

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
NATIONAL INSTITUTES OF HEALTH

222<sup>nd</sup> Meeting of the  
NATIONAL DIABETES and DIGESTIVE and KIDNEY DISEASES ADVISORY COUNCIL

DIVISION OF DIGESTIVE DISEASES and NUTRITION SUBCOMMITTEE  
Meeting Summary

Wednesday, May 17, 2023  
Hybrid Meeting

**Open Session**

- 1) Dr. David Saslowsky opened the meeting by welcoming everyone.
- 2) The minutes of the January 25, 2023 subcommittee meeting were approved.
- 3) Eight DDDN Initiative Concept Clearances were presented during the Open Session of the Full Council and further discussed during the DDDN subcommittee (more details on the clearances can be found in the appendix). The discussion included the following questions and responses:
  - a) **Simulation Applications to Improve Clinical Skills and Outcomes of Practicing Clinicians Treating Conditions and Diseases within the Mission of the Division of Digestive Diseases and Nutrition (New)**
    - **Question:** Will the competencies before and after training be evaluated?
    - **Answer:** There should be a specific procedure or sets of procedures to see whether focused simulation or training provides actual results and improved outcomes, but ultimately, that will be left up to the investigators.
    - **Question:** Will different simulations be grouped together?
    - **Answer:** The investigators will have the chance to decide what disease process they're interested in and be able to focus and organize those specific studies.
    - **Question:** Will this be a partnership with professional societies to try to help develop this initiative?
    - **Answer:** Yes.
  - b) **Autoimmune Hepatitis Clinical Research Network (New)**
  - c) **Coordinating Center for the NIDDK Nutrition Obesity Research Centers (NORC) Program (New)**
    - **Question:** Will the NORC Coordinating Center interact with the Diabetes Coordinating Centers since there is a lot of overlap?
    - **Answer:** While there are some differences between the two, there are some opportunities to collaborate.
    - **Question:** Will the Coordinating Center have the opportunity to capitalize on some of the existing knowledge within the current established NORCs?
    - **Answer:** We have an expectation for collaboration should this initiative be funded.
    - **Question:** How do you plan to operationalize expansion of a pilot and feasibility program?

- **Answer:** The program would be marketed and made available to institutions who do not have a NORC.
- d) **Short-term Research Experiences in Nutrition, Obesity, and Digestive Diseases for Investigators from Diverse Backgrounds (New)**
- **Question:** Will there be two separate applications for the mentors and mentees, or will it be a joint application?
  - **Answer:** The applications will come from the mentors and those mentors should have a plan to reach out and recruit mentees.
  - **Question:** Why is there a short-term 3-month mentorship program?
  - **Answer:** This has been created to help mentees who only have the summer to participate outside of the school year.
- e) **Type 1 Diabetes in Acute Pancreatitis Consortium (T1DAPC) (Renewal)**
- f) **Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer (CPDPC) (Renewal)**
- g) **National Food and Nutrient Analysis Program (NFNAP) (Renewal)**
- h) **Automated Self-Administered Assessment tool (ASA-24) (Renewal)**
- 4) Dr. Jay Hoofnagle presented the FY2022 Liver Research Portfolio. The following questions were asked:
- **Question:** Is there active genetic research being done on cholestasis of pregnancy?
  - **Answer:** Unfortunately, there is no current research being done at this time in that area.
  - **Question:** Where in the Liver Research Portfolio would one find infections, sepsis and chronic liver disease?
  - **Answer:** “Complications of Cirrhosis.”
- 5) Dr. Saslowsky reminded everyone where to find current NIDDK Funding Opportunity Announcements <https://www.niddk.nih.gov/research-funding/current-opportunities>.
- 6) Planned Workshops (more details can be found in the appendix):
- a) **Neuroimmune Crosstalk in Gut: Impact on Local, Autonomic, and Gut-Brain Function** <https://www.niddk.nih.gov/news/meetings-workshops/2023/neuroimmune-crosstalk-workshop> will be held at The Bethesdan Hotel in Bethesda, MD on June 29, 2023. The purpose of the Neuroimmune Crosstalk Workshop is to solicit the perspectives and recommendations of experts in the fields of neurogastroenterology, immunology, and microbiology. The goal is to inform the professional community and the NIH on the research needs for advancing the understanding of neuroimmune interactions in NIDDK–relevant areas of interest, including irritable bowel syndrome, inflammatory bowel disease, celiac disease, and gut–brain communication.
- b) **Interventional Studies in Pancreatitis: Recent Progress, Knowledge Gaps and Research Opportunities** <https://www.niddk.nih.gov/news/meetings-workshops/2023/interventions-for-pancreatitis> will be held at the University Club in Pittsburgh, PA on July 26, 2023. This one-day workshop aims to inform investigators of new developments in the field and identify the knowledge gaps and research opportunities that might inform possible future funding initiatives for NIDDK.
- 7) Completed Workshops (more details can be found in the appendix):
- a) **Scientific Workshop on Expanding the Evidence Base in Gender-Affirming Care for Transgender & Gender Diverse Populations** <https://dpcpsi.nih.gov/sgmro/scientific-workshop-expanding-evidence-base-gender-affirming-care-transgender-and-gender> was held via webcast on March 27, 2023. The purpose of this workshop was to share what is

known about clinical practices with the population, including the most recent scientific findings, and to identify crucial knowledge gaps and research opportunities for studies on transgender health and gender-affirming care across the life course. Listening sessions and workshops will be posted to the link above.

**b) Neural Plasticity in Energy Homeostasis and Obesity Workshop**

<https://www.niddk.nih.gov/news/meetings-workshops/2023/neural-plasticity-in-energy-homeostasis-and-obesity> was held via webinar April 13-14, 2023. The purpose of this workshop was to bring together experts in the neural plasticity of central and peripheral circuits that control food intake, energy homeostasis, and metabolism in healthy and unhealthy states, such as obesity, to review the science, identify knowledge gaps regarding the functional plasticity within these circuits, and identify high priority areas of research that may lead to therapeutic advances for obesity and other disorders related to metabolic dysregulation and food intake. A summary of the workshop will be in publication soon.

**Closed Session**

Council members reviewed competing applications. One restoration was reviewed. There were no applicants with >\$1M in NIH funding (direct costs) requiring special council review. There were no appeals, foreign applications or skipped applications to review and vote on.

Dr. James thanked everyone for attending both in-person and via webinar. Comments and critiques regarding discussion topics and initiatives from council members are welcome and should be emailed to Drs. James and Saslowsky in advance of the next meeting.

# -Appendix-

# Concept Clearances



National Institute of  
Diabetes and Digestive  
and Kidney Diseases

# Simulation Applications to Improve Clinical Skills and Outcomes of Practicing Clinicians Treating Conditions and Diseases within the Mission of the Division of Digestive Diseases and Nutrition

**Division: DDN**

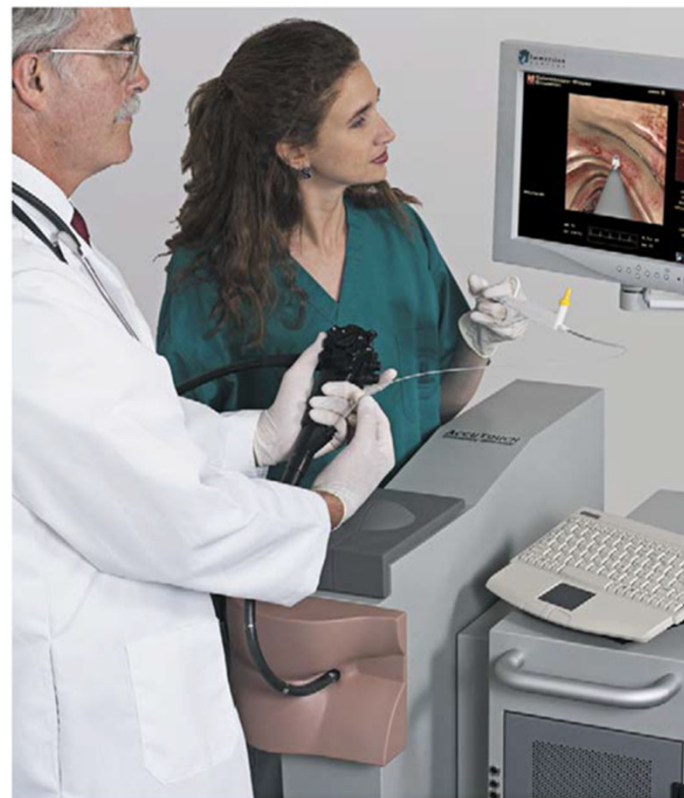
**Program Contact: Dana K. Andersen MD**



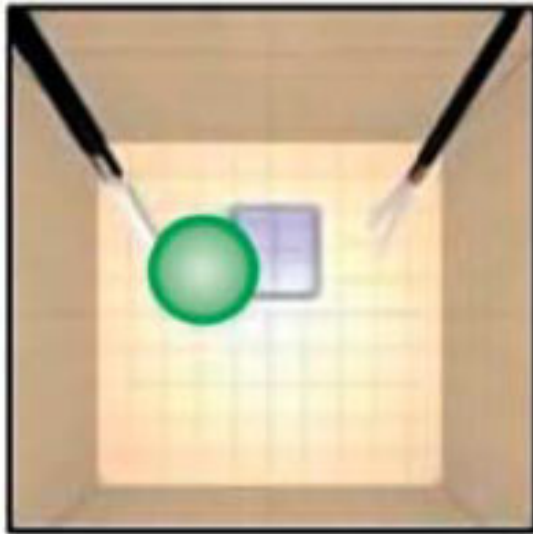
**NIH** National Institute of  
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and Kidney Diseases

# Medical Simulation

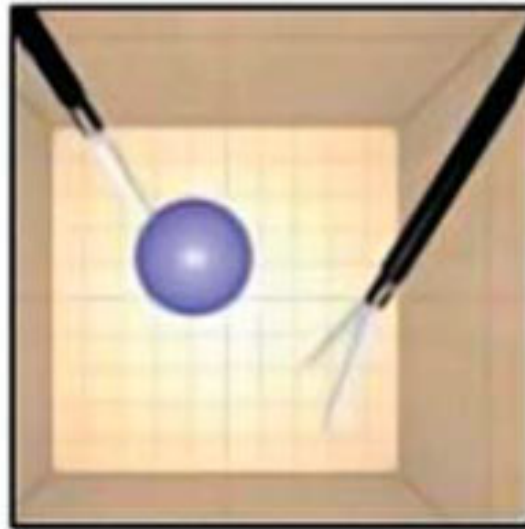
- Simulation technologies have become widely adopted in medical, surgical, nursing and allied health personnel training. Simulation Centers or Facilities exist at virtually all academic medical centers as a result of RRC requirements to include simulation in GME training programs.



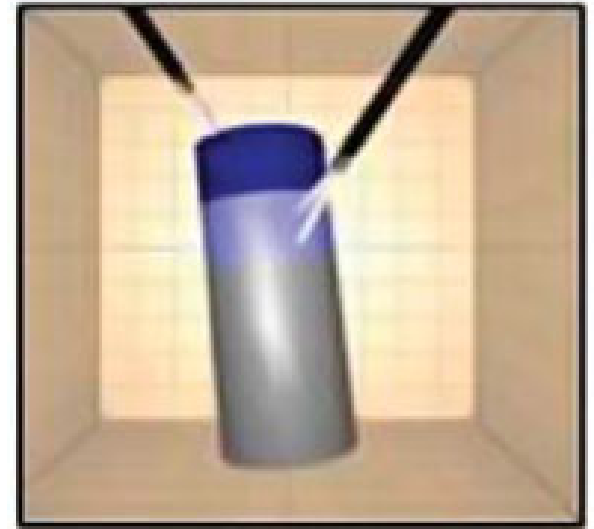
# MIST-VR Exercizes



Acquire place



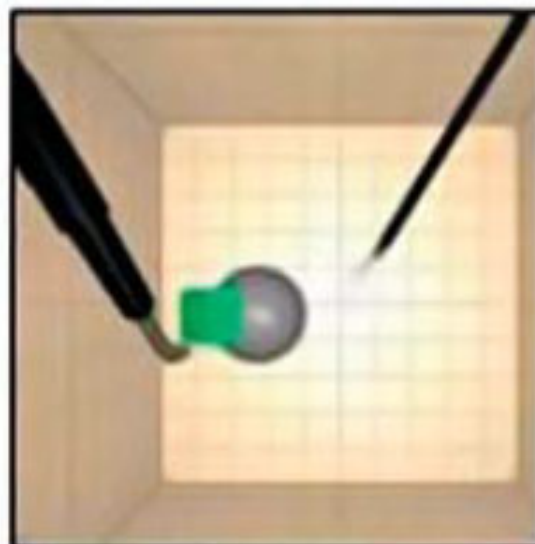
Transfer place



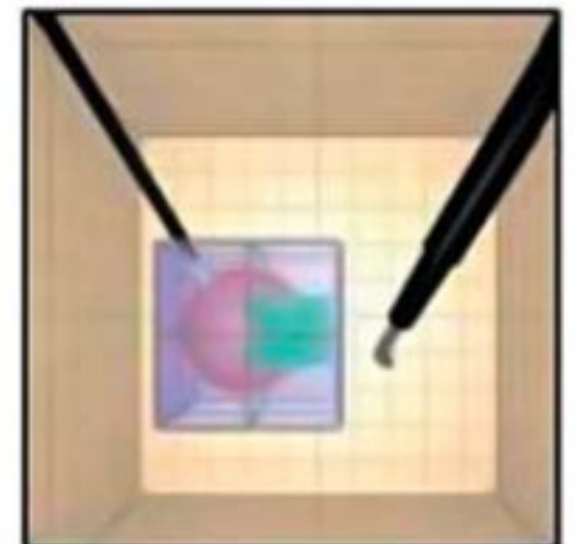
Traversal



Withdraw insert



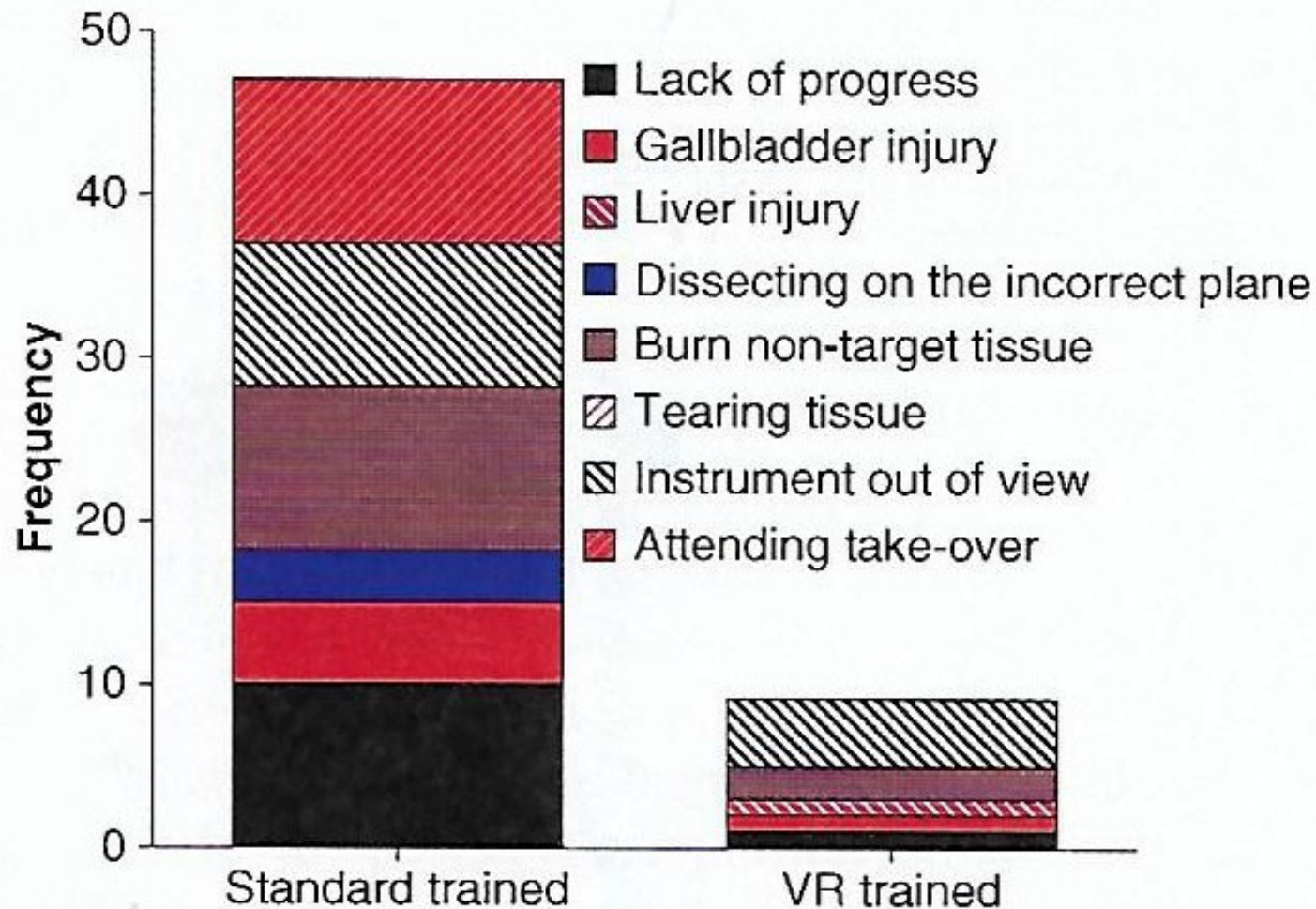
Diathermy



Manip diathermy



# Intraoperative Errors



Ann Surg 2002; 236: 458



# Medical Simulation

- Despite the adoption of simulation technologies by professional athletes, airline pilots, the military and high-risk occupations, the adoption of simulation by practicing medical providers has been low.
- The acquisition of technical and cognitive skills and the decay of those skills over time varies widely. Skill maintenance has been shown to be enhanced by “deliberate practice.”
- Part of the reluctance to embrace simulation by practicing providers is the lack of evidence that it can improve the quality of care.



# Medical Simulation

- 2016 NIDDK/NIBIB Workshop

Simulation Research in Gastrointestinal and Urologic Care—Challenges and Opportunities

- 2019 Program Announcement PA-19-065

Medical Simulators for Practicing Patient Care Providers Skill Acquisition, Outcomes Assessment and Technology Development  
(R01 Clinical Trial Not Allowed)

- 56 applications submitted
- 4 funded
- Conclusion: Clinical Trial Not Allowed NOFO may be an obstacle to attracting strong applications

# Robotic Surgery

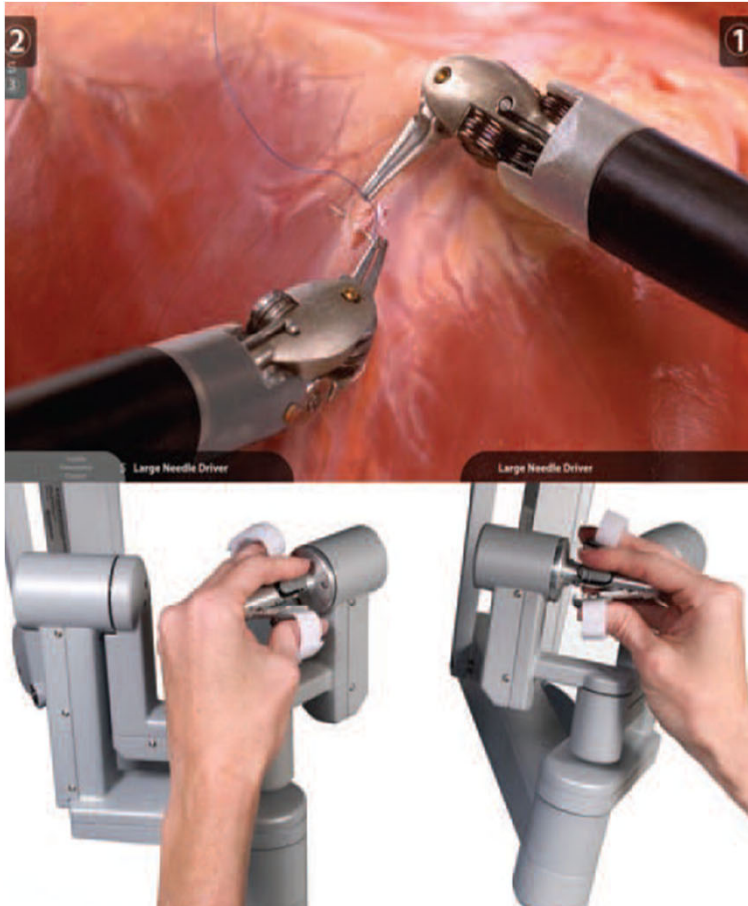
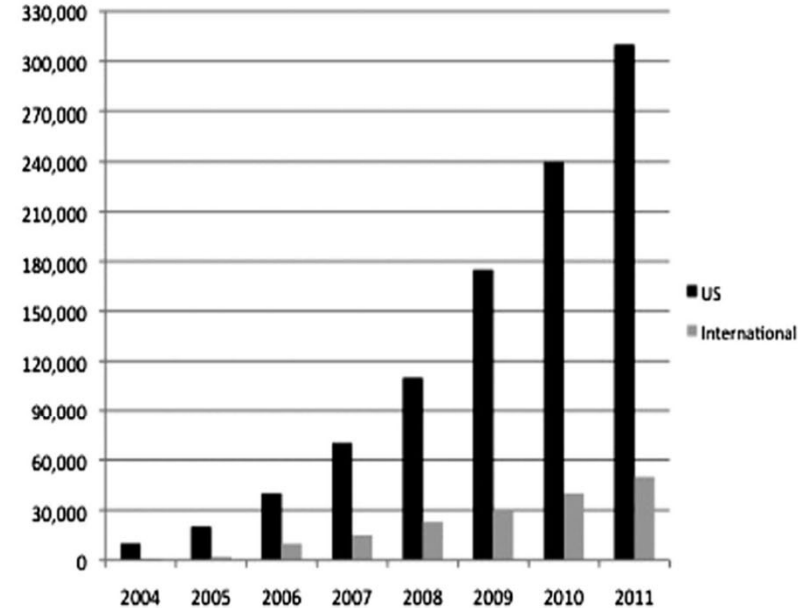


Figure 1. Annual Number of Robot-Assisted Laparoscopic Procedures from 2004 to 2011 in the United States and Internationally.



**Expanded indications (for robotic surgery) has resulted in a rapid increase in complications and deaths** J Healthcare Qual 2015; 37: 133

# Relevance of Simulation to DDDN

- Treatment of gastrointestinal and metabolic diseases requiring open, laparoscopic and robotic surgical methods and advanced endoscopy
- Treatment of rare adverse and emergency events such as toxic megacolon, penetrating abdominal injuries, upper and lower GI hemorrhage, and incarcerated hernia
- Treatment of difficult conditions and lesions such as disrupted pancreatic duct, bile leak after surgery, sessile adenomatous polyps, and choledochocoele



# Medical Simulation

- The Need:
  - To provide a funding opportunity to assess the impact of simulation adoption by practicing clinicians on the quality of care they provide (e.g., morbidity, mortality, avoidance of errors, length of stay, desired outcomes, full functional recovery)
- The Innovation:
  - To study and improve the physiology of the care providers rather than the physiology of the disease





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# Autoimmune Hepatitis Clinical Research Network

**Division: DDN**

**Program Contact:**

**Katrina Loh/Averell Sherker**



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# Need/Background

- Poorly understood cause of chronic liver disease, liver transplantation and death
- Affects individuals across the lifespan with a female predominance
- Unknown etiology & little known about pathogenesis
  - Autoimmune injury to hepatocytes
  - Mechanism(s) of cell injury and triggers are unknown
  - In Caucasians, specific HLA haplotype associations: A1-B8-DRw3
    - Associations in other ethnicities are unknown
- Current therapy developed in 1960-70s with little to no advances since
  - Immune suppression with corticosteroids and azathioprine
- Research challenges
  - Diagnostic criteria are complex and developed entirely based upon non-Hispanic white populations, not thoroughly validated and not widely used clinically
  - Heterogeneous presentation → delayed diagnosis
  - No animal models
  - Few active clinical trials
  - Lack of studies/data in under-represented minorities



# Opportunity

- AIH is a common form of liver disease, however it is not a focus for NIH-funded research or clinical trials
  - In FY2022, only 4 active awards (2 R01s, 1 R21, 1K08)
  - All but one award (R01) will conclude by the end of FY2023
  - Most of the studies and data published are from centers outside of the United States
- Research objective in Trans-NIH Action Plan that has yet to be met
  - The Autoimmune Liver Disease Working Group specifically suggested establishment of *“a multicenter research network of investigators to study the natural history, clinical course, pathogenesis, etiology and therapy of autoimmune hepatitis”*
- Current therapies are limited and NOT curative

# Approach

- Clinical research network to promote translational research in AIH
  - Elucidation of pathogenesis
  - Prevention, treatment & cure
  - Prospective clinical trials for innovative therapies
- Network Composition
  - 8-12 clinical centers
  - Safety & Data Coordinating Center
  - Genetics core
- Large patient database with focus on newly diagnosed cases
  - Geographically and ethnically diverse populations
- Ancillary studies
  - Immunologic responses, autoantibodies, cytokines, proteomics, metabolomics, genetics, search for infectious agents



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# Coordinating Center for the NIDDK Nutrition Obesity Research Centers (NORC) Program

**Division: DDN**

**Program Contact: Mary Evans**

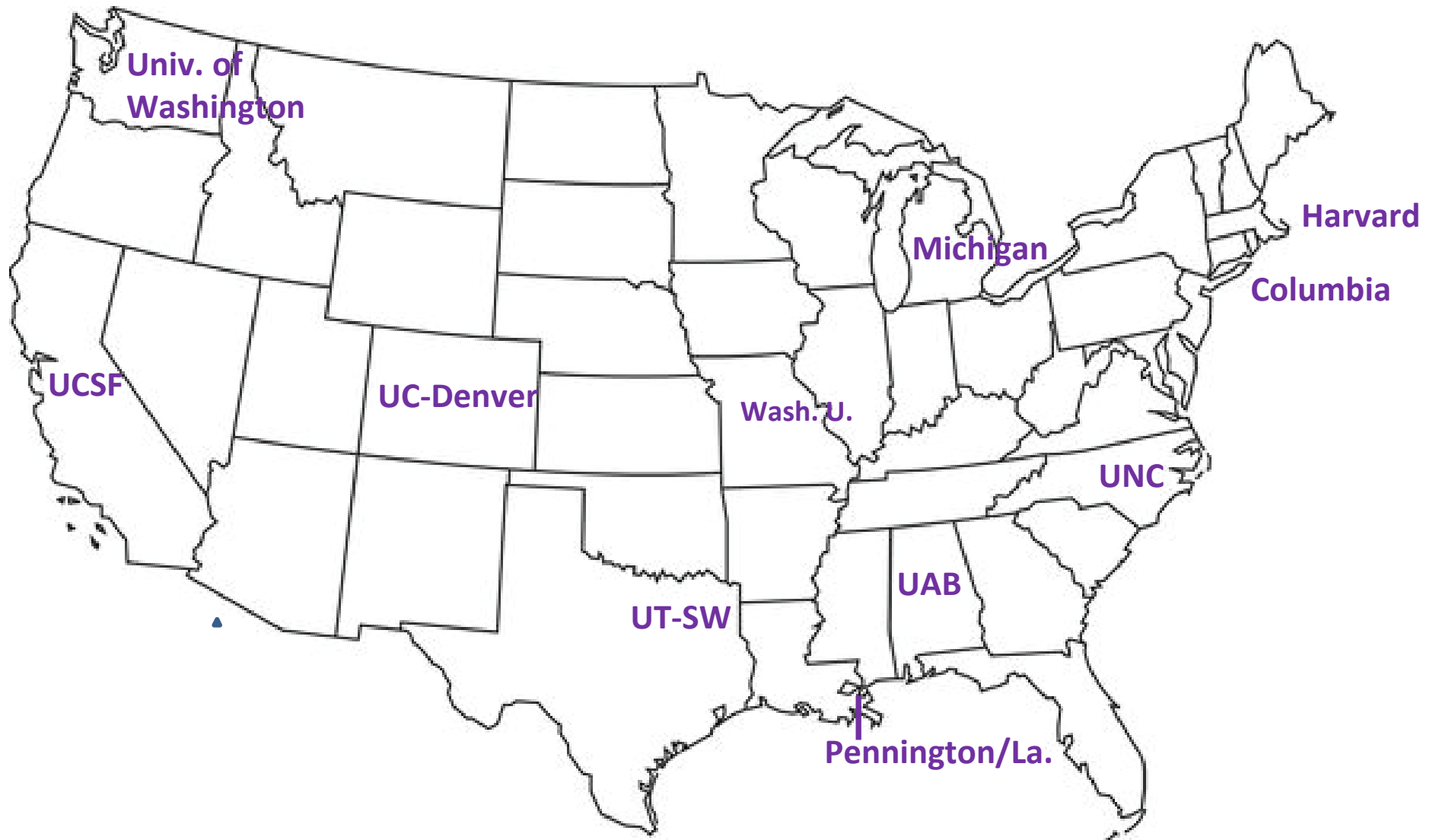


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# NORC Program

- Supports 11 Centers across the U.S. providing research infrastructure and other collaborative activities at academic/medical institutions with a track record of excellence in nutrition and obesity research
  - Foster interdisciplinary basic, clinical, and public health research
  - Enhance collaboration between established and new investigators within nutritional sciences and/or obesity themes
  - Provide cost-effective research resources to multidisciplinary groups
- Structure: 3-4 cores providing research services, a pilot and feasibility program, an enrichment program, and an administrative core

# Existing NORCs



# The Need

- Trans-NORC collaborative activities and leadership would advance the fields of nutrition and obesity research
  - Standardization of nutrition/obesity research methods
  - Sponsorship of novel symposia at national nutrition/obesity society meetings
  - Networking and career development opportunities for early career scientists
  - Initiatives to enhance diversity and inclusion in the nutrition/obesity research workforce
  - Expansion of support for health disparities research in nutrition and obesity
- Currently no coordination capacity across the NORCs
  - Gap in communication and dissemination of NORC-sponsored opportunities and resources

# Approach

- Create a NORC Coordinating Center with defined expectations:
  - Manage programs to enhance diversity and inclusion of scientists who are underrepresented in academia and to improve mentoring of early career scientists
  - Offer a Pilot and Feasibility program for non-NORC affiliated scientists
  - Provide support for methods harmonization projects
  - Coordinate annual NORC meetings, workshops, and NORC-sponsored symposia
  - Enhance nutrition/obesity health health equity research
- Requirements: strong track record of funded nutrition/obesity research, expertise in mentoring and career development, leadership in advancing diversity, and demonstrated organizational capabilities and resources



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# Short-term Research Experiences in Nutrition, Obesity, and Digestive Diseases for Investigators from Diverse Backgrounds

**Peter Perrin, Ph.D.**

**Mary Evans, Ph.D.**

**Katrina Serrano, Ph.D.**



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# Need/Background

- **Benefits to diversifying the DDDN research community include:**
  - New perspectives on Digestive Diseases, Obesity & Nutrition Research
  - Broadens the base of talented investigators
  - Provides an opportunity for Americans of all backgrounds to contribute
  
- **Disadvantages of not diversifying the DDDN research community:**
  - Over concentration of resources on research-intensive institutions limits the talent pool
  - The breadth of research questions becomes limited
  - Inconsistent with providing opportunity to everyone
  
- **Barriers to diversifying the DDDN research community:**
  - Access to technologies, mentoring, and resources not available to all
  - Cycle of limited NIH support and lack of research opportunities

# Opportunity

## ➤ Purpose

- Support short-term (~3 months with opportunity for renewal) research experiences in DDDN-funded laboratories

## ➤ Eligible Participants

- Scientists from diverse backgrounds ([NOT-OD-20-031](#))
- Appointments at non-research intensive, including minority-serving, institutions
- Early career, new PI, or at-risk established PIs

## ➤ PI/PD Teams

- From institutions with existing NIH-funded research base in nutrition, obesity, and digestive diseases
- Demonstrated history of mentoring scientists from different backgrounds

# Approach

- **Grants supporting short-term research experiences**
  - Support up to three candidates per year
  - Salary support for up to 3 CM per candidate
  - Funds for supplies, travel, relevant expenses
  - Candidates can renew for a second year
  - Salary support for mentors
- **Candidate activities**
  - Engage in research that is expected to lead to publication
  - Participation in relevant career development opportunities



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# Continuation of the Consortium for the Study of Chronic Pancreatitis, Diabetes and Pancreatic Cancer (CPDPC)

**Division: DDN**

**Program Contacts:**

**Jose Serrano MD, PhD, Project Scientist**

**Aynur Unalp-Arida MD, PhD, Program Official**

**Dana Andersen, MD, Scientific Advisor**



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# Need/Background

Research progress in diseases of the exocrine pancreas [chronic pancreatitis, pancreatogenic diabetes mellitus, and pancreatic cancer] has been hampered by:

- the disorders' heterogeneity,
- the limitations of previous small cross-sectional studies,
- the inability to safely obtain pancreatic tissue for study, and
- the lack of longitudinal epidemiologic studies, genetic testing, and biomarker development.

Mechanism-based research of these diseases has suffered from the lack of systematically collected clinical measures in longitudinal cohort studies linked with biospecimens

# Outcome of Previous RFA

During the last eight years, the CPDPC investigators have pursued and expanded the research objectives outlined in the original and subsequent RFAs in 4 areas:

Adult Chronic Pancreatitis,  
Pediatric Chronic Pancreatitis,  
DM PDAC interrelationship and  
Type3c DM.

The investigators continue to address research gaps and foster multidisciplinary collaborations to better diagnose, characterize, and manage CP and its sequelae.

# Outcome of Previous RFA

Over 95 ancillary studies have been proposed by the CPDPC investigators of which 16 have been completed. Several ongoing studies have successfully competed for NIH funding:

- Magnetic resonance Imaging as a Non-Invasive Method for Assessment of Pancreatic fibrosis (**MINIMAP**): a pilot study". R01 DK116963, Evan Fogel and Temel Tirkes
- Web-based Management of Adolescent Pain (**WebMAP**)". R01 DK118752, Aliye Uc
- Safety, tolerability, and dose limiting toxicity of lacosamide in patients with painful chronic pancreatitis" R01 DK132709-01, Evan Fogel and Fletcher White
- Mechanism-based Approach to Pain in Chronic Pancreatitis (**MAP-CP Study**)". R21 DK122293-01A1, Jamy Saloman
- P-QST Project: Pancreatic Quantitative Sensory Testing (**P-QST**) to Predict Treatment Response for Pain in Chronic Pancreatitis". R01 DK127042-01A1, Anna E Phillips
- A Pilot Clinical Trial of Paricalcitol for Chronic Pancreatitis R01 DK132631-01, Stephen Pandol and Marc Goodman

**These, like other ancillary studies, exemplify the added value of having a consortium to study rare diseases.**

# Outcome of Previous RFA

The CPDPC investigators have authored over 23 main and 63 secondary publications since 2015.

The CPDPC had collected thousand of biospecimens: saliva, urine, plasma, DNA, RNA, pancreatic juice.

**30% deposited in DKCR**



# Opportunity

Since inception, the consortium's investigators have been conducting 3 major longitudinal studies:

- A. Prospective Evaluation of Chronic Pancreatitis for Epidemiologic and Translational Studies (PROCEED) - **1,748 adults enrolled\***.
- B. Pediatric Longitudinal Cohort Study of Chronic Pancreatitis (The International Study Group of Pediatric Pancreatitis: In Search for a Cure (INSPPIRE 2) - **903 children enrolled\***.
- C. A Prospective Study to Establish a New Onset Diabetes (NOD) Cohort – **2,201 patients enrolled**. **Discontinued by NCI in 2022, due to limited enrollment (targeted 10,000).**
- D. Evaluation of a mixed meal test for Diagnosis and characterization of Pancreatogenic Diabetes secondary to pancreatic cancer and chronic pancreatitis (DETECT)- **325 patients enrolled\***

Patients from the first three studies are being followed annually.

\*Based on report from January 2023

# Opportunity

- The CPDPC have provided the first prospective, longitudinal observational cohort study of CP in the United States.
- The study is innovative in several ways – in addition to enrolling subjects representing the complete clinical spectrum of CP, it has established a biorepository to support translational studies.
- The CPDPC is providing the research infrastructure to conduct numerous clinical and translational studies, which will lead to new strategies for diagnosis, methods to monitor disease progression and treatment of CP (for which there isn't any effective preventive or treatment intervention).

# Approach

Pending advice from an External Evaluation Panel (EEP), which will meet in FY2024, we propose to issue an RFA for the continuation of the Consortium for the Study of Chronic Pancreatitis, Diabetes and Pancreatic Cancer (CPDPC) in FY 2025. Five additional years of funding, will allow:

1.- Continuation of the objectives of the three major clinical studies: PROCEED, INSPPIRE and DETECT,

2.- Completion of two studies to define and characterize pancreatogenic (Type 3c) diabetes:

- Evaluation of a mixed meal test for Diagnosis and characterization of Pancreatogenic Diabetes secondary to pancreatic cancer and chronic pancreatitis (DETECT), and
- Detailed Physiologic Characterization of the Insulin Axis in Type 3c Diabetes versus Type 2 Diabetes (DEPICT3c2)

# Approach

- 3.- Completion of the several of the ongoing mission critical ancillary studies in support of the objectives of the CPDPC.
- 4.- Completion of genetic association studies in **pediatric** and **adult** pancreatitis cohorts
- 5.- Provide seed funds to launch pilot studies in support of the objectives of the CPDPC.



# Continuation of the Type 1 Diabetes in Acute Pancreatitis Consortium (T1DAPC)

**Divisions:** DDN, DEM

**Program Contact:**

**Aynur Unalp-Arida, MD, PhD**

**Maren Laughlin, PhD**

**Beena Akolkar, PhD**

**Jose Serrano, MD, PhD**

**Dana Andersen, MD**



# Need

- AP results from acute inflammatory injury of pancreas, leads to >300,000 hospitalizations in the U.S. annually.
- Hyperglycemia was previously considered a transient complication of AP and this diabetogenic effect was thought to be due to severe pancreatic necrosis.
- Other underlying causes and contributing factors to diabetes following AP remain poorly characterized with its mechanisms and the role of beta cell autoimmunity unexplored.

# Background

- Patients with diabetes after an AP episode requires insulin therapy in more than 20% of cases.
- The immunology of diabetes after AP remains to be elucidated and may have some commonality with T1D.
- The balance between the inflammatory (auto-reactive) and anti-inflammatory (regulatory) T cells may play a role in subsequent injury to pancreas and other organs.
- It is unknown whether the type and severity of the diabetes is related to the etiology of AP.

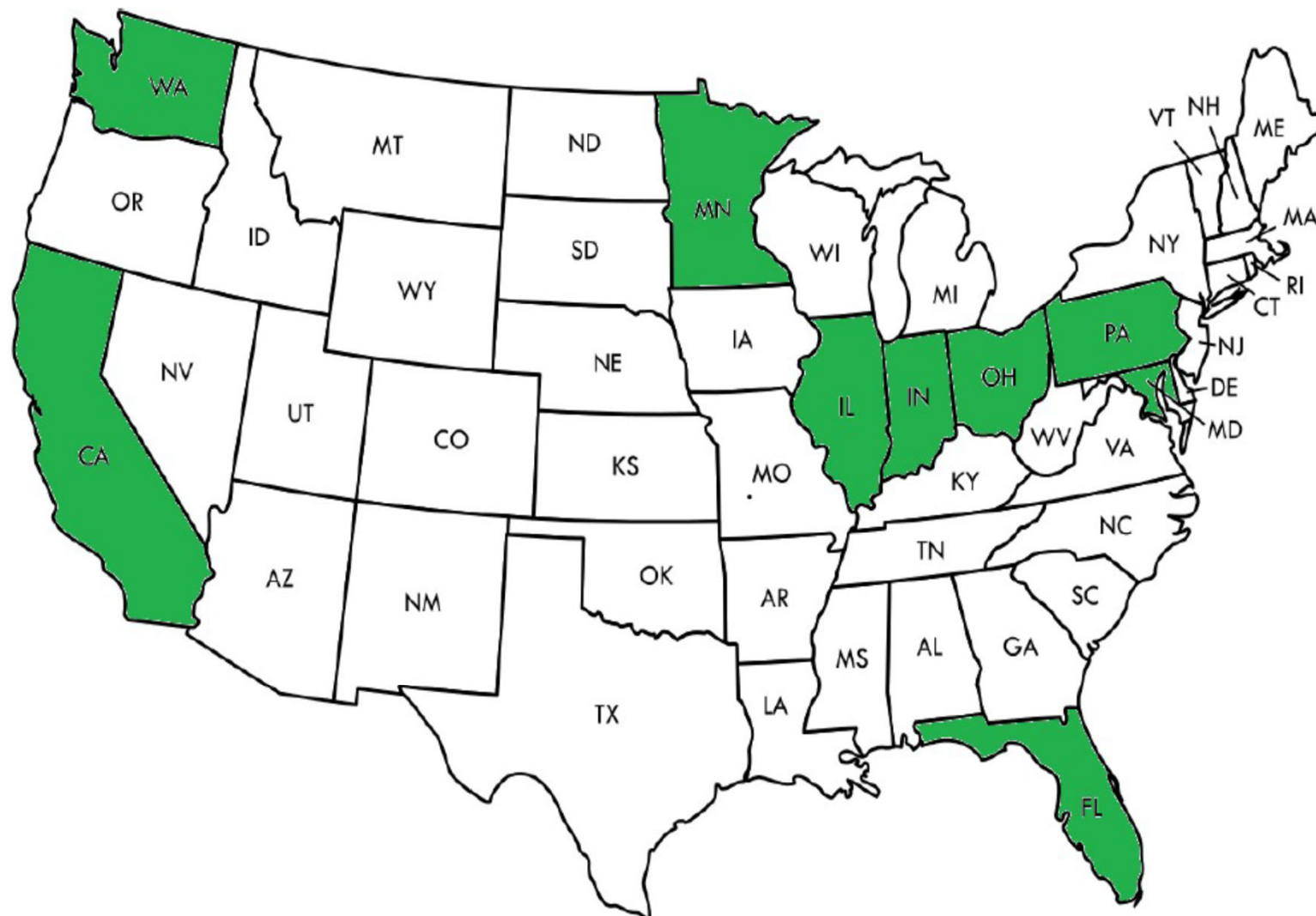
# Opportunity

- The T1DAPC has assembled the first longitudinal study of diabetes after AP in the United States.
- The DREAM Study participants represent the complete clinical spectrum of AP.
- The study is innovative with a biorepository to support translational studies including diagnostic, predictive and prognostic biomarker testing.
- The consortium provides the research infrastructure to conduct numerous clinical studies, which will lead to new strategies for treatment of AP.

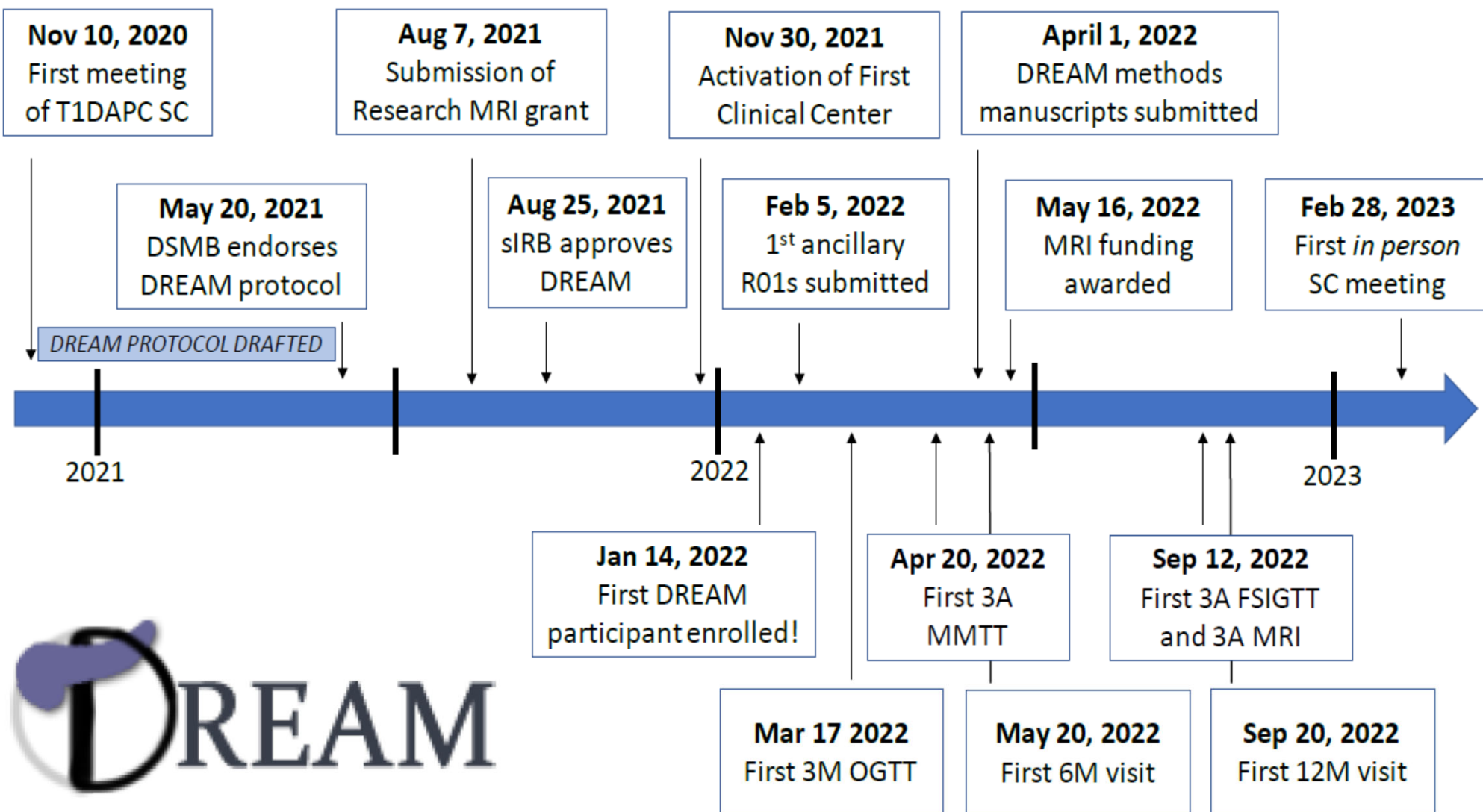


# Opportunity

## Type 1 Diabetes in Acute Pancreatitis Consortium (T1DAPC)

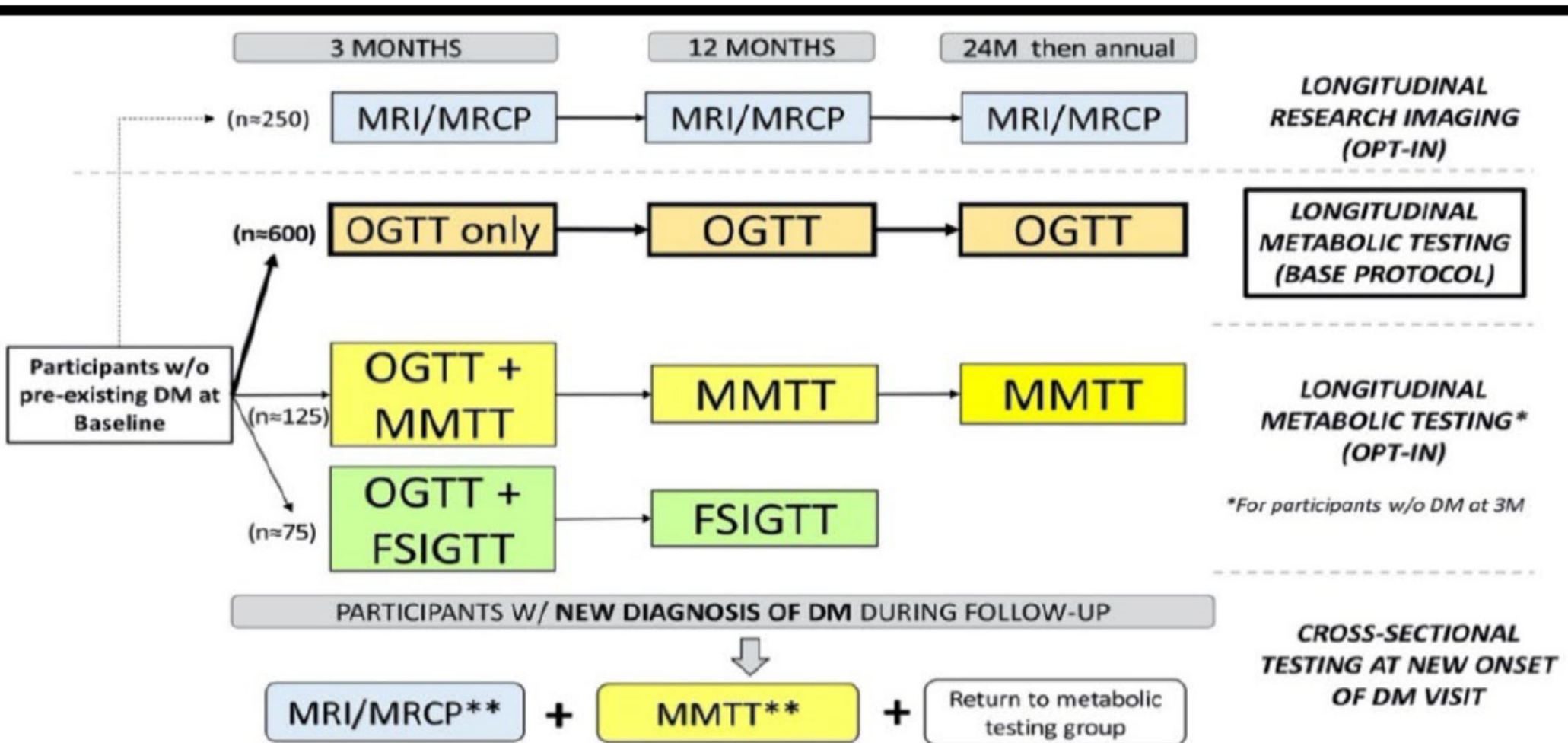


# Outcome of Previous RFAs



# Approach

Serial research MRIs are integrated within follow-up schedules

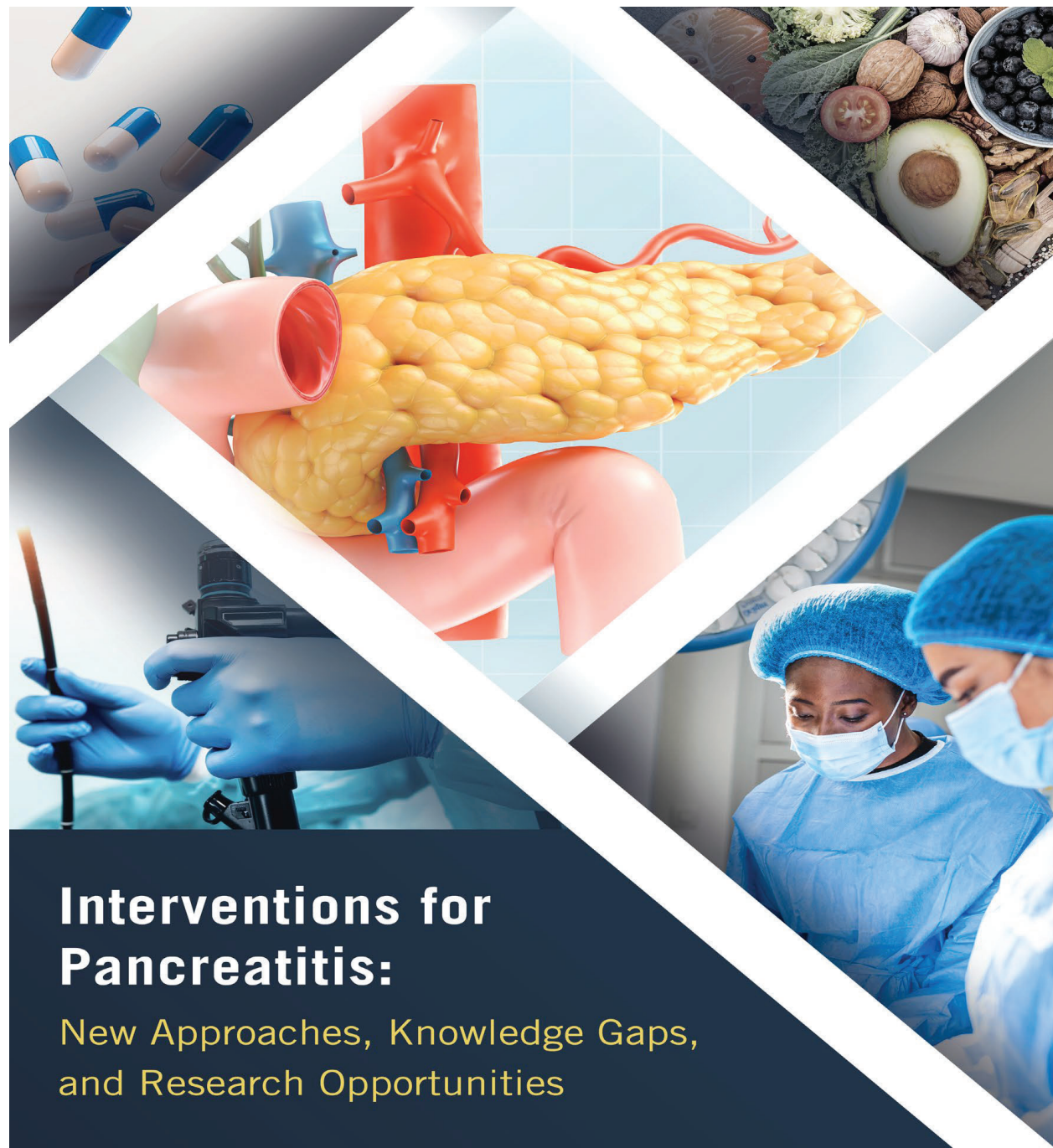


\*\* One-time MMTT and MRI are performed if participant is not previously enrolled in MRI and MMTT groups, respectively

# DREAM Study Objectives

- The primary outcome is diabetes incidence
- Participants enrolled after the qualifying AP episode and complete study visits at 3, 6, 12-mo and yearly thereafter
- Sample size is 800 non-diabetic participants at 3-month with metabolic testing, assuming a 15% diabetes incidence at 24 months
- Longitudinal metabolic, radiologic, immunologic measures will inform on the mechanism and type of diabetes after AP, and potentially provide predictive biomarkers.

# Planned Workshops



# Interventions for Pancreatitis:

New Approaches, Knowledge Gaps,  
and Research Opportunities

**JULY 26, 2023**

The University Club | 123 University Place | Pittsburgh, PA



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WITH THE ADDITIONAL SUPPORT OF  
THE NATIONAL PANCREAS FOUNDATION

# Rationale for Workshop

- Recent NIDDK Workshops have focused on the requirements for designing and conducting clinical trials in pancreatitis.
- The breadth and variety of interventions which are planned or underway include pharmacologic studies, nutritional studies and mechanical studies with devices, endoscopy and surgery.
- The purpose of this one day workshop is to inform investigators of new developments and to identify the knowledge gaps and research opportunities.

# Workshop Agenda

- Keynote Speakers
  - Patient Advocate Ms. Cowdin – Patient Priorities
  - Investigator Dr. Forsmark – Overview of Knowledge Gaps
- Promising, New or Novel Bio-Pharmacol Interventions
  - Repurposing Approved Anti-inflammatory Drugs, New Drugs, Stem Cell Treatment, Chemical Ablation of Acinar Tissue
- Nutritional Interventions
  - Food as Medicine, Food as Causation, Oral versus Intrajejunal feeding, Alcohol Cessation Therapy
- Mechanical and Device Interventions
  - Intraductal Infusion of Drugs and Chemicals, Resection versus Excavation in Surgery, Timing and Subject Selection in Surgical Trials, Studies of Therapeutic Endoscopy



# Workshop Faculty - Speakers

- Adam Bell PhD – Neuraly
- Adriana Cowdin - NPF
- Vikas Dudeja MD – UAB
- Evan Fogel MD – IU
- Jay Freeman MD – OSU
- William Nealon MD – Hofstra
- Tonya Palermo PhD – UW
- Martin Rosenthal MD – UFL
- Nick Zyromski MD - IU
- Greg Cote' – OHSU
- Nancy Diazgranados PhD – NIAAA
- Sinead Duggan PhD – TCD
- Chris Forsmark MD – UFL
- George Gittes MD – UPitt
- John Neoptolemos MD – UH
- Kristen Roberts PhD – OSU
- Dhiraj Yadav MD MPH –UPitt

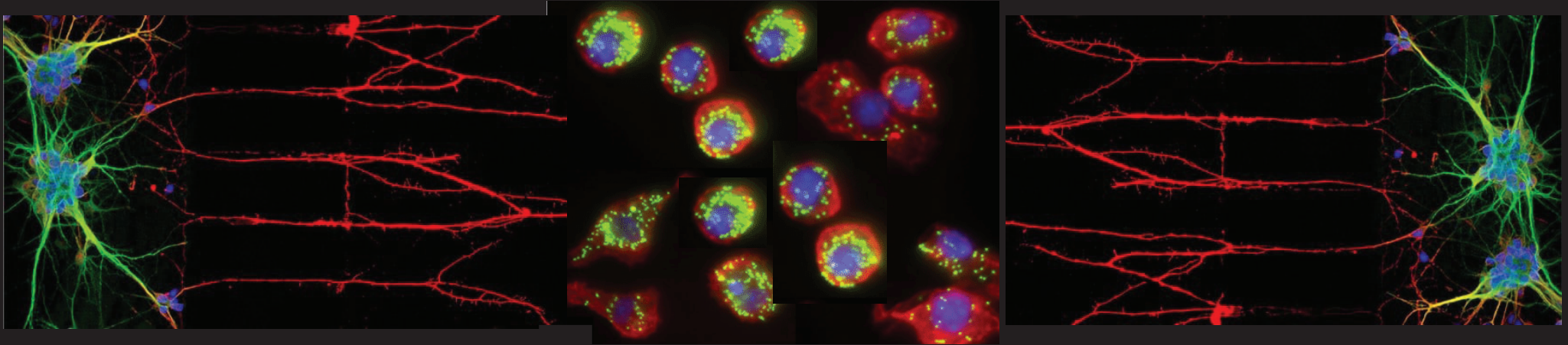
# Workshop Faculty - Moderators

- Steve Hughes MD – UFL \*
- Anna Evans Phillips MD MSc – UPitt\*
- Randall Brand MD – UPitt
- Phil Hart MD – OSU
- Christie Jeon DSc – Cedars Sinai
- Steve Pandol MD – Cedars Sinai
- Vikesh Singh MD MSc – Hopkins
- David Whitcomb MD PhD – UPitt

\* Workshop Co-Chairs

# Workshop Logistics

- Date and Venue
  - Wednesday July 26, 2023 - University Club, Pittsburgh PA
  - The annual PancreasFest meeting will follow and will include a consensus meeting to identify standardized outcome measures to be used in pancreatitis trials
- Registration
  - The workshop will be in hybrid format for both in-person and virtual attendance by Zoom
  - Attendance is free and open to the public but advanced registration is required
  - [www.NIDDK.gov/Future Meetings/](http://www.NIDDK.gov/FutureMeetings/)
- Deliverables
  - Conference Summary manuscript to be published
  - Recommendations may Inform possible future funding initiatives of NIDDK



# *Neuroimmune Crosstalk in the Gut*

## *Impact on Local, Autonomic, and Gut-Brain Function*

June 29-30, 2023  
Bethesda, Maryland

# Neuroimmune Crosstalk in the Gut

## Impact on Local, Autonomic, and Gut-Brain Function

### Background

- The enteric nervous system (ENS) is the largest nervous system (>300 million neurons in humans) outside the brain and regulates a variety of complex digestive functions.
- The microbiome plays a key role neuroimmune crosstalk as germ free mice do not develop a normal ENS or gut associated lymphoid tissue.
- Interactions between the ENS, immune system, and gut microbiota regulate intestinal homeostasis and dysfunctional neuroimmune crosstalk likely contributes to symptoms and disease severity in GI disorders such as IBD, IBS, celiac disease, esophagitis, and others.
- The crosstalk between nerves and immune cells is implicated in allostasis and thus neuroimmune interactions may play an important role in disease chronicity.
- Neuroimmune targets are at the crossroads of health and disease are promising therapeutic targets for GI pathologies.

# Neuroimmune Crosstalk in the Gut

Impact on Local, Autonomic, and Gut-Brain Function

## Purpose

- To facilitate in-person networking among mucosal immunologists, enteric neuroscientists, and microbiologists to expand the scope of current NIDDK funding in this area
- To explore recent advances in state- of-the-art molecular, imaging and genetic technologies that can be leveraged across these disciplines.
- To better characterize the nature and specificity of neuroimmune interactions in the gut to allow more precise targeting for development of novel therapeutics for GI pathologies.

# Neuroimmune Crosstalk in the Gut

Impact on Local, Autonomic, and Gut-Brain Function

## Organizing Committee

### ■ External members

- Issac Chiu PhD (Harvard)
- Brain Gulbransen PhD (MSU)
- Kara Margolis MD (NYU)

### ■ Internal Members

- Diana Cummings PhD
- Patricia Greenwel PhD
- Dwayne Lunsford PhD
- Terez Shea-Donohue PhD

## Format

- In person 1.5 day meeting
- Six scientific basic and translational science sessions followed by 3 breakouts focused on clinical concepts

## Faculty

- Emphasis on early and mid-stage investigators
- Inclusion of K awardees

# Neuroimmune Crosstalk in the Gut

Impact on Local, Autonomic, and Gut-Brain Function

## Scientific Sessions

1. Neuroimmune Overview – cross talk from the immunology and neurobiology perspectives
2. ENS Development and Immune Interactions – neuronal development shaped by immune factors
3. Visualizing Neuroimmune Interactions – state of the art imaging of ENS, ANS and CNS
4. Mechanisms of Neuroimmune Communication – key components in health and disease
5. Neuroimmune Interactions and Gut Sensation – how changes in enteric neuroimmune interactions affect processing of information from the gut lumen
6. Neuroimmune Interactions along the Gut Brain Axis – impact of neuroimmune crosstalk in the gut on ANS and CNS.

Three clinically oriented break out sessions to identify gaps and opportunities needed to advance research in this area.



# Completed Workshops



Scientific Workshop on Expanding the Evidence Base in  
**GENDER-AFFIRMING CARE**  
for Transgender & Gender Diverse Populations

**March 27, 2023 by NIH webcast**

## **Rationale For Workshop**

Despite becoming more visible in society, transgender persons suffer from substandard treatment within health care systems

## **Purpose**

Identify and prioritize knowledge gaps and research needed to further the evidence base in gender-affirming care for transgender and gender diverse populations

## **Sponsors**

Sexual & Gender Minority Research Office (SGMRO)  
10 NIH ICOs, including NIDDK



# Multi-Phase Project

- Phase I: Request for Information on Agenda Framework
  - Fall 2022
- Phase II: Listening Sessions (Invitation Only)
  - December 2022
- Phase III: Virtual Working Groups (Invitation Only)
  - January-March 2023
- Phase IV: Virtual Workshop (Open to the public)
  - March 27, 2023
  - Over 100 registrants, including scientists across disciplines, clinicians, patients and patient advocates, federal staff



# Gender- Affirming Care and NIDDK Mission

- Effects of gender-affirming hormones on NIDDK organs and processes
  - e.g. metabolism, diabetes, kidney, liver, GI tract, adipose tissue
- Surgical outcomes of gender affirming care, including genital surgery
- Impact of stigma and discrimination on NIDDK conditions



# Scientific Workshop Agenda Highlights

**Welcome:** Admiral Rachel L. Levine, MD, Assistant Secretary for Health for the U.S. Department of Health and Human Services

## **Keynote Presentations:**

- Overview of WPATH Standards of Care
- U.S. Trans Survey results

## **Working Group Reports on Research Opportunities in:**

- Pediatric and Adolescent Care
- Adult and Older Adult Care
- Systemic, Institutional, and Ethical Policies



# Deliverables

Summaries of RFI, listening sessions and workshop  
will be posted soon:

<https://dpcpsi.nih.gov/sgmro/scientific-workshop-expanding-evidence-base-gender-affirming-care-transgender-and-gender>

# Neural Plasticity in Energy Homeostasis and Obesity Workshop

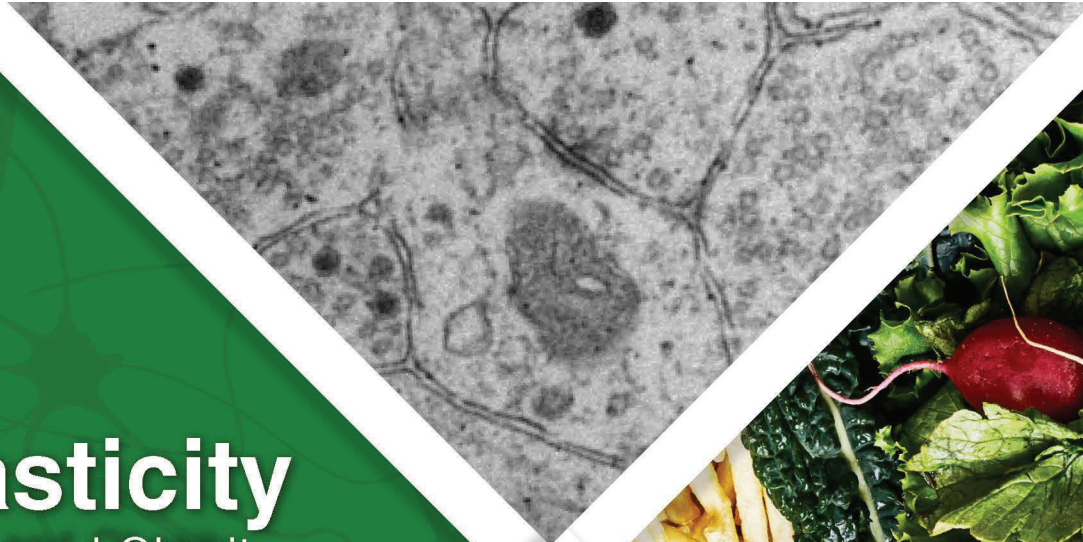
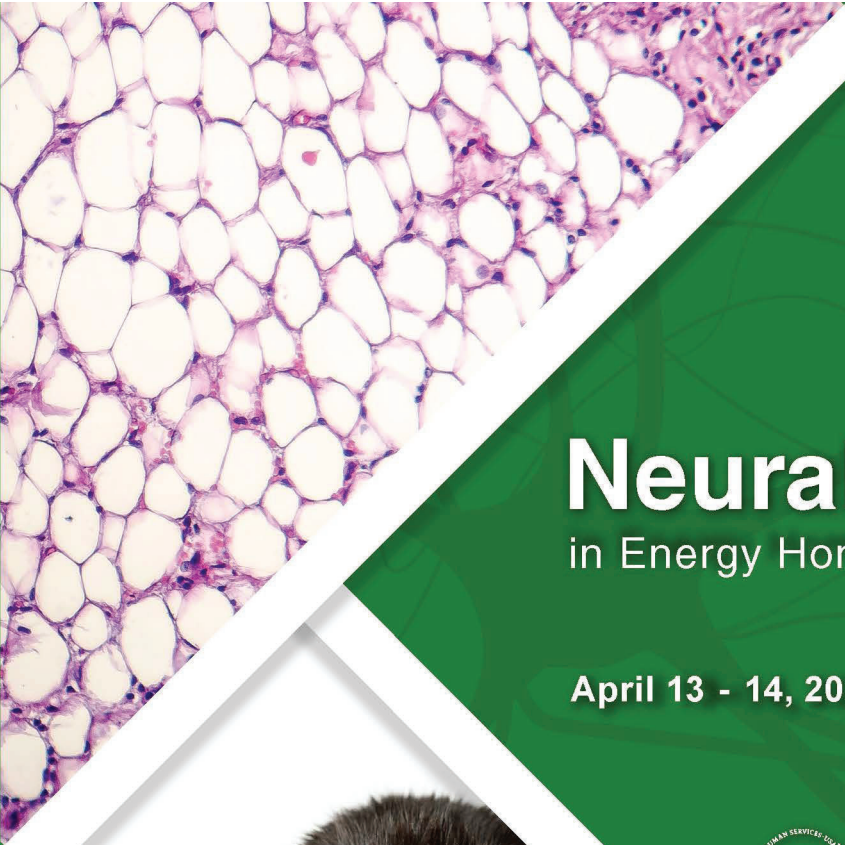
## Neural Plasticity in Energy Homeostasis and Obesity

April 13 - 14, 2023

WORKSHOP



National Institute of  
Diabetes and Digestive  
and Kidney Diseases



# Neural Plasticity in Energy Homeostasis and Obesity Workshop

## Rationale

- Understanding the circuits and pathways that mediate energy homeostasis may reveal therapeutic targets for treating disorders related to food intake such as obesity.
- This 2-day, virtual workshop examined the neurobiological regulation of ingestive behaviors, energy balance, and the development of obesity with a focus on neural plasticity.
- Session presentations, moderated discussions, and breakout groups explored the state of the science to elucidate knowledge gaps and research opportunities.



# Organizing Committee

## External Workshop Chairs:



Dr. Carrie Ferrario,  
University of  
Michigan



Dr. Heike Muenzberg-  
Gruening, Pennington  
Biomedical Research  
Center



Dr. Linda Rinaman,  
Florida State  
University

## NIH Planning Committee:

Brad Cooke – DEM/NIDDK/NIH

Diana Cummings – DDN/NIDDK/NIH

Padma Maruvada – DDN/NIDDK/NIH

Dana Schloesser – OBSSR/NIH

# Workshop Agenda

- Overview: Neural Systems that Control Food Intake and Energy Balance – Alan Watts

## Sessions:

- Plasticity in Chemosensory Signaling
- Plasticity in Visceral Sensory & Humoral Pathways
- Plasticity in Autonomic & Hormonal Pathways
- Energy Sensing & Homeostasis: CNS Circuits
- Neural Plasticity in Feeding-Related Learning & Memory
- Cellular Regulators of Neural Plasticity
- Breakout Groups and Report Back

# Workshop Speakers

- Nicholas Betley, PhD, UPenn
- Diego Bohorquez, PhD, Duke
- Stephanie Borgland, PhD, U Calgary
- Kirsteen Browning, PhD, Penn State
- Ivan De Araujo, PhD, Mt. Sinai
- Claire de La Serre, PhD, UGA
- Monica Dus, PhD, U Michigan
- Debra Fadool, PhD, FSU
- Carrie Ferrario, PhD, U Michigan
- David Hill, PhD, UVA
- Tamas Horvath, DVM, PhD, Yale
- Scott Kanoski, PhD, USC
- Brad Lowell, MD, PhD, Harvard
- Kathryn Medler, PhD, U Buffalo
- Greg Morton, PhD, UW
- Maribel Rios, PhD, Tufts University
- Darleen Sandoval, PhD, U Colorado
- Richard Simerly, PhD, Vanderbilt
- Sarah Stanley, PhD, Cornell
- Alexis Stranahan, PhD, Augusta U
- Kristy Townsend, PhD, OSU
- Alan Watts, PhD, USC
- Kevin Williams, UTSW

# Logistics & Deliverables

- Date and Format:
  - Virtual Workshop
  - April 13-14, 2023
- Deliverables:
  - Workshop Summary Publication
  - Recommendations that may inform potential future NIDDK funding initiatives