDK's strategic priorities, workforce development and growing the field of implementation science are key strategies to close the gap between research and practice. However, NIDDK investments in implementation science have thus far been mostly limited to diabetes programs. Yet, promising interventions for many NIDDK diseases and conditions are ripe for testing appropriate adaptation and evaluation methods to increase their potential benefit in diverse patient populations and various community and health care settings. PrISHES leverages lessons from NIDDK and NIH investments to provide intensive short courses in relevant methodologies followed by mentorship activities with cohorts of multidisciplinary scholars. Anticipated outcomes include a cadre of investigators with advanced implementation science and health equity research competencies, leading to publications, grants, and overall retention in fields that can advance NIDDK disease prevention and management for all.

Integration of Social and Medical Care (Renewal)

Adverse social determinants of health, also called social risks, drive obesity, diabetes, and kidney disease outcomes. Social risks disproportionately affect racial and ethnic minority groups, rural populations, sexual and gender minority groups, and socioeconomically disadvantaged communities, and contribute to health inequities in NIDDK diseases. RFA-DK-22-038 requested pilot trials to test approaches to integrate social and medical care in health care settings. The trials will determine: 1) feasibility and acceptability of screening for social risks, identifying social needs and implementing referral service linkages (e.g., addressing transportation, housing, or food needs, etc.) within the context of a healthcare visit; and 2) preliminary signals of the intervention's impact on both the social risk/need(s) and NIDDK disease outcomes. These pilots will lay the foundation for larger, fully powered clinical trials. This FY 2024 initiative was intended to 1) jump start novel research to systematically screen for and address patients' social risks to improve health outcomes in NIDDK diseases; and 2) grow a community of NIDDK researchers who can share effective strategies to integrate medical and social care in the context of healthcare delivery. A budget cut to the FY 2024 initiative decreased the number of awards and eliminated the proposed 2nd receipt date. Funds are requested to re-issue the RFA with an FY 2026 receipt date to better achieve the goals of this initiative.

Dr. Germino invited Council members to ask any questions related to the Health Equity concepts.

Comment from Council: *Is the PrISHES program similar to the K awards program?*

Dr. Thornton responded that PrISHES is a training program more like an R25 than a K award. The scholars would be funded for a short-term intensive training experience, and then the program would support the mentors for a 2-year mentoring program to involve the scholars in grant writing, publications, and more. At this stage, Dr. Thornton expects many of the scholars would also have K awards or be involved with other supportive programs.

HIV/AIDS Research

Next, Dr. Peter Perrin presented two renewal concepts.

Priority HIV/AIDS Research within the Mission of the NIDDK

This initiative seeks to stimulate basic, translational, and clinical HIV/AIDS-related research within the mission of NIDDK that is aligned with NIH HIV/AIDS research priorities. The most recent priorities are outlined in NOT-OD-20-018, UPDATE: NIH HIV/AIDS Research Priorities and Guidelines for Determining HIV/AIDS Funding. Areas of interest include pathophysiological research on NIDDK-relevant comorbidities, coinfections, and complications; research toward an HIV cure that focuses on viral reservoirs in in anatomical sites relevant to the mission of NIDDK, behavioral and social mechanisms impacting the development and management of NIDDK-relevant HIV co-occurring conditions, and NIDDK-relevant topics that cut across more than one NIH HIV/AIDS research priority.

Exploratory and Developmental HIV/AIDS Research within the NIDDK's Mission

This initiative encourages innovative basic, translational, or clinical research on NIH HIV/AIDS priority research within NIDDK's mission by facilitating exploratory and developmental research that might lead to a larger, more encompassing project. Several important HIV comorbidities, coinfections, and complications affect organs, tissues, and processes within NIDDK's mission. Examples include obesity, diabetes, and metabolic and endocrine complications; kidney, urologic and hematologic diseases; enteropathy and its impact on the digestive system as well as other organs and tissues; noncommunicable liver disease; and viral hepatitis. Understanding disease mechanisms in the context of HIV or its treatment is essential for prevention and management of these conditions. In addition, the contributions of health-impeding social determinants of health must also be addressed. Elucidating mechanisms underlying HIV reservoirs in NIDDK-relevant tissues is essential toward development of strategies for long-term viral suppression or eradication of HIV from the body.

NIDDK-wide Initiatives
Various staff members presented concepts.

Novel Device Neurotechnologies for Probing Peripheral or Body-Brain Neural Processes within the Mission of NIDDK
Dr. Diana Cummings

Bidirectional brain-visceral organ communication plays a critical role in controlling physiological functions that promote health and survival (e.g., energy homeostasis, digestion, voiding, etc.), and disruptions to this communication cause or contribute to many diseases within NIDDK's mission (e.g., obesity, metabolic dysfunction, disorders of gut-brain interaction, neuro-urological disorders, etc.). Distinct challenges faced by neuroscientists who study cells, circuits, and body-brain interactions involving peripheral organ systems include the relative inaccessibility and unique anatomy and physiology of visceral organs, as well as technical difficulties inherent to simultaneous interrogation of the brain and a visceral organ. Three recent NIDDK-sponsored workshops, e.g., Neuroimmune Crosstalk in the Gut, Neural Plasticity of Energy Homeostasis and Obesity, and Neurourology: Bridging Basic and Clinical Science to Understand Urologic Disease, emphasized the need for better neurotechnologies for interrogating interactions between visceral organs and the associated peripheral and/or central nervous system. This initiative's purpose is to facilitate the development and translation of transformative technological approaches that will break through existing technical barriers and improve capabilities for basic, translational, and clinical research on the peripheral nervous system and/or body-brain axis that is relevant to diseases within NIDDK's

mission.

NIDDK Innovation Fund: Capitalizing on Rapid Advances in Data Science
Dr. Daniel Gossett

The field of AI and other data science technology is rapidly advancing, presenting new and revolutionary opportunities. We lack nimble processes to harness emerging opportunities to catalyze NIDDK science. Furthermore, our workforce has gaps that impact our ability to effectively leverage new data science technology to advance the NIDDK mission. There is a need for a NIDDK program that can quickly integrate new expertise and capitalize on the latest advances. The proposed initiative is to establish an innovation fund that allows NIDDK to rapidly capitalize on emerging and transformative opportunities and implement innovative ideas leveraging data science. The innovation fund will take advantage of timely and time-sensitive opportunities, prioritizing cross-cutting research that has NIDDK-wide impact and short-term efforts that limit out-year commitments. The fund will 1) support NIDDK science within NIH-wide ODSS-led efforts and 2) support a funding opportunity for short-term grants for specific emerging topics that are at the leading edge of the field, which will change over time and will be updated annually through the NIH Guide to Grants and Contracts.

There being no further questions or comments from Council, Dr. Rodgers proceeded to request a motion for concurrence with the concepts presented. The motion was made and seconded and the concepts approved by Council vote.

OPEN SESSION OF SUBCOMMITTEE MEETINGS

See Minutes posted on the NIDDK Council Minutes Website.

CLOSED SESSION OF THE SUBCOMMITTEE MEETINGS

A portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and Section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict-of-interest, real or apparent. Members were asked to sign a statement to this effect.

CLOSED SESSION OF THE FULL COUNCIL

This portion of the meeting was closed to the public, in accordance with the determination that it concerned matters exempt from mandatory disclosure under Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the 31 Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict-of-interest, real or apparent. Members were asked to sign a statement to this effect.

CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1,583 grant applications (790 primary and 793 dual), requesting support of $809,618,229 were reviewed for consideration at the May 8, 2024 Council meeting. An additional 1,224 Common Fund applications requesting $786,989,248 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1,047 applications requesting $445,798,216 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the May 8, 2024 meeting.

ADJOURNMENT

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the Council members, presenters, and other participants. He thanked the Council members for their valuable input. There being no other business, the 225th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on May 8, 2024.

I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

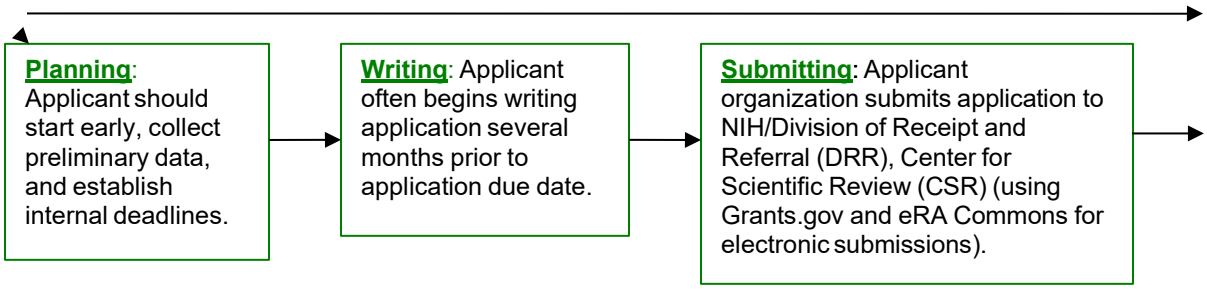
_____
Date

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council

Grants Process At-A-Glance

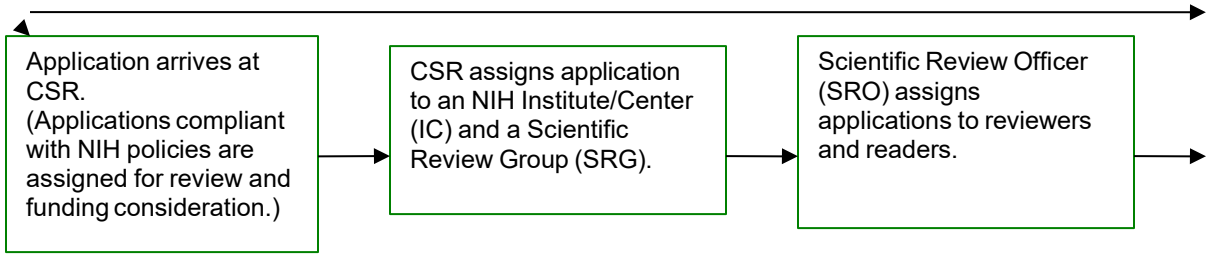
The following NIH "Grants Process At-A-Glance" chart is provided as a sample of the general time element necessary for a competing application to proceed from Receipt and Referral through the Peer Review process to negotiation and award.

Planning, Writing, Submitting



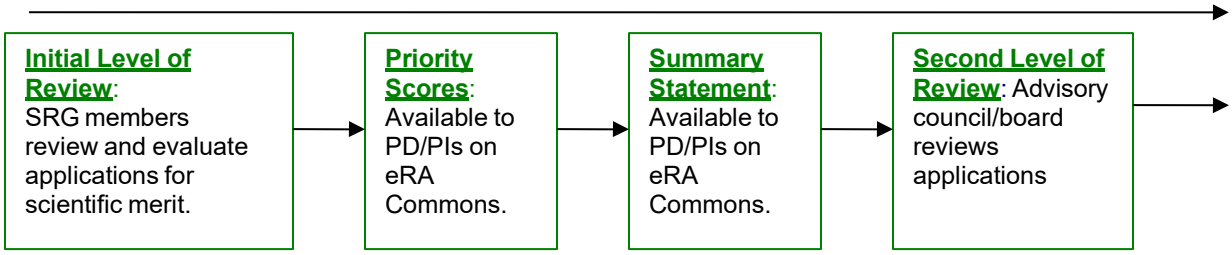
Receipt and Referral

Months 1 to 3



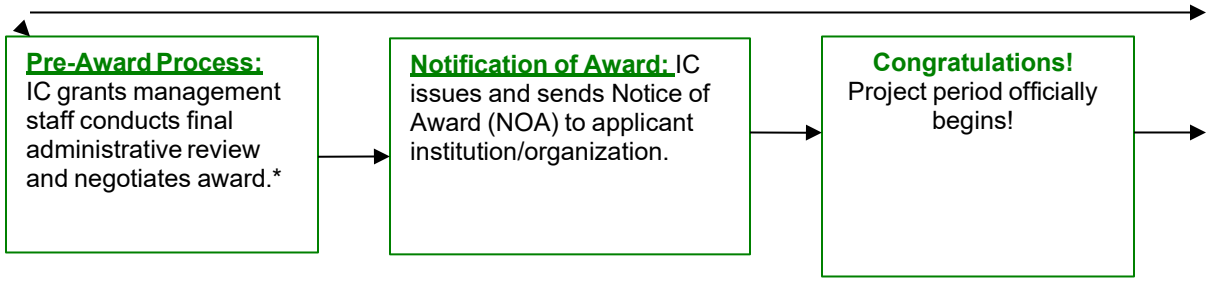
Peer Review

Months 4 to 8



Award (*Requests additional information needed just-in-time for award.)

Months 9 to 10

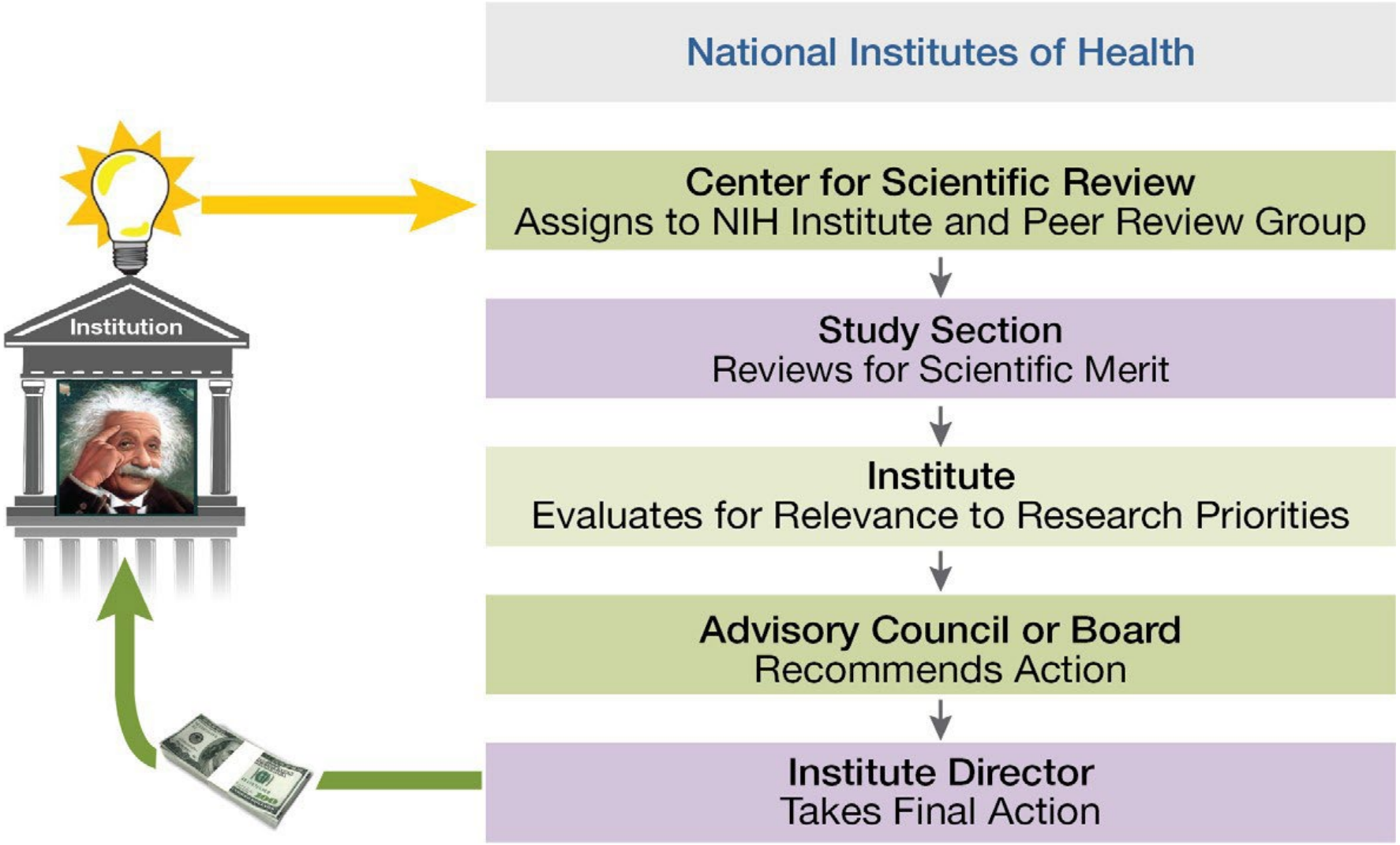


Post-Award Management

Administrative and fiscal monitoring, reporting, and compliance.

Note: Timeline is based on the standard grants process. It does not reflect a shorter timeframe for grants undergoing expedited review.

Peer Review and Funding of NIH Grant Applications



NIH Grant Receipt, Review, and Award Schedule

Jan-May **May-Sept** **Sept-Jan**	**Receipt Dates**
June-July **Oct-Nov** **Feb-Mar**	**Review Dates**
Sept-Oct **Jan-Feb** **May-June**	**National Advisory Council/Board Dates**
Dec1 **Apr 1** **July 1**	**Earliest Possible Beginning Date**

Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

NOTES:

The actual date of the Advisory Council may occur in the month before or after the month listed. For example, some ICs may actually hold the January Advisory Council meeting in February or the October Advisory Council meeting in September.

Awarding components may not always be able to honor the requested start date of an application. Before incurring any pre-award obligations or expenditures applicants should be aware of NIH policy governing pre-award costs prior to receiving a Notice of Award. See the NIH Grants Policy Statement.

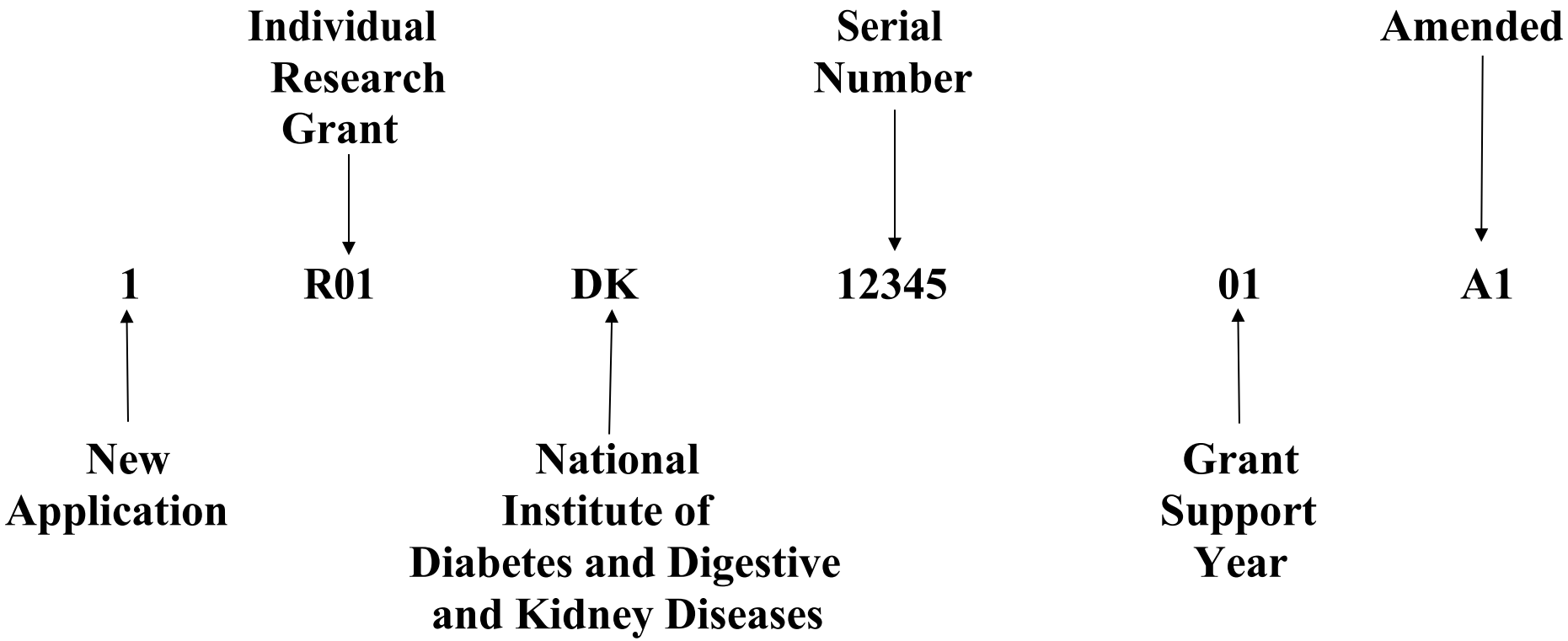
***** Advisory Council Round for Cycle I applications (Cycle III for SBIR/STTR) may be August or October, and their earliest project start date may be September or December respectively.

- https://grants.nih.gov/grants/how-to-apply-application-guide/due-dates-and-submission-policies/due-dates.htm

NIH Funding Instruments

Grant (NIH as Patron)	Cooperative Agreement (NIH as Partner)	Contract (NIH as Purchaser)
Project Conceived by Investigator	Project Conceived by Investigator or NIH	Project Conceived by NIH
NIH Supports or Assists	NIH Supports or Assists	NIH Acquires Services or Product
Performer Discusses Details and Retains Scientific Control	NIH Participates in Direction	NIH Exercises Direction and Control
NIH Maintains Cognizance	NIH Monitors	NIH Closely Monitors
Accomplishes a Public Purpose	Accomplishes a Public Purpose	For the Direct Benefit of the Government

Sample Application Number

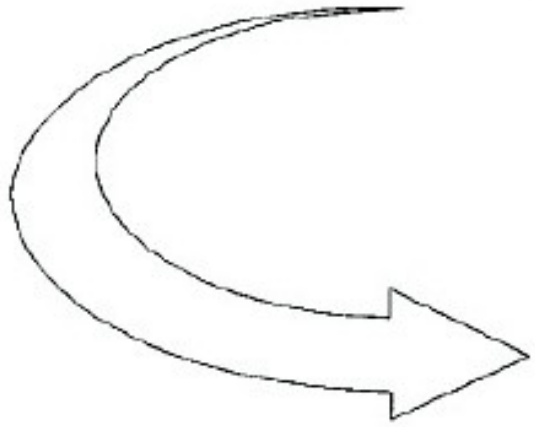


Dual Review System for Grant Applications

First Level of Review

Scientific Review Group (SRG)

- Provides Initial Scientific Merit Review of Grant Applications
- Rates Applications and Makes Recommendations for Appropriate Level of Support and Duration of Award



Second Level of Review

Council

- Assesses quality of SRG Review of Grant Applications (*See Advisory Council Voting Options)*
- Makes Recommendations to Institute Staff on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy

Second Level of Review: Advisory Council Voting Options

- Concurrence with study section action
- Modification of study section action
- Deferral for re-review

NIDDK Makes Funding Decisions Based on:

- Scientific merit
- Program considerations
- Availability of funds

Initial Review Process

Overview

NIH policy is intended to ensure that grant applications submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects."

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils are composed of both scientific and lay members chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council may be recommended for funding.

First Level of Review

Initial peer review meetings are administered by either the Center for Scientific Review (CSR) or another NIH IC. The focus of review is specified in the Funding Opportunity Announcement. Peer review meetings are announced in the Federal Register. The meetings are closed to the public, although some meetings may have an open session; the Federal Register provides the details of each meeting.

A. Peer Review Roles and Meeting Overview

Scientific Review Officer:

Each SRG is led by a Scientific Review Officer (SRO), formerly Scientific Review Administrator (SRA)]. The SRO is an extramural staff scientist and the Designated Federal Official responsible for ensuring that each application receives an objective and fair initial peer review, and that all applicable laws, regulations, and policies are followed.

SROs:

- Analyze the content of each application, and check for completeness.
- Document and manage conflicts of interest. See NOT-OD-11-120 issued on September 26, 2011, and briefly described at end of this chapter.
- Recruit qualified reviewers based on scientific and technical qualifications and other considerations, including:
    - Authority in their scientific field (42 CFR 52h.4)
    - Dedication to high quality, fair, and objective reviews
    - Ability to work collegially in a group setting
    - Experience in research grant review
    - Balanced representation
- Assign applications to reviewers for critique preparation and assignment of individual criterion scores.
- Attend and oversee administrative and regulatory aspects of peer review meetings.
- Prepare summary statements for all applications reviewed.

SRG Members

Chair:

- Serves as moderator of the discussion of scientific and technical merit of the applications under review.
- Is also a peer reviewer for the meeting.

Reviewers:

- Declare Conflicts of Interest (COI) with specific applications following NIH guidance. (See COI section below.)
- Receive access to the grant applications approximately six weeks prior to the peer review meeting.
- Prepare a written critique (using Review Critique Fill-able Templates) for each application assigned per the SRO, based on review criteria and judgment of merit.
- Assign a numerical score to each review criterion
- Make recommendations concerning the scientific and technical merit of applications under review, in the form of final written comments and numerical scores.
- Make recommendations concerning protections for human subjects; inclusion of women, minorities, and children in clinical research; welfare of vertebrate animals; and other areas as applicable for the application. See Review Guidelines for:
  - Protections for Human Subjects
  - Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research
  - Applications Proposing Use of Human Embryonic Stem Cells
  - Vertebrate Animals
- Make recommendations concerning appropriateness of budget requests (see Budget Information for Reviewers).

Other NIH Staff:

- Federal officials who have need-to-know or pertinent related responsibilities are permitted to attend closed review meetings.
- NIH IC or other federal staff members wishing to attend an SRG meeting must have advance approval from the responsible SRO. These individuals may provide programmatic or grants management input at the SRO's discretion.

Peer Review Meeting Procedures

- Applications are reviewed based on established review criteria (see below).
- Assigned reviewers summarize their prepared critiques for the group.
- An open discussion follows.
- Final scoring of overall impact/priority scores is conducted by private ballot.

B. Peer Review Criteria and Considerations

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Review Criteria for Research Grants and Cooperative Agreements

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria, and additional review criteria (as applicable for the project proposed).

Note the NIH is simplifying peer review criteria for applications received ***after*** January 25, 2025 (Council review September 2025 and thereafter).

- ***For application receipt dates prior to January 25, 2025 (Council review in May 2025 or before):***

Scored Review Criteria. Reviewers will consider each of the review criteria below in the determination of scientific and technical merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasib3ility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subject? If the project involves human subjects and/or NIH-defined clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sexes/gender, race, and ethnicity, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects

Inclusion of Women, Minorities, and Children Vertebrate Animals
Biohazards

Resubmission
Renewal
Revision

Additional Review Considerations. As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations
Select Agent Research
Resource Sharing Plans
Authentication of Key Biological and/or Chemical Resources
Budget and Period of Support

- For application due dates on/after January 25, 2025 (Council review September 2025 and thereafter).

The Simplified Framework for NIH Peer Review Criteria retains the five regulatory criteria (Significance, Investigators, Innovation, Approach, Environment) but reorganizes them into three factors — two will receive numerical criterion scores and one will be evaluated for sufficiency. All three factors will be considered in arriving at the Overall Impact score. The reframing of the criteria serves to focus reviewers on three central questions reviewers should be evaluating: How important is the proposed research, how rigorous and feasible are the methods, and whether the investigators and institution have the expertise/resources necessary to carry out the project.

- **Factor 1:** Importance of the Research (Significance, Innovation), scored 1-9
- **Factor 2:** Rigor and Feasibility (Approach), scored 1-9
- **Factor 3:** Expertise and Resources (Investigator, Environment), to be evaluated as either sufficient for the proposed research or not (in which case reviewers must provide an explanation)

The change to having peer reviewers assess the adequacy of investigator expertise and institutional resources as a binary choice is designed to have reviewers evaluate Investigator and Environment with respect to the work proposed. It is intended to reduce the potential for general scientific reputation to have an undue influence.

For complete information see Simplified Review Framework.

C. Scoring

The scoring system described below was implemented for applications submitted for funding consideration for FY2010 and thereafter (NOT-OD-09-024)

Before the SRG meeting, each reviewer and discussant assigned to an application will give a separate score for each of five review criteria (i.e., Significance, Investigator(s), Innovation, Approach, and Environment for research grants and cooperative agreements; see above). For all applications, even those not discussed by the full committee, the individual scores of the assigned reviewers and discussant(s) for these criteria are reported to the applicant.

In addition, each reviewer and discussant assigned to an application gives a preliminary overall impact/priority score for that application. The preliminary scores are used to determine which applications will be discussed in full. For each application that is discussed at the meeting, a final impact/priority score is given by each eligible committee member (without conflicts of interest) including the assigned reviewers. Each member's score reflects his/her evaluation of the overall impact that the project is likely to have on the research field(s) involved, rather than being a calculation of the reviewer's scores for each criterion.

The scoring system utilizes a 9-point rating scale (1 = exceptional; 9 = poor). The final overall impact/priority score for each discussed application is determined by calculating the mean score from all the eligible members' impact/priority scores and multiplying the average by 10; the final overall impact/priority score is reported on the summary statement. Thus, the final overall impact/priority scores range from 10 (high impact) through 90 (low impact). Numerical impact/priority scores are not reported for applications that are not discussed (ND), which may be reported as *.* on the face page of the summary statement and typically rank in the bottom half of the applications.

Applicants should contact the Program Officer for the application to seek additional feedback on the score and summary statement.

An application may be designated Not Recommended for Further Consideration (NRFC) by the Scientific Review Group if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

The following guidance has been given to reviewers to determine individual review criterion and overall impact/priority scores:

High Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
Medium Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
Low Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact

D. Summary Statement

Applications that are not discussed at the meeting will be given the designation “ND” as an overall impact/priority score, but the applicant, as well as NIH staff, will see the scores from the assigned reviewers and discussants for each of the review criteria as additional feedback on their summary statement.

Understanding the Percentile

- A percentile is the approximate percentage of applications that received a better overall impact/priority score from the study section during the past year.
- All percentiles are reported as whole numbers
- Only a subset of all applications receive percentiles. Which types of applications are percentiled varies across different NIH Institutes and Centers.
- The summary statement will identify the base that was used to determine the percentile.

E. Appeals

To preserve and underscore the fairness of the NIH peer review process, NIH established a peer review appeal system (see NIH Guide Notice NOT-OD-11-064) to provide investigators and applicant organizations the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was flawed as outlined below. The appeals policy applies to appeal letters received with respect to the initial peer review of all competing applications submitted to the NIH for support for the January 25, 2011 due date and thereafter, including: 1) reviews conducted by the NIH Center for Scientific Review (CSR) and reviews conducted by the NIH Institutes and other NIH Centers; and 2) applications such as fellowship application that typically do not require Council review. This policy does not apply to appeals of the technical evaluation of R&D contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT award.

An appeal is a written communication from a Project Director/Principal Investigator (PD/PI) and/or official of the applicant institution [not necessarily the Authorized Organization Representative (AOR)] that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence of the AOR. An appeal letter will be accepted only if the letter 1) describes a flaw(s) or perceived flaw(s) in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers
- Conflict of interest, as specified in regulation at 42 CFR 52h "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more non-federal peer reviewers
- Lack of appropriate expertise within the SRG
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

The IC cannot deny the PD/PI and/or the applicant institution the opportunity to have an appeal letter made available to Council, but the IC may determine which appeal letters warrant discussion by the Council members, and Council members may raise certain ones for discussion if they so choose. The Council may concur:

- with the appeal and recommend that the application be re-reviewed.
- with the SRG's recommendation and deny the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

Information from http://grants.nih.gov/grants/peer_review_process.htm.

F. Revised Conflict of Interest Policy for Initial Review

The NIH initial peer review process involves the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of grant and cooperative agreement applications to the National Institutes of Health (NIH). The process, defined in regulation at 42 CFR Part 52h, is extended by policy to other types of applications submitted to the agency.

On September 26, 2011, the NIH issued a revised policy on managing conflict of interest (COI) in the initial peer review of NIH grant and cooperative agreement applications: see NOT-OD-11-120. This announcement provides revised policy for managing COI, the appearance of COI, prejudice, bias, or predisposition in the NIH initial peer review process.

The announcement addresses multi-disciplinary and collaborative research and clarifies the role of non-Federal and Federal employees serving as reviewers. Unlike members of NIH Advisory Councils or Boards, reviewers in the initial level of NIH peer review are not appointed as Special Government Employees and do not submit financial disclosure forms. Therefore, SROs are not in a position to collect financial information from reviewers but can ask about professional relationships and roles as defined in the revised NIH policy and make determinations about potential bias in the initial peer review process.

The overall goal of the revised policy is to increase transparency and to inform the scientific community. With the dramatic increase in internet capability, reviewers may be looking up financial information about investigators on the websites of the investigators' institutions. Although this COI information is available publicly, SROs should instruct reviewers not to consider COI information about applicants in their reviews, discussions, or evaluations.

Similarly, applicants may be looking up financial information about reviewers on their institutions' websites and submitting appeals of initial peer review on the basis of that information. Therefore, it is important that SROs clearly explain the conflict rules for initial peer review to their reviewers.

Modified Application Submission, Referral and Review for Appointed NIH Advisory Group Members

To recognize their outstanding commitment to service to the NIH, regular members of NIH Boards of Scientific Counselors, NIH Advisory Boards or Councils, and the NIH Peer Review Advisory Committee are extended the option of modified application submission, referral and CSR review.

This alternate process is limited to R01, R21, and R34 applications that would normally be received on standard submission dates (but not special receipt dates) and will be reviewed at CSR. Depending on the timing of the submission and the number of other similar applications received during the pre-meeting time window, NIH staff will decide if the application will be reviewed in a standing Study Section or in a Special Emphasis Panel (SEP). These applications will be processed and assigned to NIH Institute Review Offices or CSR Integrated Review Groups (IRGs) using the standard referral guidelines (https://public.csr.nih.gov/StudySections).

Standard Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

Standard and Continuous Submission Due Dates

Excerpt from NOT-OD-20-060. See full notice for applicability and eligibility details.

For the Advisory Council Round:	Non-AIDS Standard Application Due Dates		Continuous Submission Non-AIDS Application Receipt Period Ends
	R01	*R21, R34*	*R01, R21, R34*
May	October 5 November 5	October 16 November 16	December 10
October	February 5 March 5	February 16 March 16	April 10
January	June 5 July 5	June 16 July 16	August 10

For the Advisory Council Round:	AIDS Application Due Dates	Continuous Submission AIDS Application Receipt Period Ends
	R01, R21, R34	*R01, R21, R34*
May	January 7	February 1
October	May 7	June 1
January	September 7	October 1

Further Information and Inquiries

How to check your Continuous Submission eligibility

- Instructions on how to check your Continuous Submission eligibility through your Commons account.

Frequently Asked Questions regarding Continuous Submission
(see https://grants.nih.gov/faqs#/continuous-submission.htm)

Updated Continuous Submission policy Notice
(see: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-060.html).

Any remaining issues/appeals may be directed to a NIH Continuous Submission Committee by emailing CSR.cont.sub.comm@csr.nih.gov.

Second-Level Review Procedures

The Advisory Council/Board of the potential awarding Institute or Center (IC) performs the second level of review. Advisory Councils/Boards are composed of scientists from the extramural research community and public representatives (NIH Federal Advisory Committee Information). Members are chosen by the respective IC and are approved by the Department of Health and Human Services. For certain committees, members are appointed by the President of the United States.

On June 18, 2010, President Obama issued "Lobbyists on Agency Boards and Commissions," a memorandum directing agencies and departments in the Executive Branch not to appoint or re-appoint federally registered lobbyists to advisory committees and other boards and commissions. On October 5, 2011, the Office of Management and Budget (OMB) issued final guidance to Executive Departments and agencies concerning the appointment of federally registered lobbyists to boards and commissions. This guidance applies not only to advisory committees subject to FACA, but to all other groups as well-even to members of working groups not appointed as SGEs. See *Federal Register* / Vol. 76, No. 193 / Wednesday, October 5, 2011/Notices under OFFICE OF MANAGEMENT AND BUDGET, Final Guidance on Appointment of Lobbyists to Federal Boards and Commissions, AGENCY: Office of Management and Budget. ACTION: Notice of Final Guidance.

Second-level review is the assessment of the quality of the initial review of grant applications. By law, NIDDK's Advisory Council must recommend an application before the Institute can fund it. Second-level review is **not a second scientific review**. Rather, the Council looks at applications with potential barriers to funding such as human subjects and animal concerns or special circumstances such as foreign applications or applications requiring Special Council Review (SCR) where the principal investigator has more than $2M in NIH total cost support.

The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote. When Council recommends an application for funding, that doesn't necessarily mean it will receive an award. NIDDK makes the final decision.

Applications Requiring Individual Consideration

- Applications from Foreign Institutions

  In reviewing and making recommendations on foreign grant applications, the Council members should be aware that ALL of the following criteria must be met in order to be supported by the NIH:

  a. The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing United States resources.
  b. The project has specific relevance to the mission and objectives of NIDDK and has the potential for significantly advancing the health sciences in the United States.
  c. The application must be approved for funding by the Council.
  d. The application may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, and gender and minority requirements.

- Applications With Concerns about Human or Animal Subjects and/or Gender and Minority Representation

The Council will be asked to comment on any application(s) recommended for possible funding with unresolved concerns regarding the involvement of human subjects, the use of animals, and/or gender and minority representation. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern(s).

- Applications That May Not Provide for Appropriate Biosafety, Biocontainment, and Security of Select Agents

  The Council will be asked to comment on any applications recommended for possible funding with unresolved concerns regarding biosafety, biocontainment, and security of select agents. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern.

- Letters of Appeal

  The Council reviews appeal letters that were submitted by investigators subsequent to the peer review of their application and were not resolved by program and review staff. It is the responsibility of NIDDK staff to determine whether a letter is an appeal.

  An investigator may have concerns about and may wish to appeal a procedural aspect of the peer review process. Only letters concerning procedural aspects of a review are considered an appeal. Procedural issues fall under four categories and the applicant must claim one or more of the following:

  a. The initial review was biased.
  b. A conflict of interest existed.
  c. The review group lacked appropriate scientific expertise.
  d. Factual errors entered into the review.

  Differences in scientific opinion that often occur between investigators and reviewers may not be contested through these procedures. In addition, communications from investigators consisting of additional information that was not available to the reviewers are not considered to be appeals.

  The Council has two options when reviewing an appeal letter:

  a. To concur with the outcome of the initial peer review as reflected in the summary statement.
  b. To concur with the claims discussed in the applicant's appeal letter and recommend deferral for re-review either by the same or a different review group.

  Other letters, termed Council communications, may also be made available to the Council at the discretion of NIDDK staff.

Special Council Review of Research Applications from Program Directors/Principal Investigators (PDs/PIs) with more than $2.0 Million Total Costs in NIH Support

In an effort to continue responsible stewardship of public funds and to support meritorious and innovative research, NIH has instituted a policy of Special Council Review (SCR) of applications from well-funded investigators: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-049.html. Pending grants going to Council from PDs/PIs who have more than $2 million in total costs from active NIH Research Project Grants (RPGs) grants will be subjected to additional consideration. It is important to recognize that this is

a threshold only; investigators who have more research support may still receive additional awards as warranted. When making funding recommendations, staff will take into account factors such as: how innovative and distinct the pending project is from the PD/PI's other grants; the type of research (since costs requirements differ substantially by field); the public health priority of the research; and how the absence of an award impacts other collaborative or translational research efforts.

The following SCR policy guidance is designed to achieve these goals.

- Criteria Considered by NIDDK Staff for Determining Applications Subject to SCR

    a. P01s and other Multi-Component RPGs: Only funds acquired[1] through RPGs[2] should be included when calculating a given PD/PI's support.
    b. Only competing RPGs (New and Renewals) to be considered for award to investigators with $2.0M or more of total cost NIH support are subject to SCR via this policy.
    c. P01s and other Multi-Component RPGs:
        i. Competing Multi-Component RPGs are not subject to SCR unless all of the component leaders have $2.0M or more of total NIH support. The rationale for this is that failure to support one or more of the leaders who exceed the limit could significantly detract from the project as a whole.
        ii. Funded P01s and any other multi-component RPGs, including consortium/sub-award costs, contribute to the $2.0M threshold of the Program Director and sub-project leaders. Each sub-project leader's total should include the funds provided directly to him/her only through the P01; core costs should not be included.

- Multiple PD/PI Projects:
    a. Competing Multi-PI applications are only subject to SCR if all the PD/PIs exceed the $2.0M threshold.
    b. In calculating the research support available to a PD/PI who participates in a multi-PI award, the direct cost award amount to the institution should be divided evenly among PIs at that institution. Budgets of multi-PIs at other institutions may be determined using the funds allocated to their subcontract costs.

- Requests for Applications (RFAs):
    a. Pending applications submitted in response to RFAs will not be subjected to SCR. The rationale is that these applications have been solicited by the IC to accomplish a specific purpose. The intent is to award the best proposal(s) designed to achieve the IC's specified goal(s).
    b. Funds provided through these grants will contribute to the $2.0M threshold for the investigators' future applications.

- Competing revisions and administrative supplements:
    a. These types of grants are not expected to be a significant contributing factor in reaching the threshold, since many will not incur future year commitments. However, multi-year supplements are included in grant's out-year commitments and do contribute to the $2.0M threshold. In order

[1] Funds acquired include active RPG awards for the PD/PI (exclusive of projects in no cost extension) when the application subjected to SCR is pending Council review and funds for multi-year projects allocable to the current Fiscal Year (Multi-Yr: R15, DP2, DP3, DP4, RC3, RC4, R55, RC1)
[2] Defined as R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, RC2, RC3, RC4, RL1, RL2, RL5, RL9, P01, P42, PN1, UA5, UC1, UC2, UC4, UC7, UH2, UH3, UH5, UM1, U01, U19, U34, DP1, DP2, DP3, DP4, and DP5.

to prevent Re-entry and Diversity Supplements from being an impediment to an investigator, to the extent possible, these supplements should be excluded from the threshold count.

- Guidelines for Council Consideration (Council role):

  a. When applied to new projects, SCR will focus on the unique opportunities afforded to the investigator to advance his/her research in directions that are highly promising and distinct from his/her other funded projects.
  b. SCR of renewal applications may also consider the value of continuing a productive project and the contribution this project makes to the investigator's research program and ongoing collaborations.
  c. Consideration may also be given to the PD/PI's field of research when evaluating the appropriateness of awarding new grants above the $2.0M total cost threshold. The rationales for this consideration are that 1) different types of research (e.g., clinical trials, population sciences) may require larger awards than other fields and 2) non-RPG mechanisms often used for an IC's specialized purposes/goals typically receive separate Council consideration. Since some RPGs, such as U01s, are also used for projects with specialized purposes/goals, each IC, working with its Council, may create defaults for these and other RPG mechanisms or programs to simplify SCR.

NIDDK Implementation of the Special Council Review Policy

Each Council round, the NIDDK Council members will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under the NIH policy as outlined above. During the closed session, for each application on the list that might actually be funded, NIDDK staff will provide information about the other NIH funding for the PI that brings his/her direct cost total to the $2 million threshold and a justification for possibly funding the application under consideration. Council members will review these cases and decide whether they have concerns.

Recommendation Process

- NIDDK program staff members examine applications, their overall impact/priority scores, percentile rankings, and their summary statements and consider these against NIDDK's needs.
- The Advisory Council also considers NIDDK's goals and needs and advises the NIDDK Director.
- The NIDDK director makes the final funding decisions based on staff and Advisory Council advice.

Post-Review

- **Not Funded – What Next?**
  The NIH receives thousands of applications for each application receipt round. Funding on the first attempt is difficult, but not impossible. If an application does not result in funding, NIH has resources available for limited circumstances to help applicants prepare a possible resubmission. Applications in response to a specific initiative with set-aside money typically cannot be resubmitted, but the Program Official should be consulted about next steps.

- **Fundable Score – What Next?**
  If an application results in an award, the applicant will be working closely with the NIDDK Program Official on scientific and programmatic matters and a Grants Management Officer on budgetary or administrative issues.

Grant Review-Related Policies

Foreign Organizations

In addition to the regular review criteria, foreign applications are evaluated in terms of special opportunities for furthering research programs through the use of special talents, resources (human subjects, animals, diseases, equipment or technologies), populations or environmental conditions in the applicant country which are not readily available in the United States or which provide augmentation of existing United States resources. In addition, it should be noted whether similar research is being done in the United States and whether there is a need for additional research in the area of the proposal. These special review criteria are not applied to applications from domestic institutions that include a significant foreign component.

Research Involving Human Subjects

The rights of all human subjects involved in NIH-supported research are of paramount importance to the Federal Government. Safe-guarding these rights is primarily the responsibility of the institution that receives or is accountable for the funds awarded for support of the research. However, NIH also relies on its scientific review groups (SRGs) and National Advisory Councils or Boards to evaluate all applications and proposals involving human subjects for compliance with the Department of Health and Human Services human subject regulations (Code of Federal Regulations, Title 45 Part 46).

There are several considerations for review of applications involving human subjects. These can be clustered into two broad areas: Protection of subjects from research risks; and the inclusiveness of the study population. Protection issues include questions regarding safety and welfare of the subjects, including data and safety monitoring where applicable. Inclusion issues reflect the appropriate involvement of women, minorities and children.

SROs now assign inclusion codes informed by the reviewer critiques and discussion at the review meeting to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below). The evaluation by Council will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

NIH will fund research covered by the regulations only if the institution has filed an assurance with the Office for Human Research Protections (OHRP) and has certified that the research has been approved by an institutional review board (IRB), a board at the requesting institution formed solely for this purpose.

More detailed instructions for reviewing grant applications involving human subjects, and exemptions, are available at the following URL:
https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf.

Definitions:

Human subjects: Federal regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. A subset of research involving human subjects may qualify for exemption, but justification must be provided under the heading "Protection of Human Subjects from Research Risk". The use of autopsy materials is governed by applicable state and local law and is not directly regulated by the Federal human subject regulations.

Clinical research is defined as: (1) Patient-oriented research, i.e., research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. (Excluded from the definition of patient-oriented research are in vitro studies that utilize human tissues that cannot be linked to a living individual.) Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; or (3) Outcomes research and health services research.

A Clinical Trial is operationally defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

An NIH-defined Phase III clinical trial is a broadly based prospective clinical investigation for the purpose of investigating the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

A ***valid analysis*** is required in phase III clinical trials. This means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis are:

- Allocation of study participants of both sexes/genders and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- Unbiased evaluation of the outcome(s) of study participants, and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Research Conducted in a Foreign Country: For foreign awards, and domestic awards with a foreign component, the NIH policy on inclusion of women and minority groups in research is the same as that for research conducted in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

Children: For purposes of this policy, a child is an individual under the age of 18 years. This definition does not affect the human subject protection regulations for research on children (45 CFR 46) and their provisions for assent, permission, and consent, which remain unchanged. State laws

define what constitutes a "child," for the purpose of determining whether or not a person can legally consent to participate in a research study.

Exemption from Human Subjects Regulations

If the applicant designates an exemption from the human subjects regulations, reviewers should evaluate the information provided to determine if the designated exemption is appropriate. With regard to exemption 4, although reviewers need not evaluate questions related to research risks or the inclusion of women and minorities, the appropriate inclusion of children ***DOES*** need to be addressed for these applications.

Protection of Human Subjects

If the proposed research involves human subjects, and does not qualify as being exempt, it is considered clinical research (see definition above) and reviewers must evaluate the plan to protect human subjects. The applicant's research plan should include four elements under the heading "Protection of Human Subjects from Research Risk". Reviewers are asked to evaluate each of the four elements:

- ***Risks to the subjects***
- ***Adequacy of protection against risks***
- ***Potential benefit of the proposed research to the subjects and others***
- ***Importance of the Knowledge to be gained***
- ***Data and Safety Monitoring Plan/Board***

Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Participants in Research Involving Human Subjects is available at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Women and Minorities in Study Populations

There are clear scientific and public health reasons for including women and minorities in study populations. Accordingly, the NIH requires that applications for clinical research give appropriate attention to including members of these groups in studies. If this is impossible (for example, because the disease occurs only in men or is prevalent only in one racial or ethnic group), or is inappropriate with respect to the health of the subjects, a strong scientific rationale or other well-supported justification is necessary. Unless the rationale/justification is compelling, NIH will not fund such applications. This policy covers research grants, cooperative agreements, and research contracts.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns. These inclusion codes, described below, appear on the summary statement.

Council will consider the degree to which the applicants have addressed this policy when it evaluates applications. Applications with inadequate representation of women and minorities and/or inadequate justification may be deferred, approved based on portfolio considerations, or approved with the condition that staff will ensure compliance with the policy before award. Council will be subsequently notified of awards for these types of approvals.

The NIH will not award research grants, cooperative agreements, or contracts to applicants who do not follow this policy.

Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

It is NIH policy that individuals of all ages, including children (i.e., individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html). The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

Applications or proposals for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. Applications/proposals must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the recipient/offeror must provide an acceptable justification for the exclusion. Acceptable reasons for excluding individuals based on age may include:

- The disease or condition does not occur in the excluded age group, or the research topic is not relevant to the excluded age group.
    - *Example: A study of Alzheimer's disease proposes to exclude children.*

- The knowledge being sought in the research is already available for the excluded age group or will be obtained from another ongoing study, and an additional study will be redundant.
    - *Example: A drug studied and approved for use in children will now be studied only in adults.*

- A separate, age-specific study in the excluded age group is warranted and preferable. While this situation may represent a justification for excluding individuals based on age, consideration should be given to taking age differences into account in the study design, whenever feasible.
    - *Example: A clinical trial designed to promote self-monitoring of blood glucose levels in adolescents with Type 1 diabetes proposes to include only adolescents.*

- The study will collect or analyze data on pre-enrolled study participants (e.g., longitudinal follow-up studies that did not include data on children, or analysis of an existing dataset) and data inclusive of individuals across the lifespan are not available to address the scientific question.
    - *Example: A study which began prior to implementation of the NIH Policy and Guidelines on the Inclusion of Children proposes follow-up to examine long-term outcomes of individuals with the condition. The original study excluded children, and similar data are not available from a cohort that includes children.*

- There are laws or regulations barring the inclusion of individuals in a specific age group in research.
    - *Example: Regulations for protection of human subjects allow consenting adults to accept a higher level of risk than are permitted for children*.

- The study poses an unacceptable risk to the excluded group, such that their participation would not be considered ethical by the local IRB, peer review and/or NIH staff.

- *Example: Children are excluded from a Phase I study for a treatment that includes significant risk, including death. Evidence suggests the potential benefits to children do not outweigh the risks.*

Scientific review groups at the NIH will assess each application/proposal as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project, in addition to evaluating the plans for conducting the research in accord with these provisions. NIH staff will monitor implementation of this policy during the development, review, award and conduct of research; and manage the NIH research portfolio to comply with the policy.

Age Data Collection

NIH recipients/offerors must submit data on participant age at enrollment in progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided to NIH in progress reports. Age at enrollment may be reported to NIH in units ranging from hours to years. Recipients/offerors are responsible for ensuring informed consent documents allow submission of de-identified individual-level data on participant sex/gender, race, ethnicity, and age at enrollment to NIH.

Use of Human Embryonic Stem Cells In NIH-Supported Research

The National Institutes of Health (NIH) has published final "National Institutes of Health Guidelines for Human Stem Cell Research" (Guidelines).

On March 9, 2009, President Barack H. Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.* The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law.

These Guidelines implement Executive Order 13505, as it pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and helps ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH policies and procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH stem cell research.

EFFECTIVE DATE: These Guidelines are effective on July 7, 2009.

SUMMARY OF PUBLIC COMMENTS ON DRAFT GUIDELINES: On April 23, 2009 the NIH published draft Guidelines for research involving hESCs in the Federal Register for public comment, 74 Fed. Reg. 18578 (April 23, 2009). The comment period ended on May 26, 2009.

The NIH received approximately 49,000 comments from patient advocacy groups, scientists and scientific societies, academic institutions, medical organizations, religious organizations, and private citizens. The NIH also received comments from members of Congress. Read the NIH response to the public comments that addressed provisions of the Guidelines at https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research.

NATIONAL INSTITUTES OF HEALTH GUIDELINES FOR RESEARCH USING HUMAN STEM CELLS

I. Scope of Guidelines

These Guidelines apply to the expenditure of National Institutes of Health (NIH) funds for research using human embryonic stem cells (hESCs) and certain uses of induced pluripotent stem cells (See Section IV). The Guidelines implement Executive Order 13505.

Long-standing HHS regulations for Protection of Human Subjects, 45 C.F.R. 46, Subpart A establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. *When research* involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 C.F.R. 46, Subpart A.

It is also important to note that the HHS regulation, *Protection of Human Subjects*, 45 C.F.R. Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 C.F.R. § 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidance at http://www.hhs.gov/ohrp/policy/index.html#topics

To ensure that the greatest number of responsibly derived hESCs are eligible for research using NIH funding, these Guidelines are divided into several sections, which apply specifically to embryos donated in the U.S. and foreign countries, both before and on or after the effective date of these Guidelines. Section II (A) and (B) describe the conditions and review processes for determining hESC eligibility for NIH funds. Further information on these review processes may be found at www.NIH.gov. Sections IV and V describe research that is not eligible for NIH funding.

These guidelines are based on the following principles:

1. Responsible research with hESCs has the potential to improve our understanding of human health and illness and discover new ways to prevent and/or treat illness.
2. Individuals donating embryos for research purposes should do so freely, with voluntary and informed consent.

As directed by Executive Order 13505, the NIH shall review and update these Guidelines periodically, as appropriate.

II. Eligibility of Human Embryonic Stem Cells for Research with NIH Funding

For the purpose of these Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing

without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. All of the processes and procedures for review of the eligibility of hESCs will be centralized at the NIH according to the guidelines available at Guidelines.

Use of NIH Funds

Prior to the use of NIH funds, funding recipients should provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs are listed on the NIH registry.

III. Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding

This section governs research using hESCs and human induced pluripotent stem cells, i.e., human cells that are capable of dividing without differentiating for a prolonged period in culture and are known to develop into cells and tissues of the three primary germ layers. Although the cells may come from eligible sources, the following uses of these cells are nevertheless ineligible for NIH funding, as follows:

A. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
B. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.

IV. Other Research Not Eligible for NIH Funding

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 3/11/09), otherwise known as the Dickey Amendment.
B. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

   See also: NIH research Involving Introduction of Human Pluripotent Cells in to Non-Human Vertebrate Animal Pre-Gastrulation Embryos: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-158.html

Research Involving Vertebrate Animals

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH relies on its staff, scientific review groups, and Advisory Councils to share this responsibility and review research activities for compliance with the Public Health Service policy for the care and use of vertebrate animals. The general intent of the law and policy can be summarized as two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists;
- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner to avoid any unnecessary discomfort, pain, or injury. Special attention must be provided when the proposed research involves dogs, cats, nonhuman primates, large numbers of animals, or animals that are in short supply or are costly.

Any comments or concerns that scientific review group members may wish to express regarding the appropriateness of the choice of species and numbers involved, the justification for their use, and the care and maintenance of vertebrate animals used in the project will be discussed in a special note in the summary statement. A "concern" is a scientific review group finding regarding animal care or use that requires resolution by program staff prior to award; a "comment" is a scientific review group observation that will be communicated in the summary statement as a suggestion to the principal investigator. For projects involving animals, the species used is separately identified at the end of the "Description" in the summary statement. Any comments or concerns that members have regarding treatment and welfare of research animals used in the project are explained in a separate paragraph in the summary statement. Any questions Council members may have should be directed to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) staff.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below).

No research involving animals may be conducted or supported by NIH until the institution proposing the research has provided a written assurance acceptable to NIH.

Biomedical Safety

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the scientific review group in identifying potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

If applications pose special hazards, these hazards will be identified and any concerns about the adequacy of safety procedures highlighted as a special note (**BIOHAZARD**) on the summary statement.

In the case of research involving human immunodeficiency virus, researchers are expected to follow the latest Centers for Disease Control and Prevention recommendations and guidelines for health care workers and laboratory personnel. In research involving recombinant DNA, assessment of an applicant's compliance with Public Health Service guidelines is the responsibility of the NIH Office of Recombinant DNA Activities.

No award will be made until all concerns about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

Advisory Council Policy/Logistical Documents

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Members of Council must return or destroy the material given to them to the Executive Secretary at the conclusion of the meeting. All materials members have received at home or at their institutions also must be returned for disposition or destroyed.

There should be no direct communication between members of Council and applicants. In addition to legal considerations, pre-mature notification of recommendations to applicants often leads to misinterpretation and distortion of discussions and recommendations.

As soon after the Council meeting as possible, applicants will be notified by NIDDK staff about the status of their applications.

Conflict of Interest

NIH takes extreme precautions to avoid placing Council members in situations where there might be an actual or apparent conflict of interest. Thus, at each Council meeting, procedures are delineated to avoid such conflicts.

A member must be absent from the meeting room during review of an application submitted by an institution, or a component of a system of institutions, in which the member or member's spouse, parent, child, partner, or close professional associate is an employee, or in which there is a directive or consultative relationship or financial interest. This includes ownership of stock in, or being a consultant for a for-profit organization. A reviewer should also leave the room during discussion of an application if being present would give the **appearance** of a conflict of interest. Examples would be an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory.

The NIH has been granted a regulatory waiver by the Office of Government Ethics so that faculty of multi-campus institutions of higher education who serve as experts or consultants to DHHS may participate in matters affecting one campus of a state multi-campus institution if the expert's disqualifying financial interest is employment with no multi-campus responsibilities at a separate campus.

Additionally, a Council member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, a recent collaborator, or a close personal friend. Further, a member should not take part in the discussion of an application from a scientist with whom the member has had long-standing differences which reasonably could be viewed as affecting the member's objectivity.

Council members present at each Council meeting sign a statement certifying that they did not participate in the discussion of, or vote on, any application from their own institution or an institution in which they have a financial interest.

Though the staff attempts to identify possible conflicts of interest and bring them to the attention of the Chairperson, the National Diabetes and Digestive and Kidney Diseases Advisory Council needs the assistance of members to ensure that such conflicts do not arise.

Lobbying

Technically, Council members are Government employees and governed by DHHS standards of conduct during the days they are being paid for duty. Thus, during the full midnight-to-midnight period of each of these days, members cannot transact personal business, enter into personal activities with the Legislative or Executive branches of Government, or discuss with NIH staff matters pertaining to their institution's federally funded activities. During this same period, members of Council also must not discuss with members of Congress proposed or pending legislation or appropriations that concern the Public Health Service or DHHS.

Freedom of Information and Privacy Act

The Freedom of Information Act (FOIA) of 1967 and the Privacy Act of 1974 have significantly affected the NIH review and disclosure processes. Under FOIA, a person may obtain access to any Government record, including records about himself or herself, unless the records fall within one of nine exemptions to the Act. The Privacy Act, on the other hand, is limited to records about individuals which are maintained in a "system of records" from which information is retrieved by his or her name or other personal identifier.

For example, under FOIA, third parties may receive copies of awarded grant applications, but they may not receive copies of applications that were scored but not funded or applications that were not recommended for further consideration. Also, under the Privacy Act, Principal Investigators may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports and summary statements, but not individual reviews. Reviewers' written comments are not retained after their substance has been incorporated into summary statements or site visit reports.

Emoluments Clause of the U.S. Constitution

The Emoluments Clause of the United States Constitution applies to all U.S. Government employees, including most Special Government Employees (SGE's). The Clause places Constitutional limitations on a SGE advisory committee member's employment by a foreign government, including political subdivisions of a foreign government. This provision has particular relevance to positions with foreign universities that are government-operated rather than private institutions. United States Constitution, art. I 9, cl. 8.

The Emoluments Clause **applies at all times during an SGE's appointment**, and not just the periods of time during their actual duty on behalf of NIH. During an SGE's advisory committee appointment, they cannot be an employee of a foreign government entity. Without the consent of Congress, they cannot receive any present, emolument, office, or title of any kind whatsoever from a foreign state. They cannot accept concurrent outside employment with a foreign government or a political subdivision of a foreign government, including a public university or commercial enterprise* owned or operated by a foreign government. The constitutional ban does not apply to employment with, or presents or emoluments received from, a foreign privately owned corporation or an international organization. An emolument includes salary, honoraria, transportation, per diem allowances, household goods shipment costs, and housing allowances.

Under the Foreign Gifts and Decorations Act, 5 U.S.C. 7342, Congress has authorized employees, including advisory committee members, to accept items from a foreign government that do not exceed minimal value (currently $350). The Act authorizes acceptance of items over minimal value

when such items consist of an educational scholarship, medical treatment, or expenses for travel taking place entirely outside the United States, thus permitting hotel and meal reimbursements in the foreign country, but not airfare for flights originating or terminating in the United States. The statutory restriction on gifts over minimal value extends to the spouse and dependents of the employee.

The restrictions of the Emoluments Clause are constitutional and are not matters of policy that can be waived or reconsidered. Questions regarding possible conflicts relating to the Emoluments Clause may be referred to the Deputy Ethics Counselor for the institute the SGE committee member advises, or to the Committee's Executive Secretary.

* A list of foreign entities that are considered independent of their foreign government may be found at: https://ethics.od.nih.gov/foreign

The Freedom of Information and Privacy Acts

	FREEDOM OF INFORMATION REFORM ACT OF 1986 (P.L. 93-570)	**PRIVACY ACT OF 1974 (P.L. 93-579, DEC. 1974)**
PURPOSE	To allow access by the public to government records.	To provide safeguards for an individual against invasion of personal privacy.
SCOPE	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • methods whereby public may obtain records; • types of records available to the public; • exemptions that permit agencies to withhold certain types of records	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • any system of records from which information is retrieved by an individual's name, identifying number, or other identifying particular assigned to an individual; • any system of records maintained by a government contractor if the agency provides by contract for the "operation by or on behalf of the agency to accomplish an agency function."
REQUIREMENTS	Requires Federal agencies to: • publish in the Federal Register organizational descriptions and locations of agency records; • make all Agency opinions, orders, policy statements, manuals, and instructions available for public inspection and copying; • publish rules stating time, place, fees (as authorized), and procedure to be followed for requesting records; • make records promptly available to any person following the established guidelines for requesting such records; • make available for public inspection a record of the final votes of each member in every Agency proceeding, except as exempted; • release all portions of records not covered by FOIA exemptions. Exemptions that may apply to grants records include those permitting the deletions of commercial information, information that would invade personal privacy, and internal government options and advice.	Requires Federal agencies to: • permit individuals to determine what records pertaining to them the agency collects, maintains, uses, or disseminates; • permit individuals to prevent records pertaining to them obtained for a particular purpose from being used or made available for another purpose without their consent; • permit individuals to gain access to information pertaining to them in agency records, to have a copy made of their records, and to correct or amend their records; • collect, maintain, use, or disseminate records of identifiable personal information in a manner that assures that such action is for a necessary and lawful purpose, that the information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of information; • be subject to civil or criminal sanctions as a result of willful or intentional actions which violate any individual's rights under the Act; • publish annually a notice in the Federal Register indicating the existence and character of the system records.
SUMMARY	Makes possible disclosure of policy, procedures, and records to the public.	Safeguards the privacy of individuals in the face of disclosure.

Travel Procedures for NIDDK Advisory Council Members 2025

When you travel to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKDAC) meeting, **you are considered a Government employee** of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and therefore traveling on official Government business. Your expenses are reimbursed according to Federal travel regulations.

In order for you to be reimbursed in a timely manner and to ensure that you will be reimbursed for your travel expenses, please be sure to read the information below.

Note: If you will **not be attending** the meeting, please call or email Dr. Karl Malik at (301) 594-8843 or malikk@niddk.nih.gov to inform him of your absence.

Overview of Expenses and Reimbursement

Allowable consultant expenses for members of NDDKDAC are as follows:
Air/Rail Transportation. Round-trip transportation (from home to Bethesda, Maryland, and back).

Ground Transportation. This includes costs for taxis (including a 15 percent tip), shuttle services, parking, tolls, subway fare, and any other reasonable transportation costs.

Travel by Privately Owned Vehicle. If you drive your car to the meeting or to the airport, you will be reimbursed for the miles, tolls, and parking expenses incurred. The current Government rate is $0.67 per mile.

Hotel. You will be reimbursed for the Government room rate and associated taxes.

Meals and Incidental Expenses (M&IE). This is a fixed rate, currently $92.00 per day for the Washington, D.C., metropolitan area. You will receive ¾ of the M&IE rate for a maximum of 2 travel days. For any non-travel days spent at the meeting, you will receive the full per diem less any meals provided.

Honorarium. You will receive a $200.00 honorarium for each day or fraction of a day that you attend the Advisory Council meeting. For virtual-only Council meetings, you will still receive a $200.00 honorarium for each day or fraction of a day that you attend the Council meeting. These checks are processed separately using Electronic Funds Transfer.

Travel Instructions

Per Federal travel regulations, all Government employees are required to use their agency's travel management center. Therefore, **you are required to book your air or train fare through Omega World Travel (OWT) and you must book coach class.** Please mention you are attending the "NIDDK Advisory Council Meeting in Bethesda, Maryland".

It is the Council member's responsibility to contact Omega Travel at 855-326-5407 (M-F 7am-10pm; for after-hours emergencies please contact 855-326-5407) to confirm/change the travel reservation. All airline tickets will be processed as electronic tickets. When using Omega World Travel, the ticket will be paid for by the National Institutes of Health. When air/rail transportation is used, travelers must use the most economical means. All travel should be by the most direct route.

What do I need to do to make a change on my airfare so I can be reimbursed for additional expenses due to changes?

If you need to make a change on your airfare, you are required to contact OWT (see phone numbers above). **We recommend that you carry their after-hours number with you in case you need to make a change to your airfare or train ticket.**

What if I don't contact OWT? How will this affect my reimbursement?

Please note that if you book either business class for airfare and/or a train ticket, you will not be reimbursed. In addition**, you cannot pay the difference for a change in your airfare or train ticket by paying the additional money in cash.** Again, you must contact OWT; they will charge additional travel expenses to our government account. *Travelers who choose to not use Omega World Travel to make their travel reservations will not be reimbursed by NIH/NIDDK*.

Will I receive a confirmation from OWT of my airfare or train ticket reservations?

Yes. OWT will process your reservation with an electronic ticket and send you a confirmation notice via email. Retain this confirmation number.

Can I be reimbursed for rental car expenses?

Rental car expenses are rarely approved and must be pre-approved on the travel order. Under no circumstances will rental care expenses be reimbursed without prior authorization.

Can I be reimbursed for the expense of using a sedan instead of a taxi

You can always be reimbursed for taxis but not for use of a sedan.

What documents should I carry with me when I travel?

- OWT's phone numbers in case you need to make a change in your itinerary

OMEGA WORLD TRAVEL Business Hours: (855) 326-5407 (M-F: 7am-10pm EST) After-hours Emergency: (855) 326-5407

- A **government-issued photo ID** (license, passport, etc.)
- A **copy of your electronic ticket** with confirmation number.
- The **NIH travel order** to verify that you are traveling on official Government business. NIDDK will fax the travel order to you prior to your travel.

Hotel Information

NIH/NIDDK books and pays for hotel rooms for all Council members. Hotel room confirmation numbers will be submitted to you prior to your departure. Also please confirm your check-in and check-out dates, especially if arriving late. You will typically be lodging at the Hyatt Regency Bethesda.

Hyatt Regency Bethesda
7400 Wisconsin Avenue
Bethesda, MD 20814
T: (301) 657-1234
F: (301) 657-6453
http://bethesda.hyatt.com/en/hotel/home.html?src=agn_mls_hr_lclb_blocal_bethe

Expense Reimbursement

After completion of travel, Council members must file a Travel Expense Form (sample attached). It is necessary to include:

- Travel stubs or the travel itinerary showing the price of the ticket
- Other travel related receipts over $75.00 (e.g., receipts for taxi fares, tolls, parking fees)
- Original hotel bill
- Rental car receipt (reimbursement must be pre-approved).

Travelers are reimbursed for three-quarters of a day's per diem on arrival and departure days. No receipts are needed. (See M&IE above.)

Travel Expense forms and receipts should be sent or emailed within 5 days of your complete travel to:

Samone Johnson, Program Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 7300
6707 Democracy Boulevard
Bethesda, MD 20892-5452
Email: samone.johnson@nih.gov

Once your completed Travel Expense Form with all receipts attached is received, you will be sent a travel voucher for your signature. The travel voucher is a document prepared at the conclusion of your trip itemizing all claims for reimbursement.

After the travel voucher is received at NIH, the payment will be deposited into your banking account within 14 business days in the amount indicated on the travel voucher as "NET TO TRAVELER."

Note: Your honorarium will be processed separately as noted above.

If you have any questions, please do not hesitate to contact Samone at 301.827.4420 or email her at samone.johnson@nih.gov.

NIDDK ADVISORY COUNCIL TRAVEL EXPENSE FORM

(NIDDK Advisory Council Meeting)

REQUIRED RECEIPTS: (Please attach to this form)

- **Travel Stubs/Itinerary** with total price of ticket $_____
- **Original Hotel** itemized receipt:
  - Room Rate $_____
  - Hotel Taxes $_____
  - Phone Calls ($5.00 per day are reimbursable) $_____
- Other travel-related receipts **over $75.00** $_____
- Rental car (reimbursement must be pre-approved) $_____

OTHER REIMBURSEABLE EXPENSES:

- Privately-Owned Vehicle (Number of Miles x $0.67 cents) $_____
- Parking Fees $_____
- Taxis:
  - From Residence to Terminal $_____
  - From Terminal to Hotel $_____
  - From NIH Campus to Terminal $_____
  - From Terminal to Residence $_____
  - Other $_____
- Tolls $_____
- Other miscellaneous expenses $_____

  (Please describe:_____)

DO NOT CLAIM ANY MEALS FOR REIMBURSEMENT. The amount of Meals and Incidental Expenses (M&IE) reimbursed is set at a fixed rate of $92.00 per day while you are on official government business. You will receive ¾ of the M&IE rate for each day you are in travel.

PRINT NAME: _____

SIGNATURE: _____

DATE: _____

RESPONSIBILITIES OF NIDDK ADVISORY COUNCIL MEMBERS

(A Cheat Sheet for New NIDDK Council Members)

I. Before the meeting

Early Concurrence

- All grant applications (excluding those from foreign organizations) which have no concerns noted that would represent a bar to award (e.g., human subjects, animal welfare, biohazards, etc.) or need Special Council Review, will follow an expedited concurrence process.
- A few weeks prior to the meeting NIDDK will alert the early concurrence committee members that these applications are available in the Electronic Council Book (ECB).
- As a new member it is unlikely that you will be asked to be a member of the early concurrence committee, but during this process all Council members are provided the list of all applications eligible for early concurrence for review and any member may bring any of these applications to full Council consideration.

Bottom line: *You may wish to spend a little time looking over the early concurrence list to see if you have any concerns--and if you do let Karl Malik know A.S.A.P.*

Council Materials

- About fourteen days before the Council meeting Council Members are notified that materials for the meetings are available for their review.
- These materials are available via the ECB using the same access information that was earlier given for access to the early concurrence list.
- Scientific members are frequently asked in advance to review particular applications or proposed actions in the closed portion of the subcommittee meeting, and they are often provided additional materials.

Bottom line: *Please thoroughly review these materials prior to the meeting & contact the appropriate NIDDK Division Director if you have any concerns or if you would like additional information.*

Additional Requests

- Occasionally a Division Director, or other NIDDK staff member, will contact a Council member to request that they participate as a discussant of a presentation at an open portion of the meeting.
- If available, the slide set or additional materials will usually be provided to the Council member.

Bottom line: *Please review these materials & come to the meeting prepared to participate as requested. Please be sure that you understand & follow any specific guidance — especially when considering appeals. NIDDK needs advice on the merit of the appeal, not the merit of the application.*

Attendance

- Members are encouraged to attend meetings in-person and attend the entire Council meeting. Staff will work with you or your assistant to arrange travel plans that will allow you plenty of time to catch your flight after the meeting.

Bottom line: *Please try to attend meeting in-person and don't plan on leaving Council meetings early.*

II. At the meeting

Closed Sessions

- Council members are requested to come prepared to fully participate in the closed sessions.
- Members are reminded that all matters discussed or materials available for discussion in closed sessions and the discussions themselves are confidential and should not be shared with anyone outside of the meeting.

Bottom line: *What happens in closed session stays in closed session.*

Open Sessions

- Council members are requested to come prepared to participate fully in the open sessions, including the discussions that follow presentations.
- Members are encouraged to provide specific feedback to NIDDK staff about any of the matters discussed or potential matters or issues they would like to hear discussed at a future meeting.
- Remember that ***members of the public, of advocacy groups, and of the press may attend our Council meetings*** and anything that you say in the open sessions of Council meetings could be reported.

Bottom line: *Please interact & give us your perspective and advice, but be careful about seeming/being too prescriptive in open session and also please be careful in open session not to say anything that you (and we) might regret if it gets reported and appears in print.*

III. After the meeting

Special Requests

- Occasionally Council members may be requested to review certain matters (for example, an appeal that arrived too late for consideration at the meeting) after the meeting.
- Please provide the requested advice within the timeframe allowed and treat all of these matters as confidential, just as you would were they are being considered within closed session.

Bottom line: *These matters are essentially an extension of the closed session.*

What do we really want from you?

- Your scientific expertise
- Your understanding of patient and clinical issues
- Your wise council about our general portfolio
- Your thoughts about NIH/NIDDK policies, the public landscape and help in avoiding pitfalls
- Your outreach and advocacy on behalf of NIH/NIDDK both within your community and to the public to explain the processes, the considerations, the rigor, and the fairness of how we do business and the important work that we support
- Your help in keeping NIDDK at the cutting edge of science and scientific administration

What should you be careful about?

- Keeping closed session materials and discussions confidential

- Paying attention to and avoiding/disclosing any real or apparent conflicts of interest as soon as they arise

- Advocating to elected officials while on official government travel
    - You are a special government employee when you are traveling to attend Council meetings and during this time you are not allowed to advocate!
- Keeping in mind that anything you say in the open sessions of the Council meeting (both the main sessions and open sessions of the sub-councils) could wind up in print
- Not appearing to be too prescriptive in your remarks – You represent NIDDK's broad community rather than advocating for a particular segment of that community
    - Sparking disease or research area wars is not in anyone's best interest

NIDDK Advisory Council Orientation Reference Links
January 2025

General background information about Council

- **Advisory Council page on the web:**
  https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees
- **Advisory Council Charter:**
  https://www.niddk.nih.gov/-/media/Files/Advisory-Coordinating-Committees/NIDDK-Advisory-Council/Council-Charter.pdf
- **Advisory Council Operating Procedures:**
  https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/operating-procedures
- **Advisory Council Membership Roster:**
  https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/members

General background information about NIDDK and funding

- **NIDDK Mission, Vision, & Guiding Principles:**
  https://www.niddk.nih.gov/about-niddk/meet-director
- **NIDDK Organization:**
  https://www.niddk.nih.gov/about-niddk/offices-divisions
- **NIDDK Research Programs & Contacts:**

  https://www.niddk.nih.gov/research-funding/research-programs
- **NIDDK Funding Policy:**
  http://www.niddk.nih.gov/research-funding/process/award-funding-policy/Pages/award-funding-policy.aspx

Administrative matters regarding Council membership

- **Ethics Training for Special Government Employees**
  (Financial Disclosure, Conflict of Interest, Representation, Misuse of Position)**:**
  https://www.oge.gov/web/oge.nsf/0/77E34818F9A59979852585B6005A24BB/$FILE/Guide%20for%20Nominees%202020_accessible.pdf
- **Procedures for Avoiding Conflict of Interest for Special Government Employees:**
  http://oma1.od.nih.gov/manualchapters/management/1810-1/
- **Travel Reimbursement:**
  https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/travel-expenses-reimbursement

The Grant Process

- **NIH Grants Process Overview, from application to award:**
  http://grants.nih.gov/grants/grants_process.htm
- **Types of NIH grants:**
  http://grants.nih.gov/grants/funding/funding_program.htm
- **About Funding Mechanisms, including information about how NIDDK utilizes certain funding mechanisms:**
  https://www.niddk.nih.gov/research-funding/process/apply/funding-mechanisms
- **Peer Review Policies & Practices:**
  http://grants.nih.gov/grants/peer/peer.htm

Grant Policies & Regulations

- **FOIA & Privacy:**
  https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/freedom-information-act-5-usc-552
- **NIH Grants Policy & Guidance:**
  http://grants.nih.gov/grants/policy/policy.htm
- **NIH Intellectual Property Policy:**
  https://grants.nih.gov/grants/intell-property.htm
- **NIH Invention Reporting (iEdison):**
  https://www.nist.gov/iedison
- **NIH Public Access Policy:**
  http://publicaccess.nih.gov/
- **NIH Genomic Data Sharing Policy:**
  https://grants.nih.gov/grants/guide/notice-files/NOT-OD-24-157.html
- **NIH Sharing Policies and Related Guidance On NIH-Funded Research Resources:**
  https://sharing.nih.gov/
- **Research Integrity/Research Misconduct:**
  https://grants.nih.gov/grants/research_integrity/index.htm
- **Information about NIH grant applications from foreign countries:**
  http://grants.nih.gov/grants/foreign/index.htm
- **Simplified NIH Policy for Late Application Submission:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html
- **Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021:**
  https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html