

Funding History and Opportunities

NIDDK Funding History and Opportunities

The National Institutes of Health (NIH) comprises 27 separate Institutes and Centers and is the largest biomedical research center in the world. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) was established by Congress in 1950. Within the NIDDK, the Division of Kidney, Urology and Hematology (KUH) manages programs in kidney research.

In FY09, the NIDDK awarded >\$250M for kidney research

Exploratory Research (R21) Program

The evolution and vitality of biomedical science requires constant infusion of new ideas, techniques, and points of view. These innovations may differ substantially from current thinking or practice, and may not yet be supported by substantial evidence. The NIDDK R21 program provides a mechanism dedicated to:

- Innovative, high pay-off, paradigm-shifting projects
- Novel technology and tool development
- Applications of existing methods, technologies, or conceptual approaches from outside biomedical science to a problem in the NIDDK mission
- Pilot clinical trials or clinical studies

The following projects are NOT suitable for the R21 mechanism:

- Projects of limited scope or cost that use widely accepted approaches and methods within established fields are NOT appropriate for an R21 application.
- A proposal designed to generate preliminary data for a longer-term project in a well-established research area is NOT appropriate for an R21 application.
- R21s should NOT be used by new PIs to gather preliminary data for an R01.
- R21 proposals submitted by new PIs will NOT be given special priority for funding.

Most R21 applications can be submitted in response to:

- **NIH Exploratory Research Grant Program (NIH Parent R21)**
<http://grants.nih.gov/grants/guide/pa-files/PA-06-181.html>

However, this NIH-wide Parent R21 announcement does not cover pilot clinical studies or secondary analyses. These can be submitted in response to:

- **Pilot & Feasibility Clinical Research Grants in Kidney/Urologic Diseases (R21)**
<http://grants.nih.gov/grants/guide/pa-files/PA-06-113.html>
- **Secondary Analyses in Obesity, Diabetes, Digestive and Kidney Diseases (R21)**
<http://grants.nih.gov/grants/guide/pa-files/PA-06-151.html>

Upcoming NIDDK Meetings

- **Genetics of GU Tract Malformations**
December 8-9, 2009, Marriott Crystal City, Arlington, VA
<http://www3.nidDK.nih.gov/fund/other/GVJR2009/index.htm>
- **Best Practices for Sample Storage: Urine as a Paradigm**
Winter 2009/2010, Washington, DC
- **Inflammation in End-Stage Renal Disease: Approaches to Treatment Challenges**
Winter 2009/2010, Washington, DC
- **Clinical and Public Health Applications of MYH9 variants in CKD**
Spring/Summer 2010
- **Life After K: Completing the Transition to Independence**
Spring/Summer 2010, Washington, DC
- **Stem Cells in Repair, Regeneration and Tissue Engineering**
Summer 2010, Washington, DC
- **NIDDK New PI Workshop**
November 2010, Washington, DC

Selected Funding Announcements

Basic Research

- **Grants for Basic Research in Glomerular Diseases**
<http://grants.nih.gov/grants/guide/pa-files/PA-07-367.html>

- **Calcium Oxalate Stone Diseases**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-213.html>

- **Advances in Polycystic Kidney Disease**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-202.html>

- **Basic and Clinical Studies of Congenital Urinary Tract Obstruction (R01)**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-226.html>

Translational Research

- **Translational Research for the Prevention and Control of Diabetes and Obesity**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-176.html>

- **Development of Assays for High-Throughput Drug Screening**
<http://grants.nih.gov/grants/guide/pa-files/PA-07-320.html>

- **Development and Validation of Disease Biomarkers (R01)**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-204.html>

- **Non-Invasive Methods for Diagnosis and Progression of Diabetes, Kidney, Urological, Hematological and Digestive Diseases and Hypertensive Disorders (R01)**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-181.html>

- **Planning Grants for Translational Research for the Prevention and Control of Diabetes and Obesity (R18)**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-177.html>

Clinical Research

- **Ancillary Studies of Acute Kidney Injury, Chronic Kidney Disease, and End Stage Renal Disease Accessing Information from Clinical Trials, Epidemiological Studies, and Databases**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-196.html>

- **NIDDK Small Grants for Clinical Scientists to Promote Diversity in Health-Related Research (R03)**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-223.html>

- **Pilot and Feasibility Clinical Research Grants in Kidney or Urologic Diseases (R21)**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-077.html>

- **Ancillary Studies to Major Ongoing NIDDK Clinical Research Studies to Advance Areas of Scientific Interest within the Mission of NIDDK (R01)**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-247.html>

- **NIDDK Multi-Center Clinical Study Implementation Planning Grants (U34)**
<http://grants.nih.gov/grants/guide/pa-files/PA-08-057.html>

- **NIDDK Multi-Center Clinical Study Cooperative Agreement (U01)**
<http://grants.nih.gov/grants/guide/pa-files/PA-08-058.html>

- **Secondary Analyses in Obesity, Diabetes and Digestive and Kidney Diseases (R21)**
<http://grants.nih.gov/grants/guide/pa-files/PA-09-131.html>

- **Health Disparities in NIDDK Diseases**
<http://grants.nih.gov/grants/guide/pa-files/PA-07-027.html>

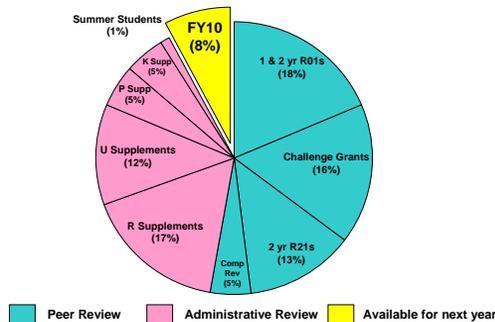
- **Multidisciplinary Translational Research in Critical Care (R01)**
<http://grants.nih.gov/grants/guide/pa-files/PA-07-233.html>

American Recovery and Reinvestment Act (ARRA)

ARRA FY09 Snapshot

FY09	Awards
1 & 2 yr R01's	22
Challenge Grants	16
2 yr R21's	26
Comp Revisions	5
Admin Supp (R's)	124
Admin Supp (U's)	33
Admin Supp (P's)	16
Admin Supp (K's)	53
Summer Students	30

TOTAL ARRA: \$84.5 million for kidney research



Administrative Supplement Funding Considerations

Administrative supplement requests were reviewed administratively by staff with expertise relevant to the proposal.

Selection factors included the following:

- Relevance of the proposal to the parent grant and determination that the activities are within the scope of the project.
- Progress of the parent grant.
- Appropriate and well-described plan to accomplish the goals within the proposed timeframe.
- Expertise of the research team.
- Appropriateness of the request to achieve ARRA goals in promoting job creation, economic development, and accelerating the pace of scientific research.
- Availability of funds and program balance and priorities.

Small Business

Small Business Funding Opportunities

Why Seek SBIR/STTR Funds?

- Over \$1 billion are available across NIH
- They provide seed money for high-risk projects
- They promote and foster partnerships with collaborators - including academia
- Intellectual property rights are normally retained by small business
- Funds are NOT A LOAN - no repayment!
- Large corporations look to small companies for initial development

Small Business Innovation Research (SBIR)

<http://www.zyn.com/sbir>
<http://grants.nih.gov/grants/oeer.htm>

- The SBIR program supports innovative research conducted by small businesses to develop products for commercialization. The PI must be employed by the small business, but a research institution may be involved.

Small Business Technology Transfer (STTR)

<http://www.zyn.com/sbir>
<http://grants.nih.gov/grants/oeer.htm>

- The STTR program supports innovative research for products that have the potential for commercialization. STTR projects must be conducted cooperatively by a small business and a research institution.

Select NIDDK-Supported Small Business Projects

- Predicting kidney stones in relatives of stone formers
- Measurement of GFR
- Computerized Clinical Decision Support

See Visonex, LLC at Poster SA-PO2801

- Commercialization of embryonic kidney stem cell lines, products and kits
- Cell Treatment for Septic Shock
- Test for Salt-Sensitivity in Essential Hypertension
- Prevention / Treatment of Diabetic Nephropathy
- Intravital kidney multiphoton microscopy assays of therapeutic agents
- Renal perfusion quantification
- Tolerance induction in transplant patients

IMPORTANT NIH CHANGES!!!

Revisions to Progress Report Form: PHS 2590

<http://grants.nih.gov/grants/guidenotice-files/NOT-09-09-139.html>

Beginning October 1, 2009, submissions of annual progress reports require the use of revised PHS 2590 forms. The revisions reflect new policy changes and include:

- **New All Personnel Report**
- **New Assurance for Institutions Receiving Awards for Training of Graduate Student for Doctoral Degrees**
- **Inclusion of Changes to Innovative Potential**
- **Changes to the Biographical Sketch**
- **Human Embryonic Stem Cell Use**

Revised forms are available at:
<http://grants.nih.gov/grants/forms.htm>

Training and Career Development

Post-Doctoral Training

<http://www.niddk.nih.gov/fund/training/training.htm#Career>

Ruth L. Kirschstein National Research Service Awards (NRSA)

Individual (F32)

These awards provide support for fellows who have received their M.D., Ph.D., or other doctoral-level degree. Fellows need to identify a mentor and plan a research project before applying for 1 to 3 years of funding.

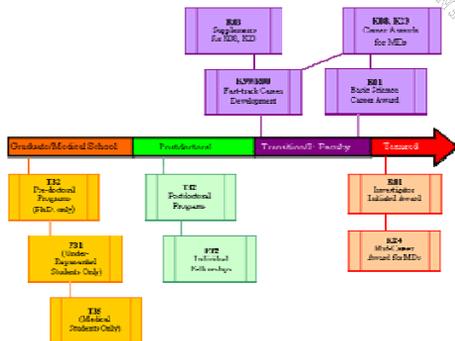
<http://grants.nih.gov/grants/guide/pa-files/PA-06-373.html>

Institutional (T32)

In place at many major universities, these grants provide pre- and postdoctoral support to fellows at those institutions. To be appointed to a training grant, contact the director of the training program at your institution.

<http://grants.nih.gov/grants/guide/pa-files/PA-08-226.html>

Training & Career Development Timeline



Loan Repayment Program

<http://www.lrp.nih.gov>

The goal of the Loan Repayment Program is to ease the debt burden clinical scientists may have incurred while attending medical school and a residency program. The NIDDK has two loan repayment programs: one for clinicians and one for pediatricians. In addition to these NIDDK programs, the NCMHD sponsors two other loan repayment programs for clinicians: one for those involved in health disparities research and another for clinical researchers from disadvantaged backgrounds. Competitive applicants must demonstrate their commitment to a research career and have a debt-to-salary ratio of at least 20 percent. The Loan Repayment Program may repay up to \$35,000 a year toward each participant's outstanding eligible educational load debt, depending on total eligible repayable debt. For more details about eligibility and to apply online, visit <http://www.lrp.nih.gov>.

Career Development Awards*

<http://www.niddk.nih.gov/fund/training/training.htm>

- K01 (Mentored Research Scientist Development Awards)**
Support Ph.D. scientists who have at least 3 to 5 years of postdoctoral training and who need to transition to independence.
- K08 (Mentored Clinical Scientist Development Awards)**
Aimed at physician-scientists to transition them to independence.
- K23 (Mentored Patient-Oriented Research Career Development Awards)**
Aimed at clinical investigators engaged in patient-based research.
- K24 (Investigator Awards in Patient-Oriented Research)**
Support mid-career physicians in patient-oriented research with funded clinical investigations and who are mentoring young clinicians.
- K25 (Mentored Quantitative Research Career Development Awards)**
Available to individuals with quantitative (E.g., engineering, mathematics, computer science, etc.) backgrounds who wish to pursue biomedical research.

Training-Related Program Announcements

Small Grant Program for NIDDK K01/K08/K23 Recipients (R03)

<http://grants.nih.gov/grants/guide/pa-files/PAR-09-230.html>

In the final two years of the career development grant, K recipients may apply for small grant funding for additional development support for their research.

NIDDK Education Program Grants (R25)

<http://grants.nih.gov/grants/guide/pa-files/PAR-06-554.html>

The R25 program provides support for educational opportunities (E.g., workshops, classes) to engage students from undergraduate to graduate in research areas relevant to NIDDK.

K99/R00 NIH Pathways to Independence

<http://grants1.nih.gov/grants/guide/pa-files/PA-06-133.html>

The NIH has another opportunity for career development. This is an ideal award for talented postdoctoral candidates on the fast-track to a productive research career. Eligible applicants must have five-years or fewer of postdoctoral research experience and may not already have an independent position. The first two years of the award, the K99 phase, are intended to be the mentored career-development phase. At the end of the second year, the applicant must have secured an independent tenure-track position to continue the final three years of the award as an R01. While this award does not require U.S. citizenship or permanent resident status, the applicant must be able to remain in the United States to conduct the full five years of the proposed work.

*All NIH fellowships and career development award mechanisms, except the K99/R00, require U.S. citizenship or permanent resident status.

Contacts

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http://www.niddk.nih.gov/welcome/org/tables/kuh_table.htm

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NIH Center for Scientific Review (CSR)

<http://www.csr.nih.gov>

The Digestive, Kidney and Urological Sciences (DKUS) IRG contains the 3 primary study sections for kidney researchers:

- Cellular and Molecular Biology of the Kidney [CMBK]**
Reviews basic and applied aspects of normal and abnormal renal physiology, epithelial biology, cell biology, transport biology (including osmoregulation and osmosensing), hormone action and signal transduction, vascular biology, genetic disorders, cell-matrix interactions, biophysics, and bioenergetics.
- Pathobiology of Kidney Disease [PBKD]**
Reviews basic and clinical studies of kidney disease including pathophysiology, diagnosis, consequences and treatment of acute and chronic disorders of the kidney, and consequences of kidney disease and failure, as well as studies of the normal structure and function of the glomerulus.
- Urologic and Kidney Development and Genitourinary Diseases [UKGD]**
Reviews normal and abnormal development of kidney, urinary tract, and male genital system, and physiologic and pathophysiologic processes of cells and tissues of the bladder, prostate, ureter, urethra, male reproductive organs, penis, and male and female pelvic floor.

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IMPORTANT NIH CHANGES!!!

New Application Page Limits: January 2010 Submissions

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-149.html>

Beginning with applications intended for the January 25, 2009, receipt date, all new (i.e., never submitted) and competing renewal applications will be required to use the newly-restructured application packages and adhere to shorter page limits for most mechanisms.

Grant applications that were previously allowed 25 pages for the research strategy (R01, Ks) will now be allowed 12 pages; grant mechanisms previously allowed fewer than 25 pages (R21, R03) will now be reduced to 6 pages.

Additionally, the application forms will be updated to reflect the response to NIH's Enhancing Peer Review initiative. The application's structure and format will now be aligned more closely with the review criteria. Please consult the most recent parent funding opportunity announcements to ensure download of the correct application forms.

Clinical and Translational Research

Clinical Trials and Epidemiological Studies

NIDDK supports a wide range of clinical trials and epidemiological studies on chronic kidney disease. While many of these programs are solicited by NIDDK through initiatives, investigators may also develop their own ideas.

Areas of General Interest

- > Clinical trials to prevent or slow chronic renal disease
- > Epidemiology, prevention, and treatment of acute kidney injury
- > Epidemiologic and genetic studies of ESRD patients
- > Clinical trials to reduce mortality and morbidity in ESRD patients
- > Epidemiology of chronic renal insufficiency, including CV disease

Mechanisms of Support

- > Investigator-initiated (R01, R21)
- > Institute-initiated research solicitations (U01, contracts)
- > Investigator-Initiated Multi-Center Clinical Studies (U34/U01) **NEW!**

<http://grants.nih.gov/grants/guide/pa-files/PAR-08-057.html>

NIDDK will support investigator-initiated, multi-center studies exclusively through a two-step application process, with an implementation planning grant (U34) application followed by a clinical study cooperative agreement (U01) application.

If you have patients with Vesicoureteral Reflux (VUR)

* RIVUR (Randomized Intervention for Vesicoureteral Reflux)

Multi-center trial of Trimethoprim-Sulfamethoxazole prophylaxis compared to placebo in children with VUR.

Study population:

Individuals between 2 months and 6 years of age with VUR and

- ✓ Diagnosed urinary tract infection (UTI) with either fever or associated symptoms
- ✓ Diagnosed with first UTI within 112 days prior to beginning study medication
- ✓ Treated for the first UTI for 7 or more days with an effective drug

For more information:

- ✓ See www.ClinicalTrials.gov identifier NCT00405704
- ✓ See <http://www.cscce.unc.edu/rivur/>

Ongoing Studies/Currently Recruiting

- > **Assessing Long Term Outcomes of Living Donation (ALTD0)**
Multi-center prospective cohort study will address whether kidney donation increases the risk of developing ESRD and/or increases the risk of developing CV disease.

Participating sites: University of Minnesota (Hennepin County), Ohio State University, Mayo Clinic, University of Iowa, Johns Hopkins University, UCSF, University of Maryland.

- > **Oral vs. IV Iron Therapy in Chronic Kidney Disease**
Single center study (Indiana University) investigating whether IV iron therapy in CKD is associated with more rapid decline in GFR than chronic oral iron therapy.

- > **Randomized Intervention for Vesicoureteral Reflux (RIVUR)**
Multi-center trial of Trimethoprim-Sulfamethoxazole prophylaxis compared to placebo in children with VUR (13 primary sites and 1 DCC). Age range 2 months – 6 years. Outcome measures will include frequency of UTI, changes in scarring measured by DMSA scan and development of antimicrobial resistance.
(www.ClinicalTrials.gov identifier NCT00405704)

Ongoing Studies/NOT Currently Recruiting

- > **Clinical Trial of FSGS in Children and Young Adults**
Cooperative agreement-supported clinical trial; 3 primary centers and 1 DCC
- > **Consortium for Radiologic Imaging Studies in PKD II (CRISP II)**
Cooperative agreement-supported clinical study; 4 centers and 1 DCC
- > **Angiotensin II Blockade in Chronic Allograft Nephropathy (ABCAN)**
Cooperative agreement-supported clinical trial; single center at University of Minnesota
- > **Folic Acid for Vascular Outcome Reduction in Transplantation (FAVORIT)**
Cooperative agreement clinical trial; 20 centers and 1 DCC
- > **Family Investigation of Nephropathy and Diabetes (FIND)**
Cooperative agreement-supported clinical study; 8 centers and 1 DCC
- > **Chronic Renal Insufficiency Cohort (CRIC) Study**
Cooperative agreement-supported prospective epidemiological study; 7 centers and 1 DCC
- > **Prospective Study of Chronic Kidney Disease in Children (CKiD)**
Cooperative agreement-supported clinical study; 2 centers and 1 DCC
- > **Frequent Hemodialysis Network (FHN)**
Cooperative agreement-supported clinical study; 2 sites and 1 DCC
- > **HALT-PKD**
Cooperative agreement-supported clinical study; 6 sites and 1 DCC
- > **The NOCTURNAL TRIAL**
1 primary site and 1 DCC

RIVUR Participating Sites:

Oregon Health and Science University, University of Oklahoma Health Sciences Center, Texas Children's Hospital, Children's Mercy Hospital, University of Wisconsin Children's Hospital, Children's Memorial Hospital, Cincinnati Children's Hospital, University of Alabama, Children's Hospital of Michigan, Akron Children's Hospital, Children's Hospital of Pittsburgh, Wake Forest University Baptist Medical Center, Women and Children's Hospital of Buffalo, Children's National Medical Center, Johns Hopkins School of Medicine, Penn State Hershey Medical Center, Children's Hospital of Philadelphia, Alfred I. DuPont Hospital for Children, Children's Hospital of Boston

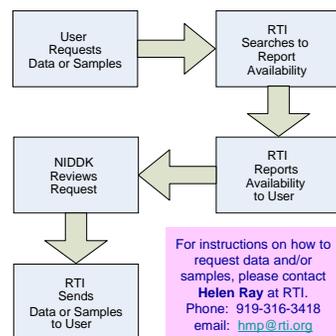
Repository

Central NIDDK Repositories Data, Biosamples, and DNA for your research

<http://www.NIDDKrepository.org>

The NIDDK Central Repositories store samples and data from NIDDK-funded clinical studies, which are made available to the community at the end of the study or when an interim phase is completed.

Visit the NIDDK Repository Booth #1809!



Data and/or samples are available from:

- > **African American Study of Kidney Disease and Hypertension (AASK)**
AASK compared the effectiveness of various antihypertensive regimens to slow or prevent progressive renal dysfunction in 1,094 African-Americans with a clinical diagnosis of hypertensive renal disease.
- > **Genetics of Kidneys in Diabetes (GoKinD)**
GoKinD created a repository of DNA and clinical information from adults with long-term Type 1 diabetes, with or without kidney disease to facilitate research into Type 1 diabetes and the genetic basis of diabetic kidney disease. The collection includes case and control singletons as well as case and control trios. In addition to phenotypic data, GWAS data from a 500K Affymetrix chip are available for all participants.
- > **National Analgesic Nephropathy Study (NANS)**
NANS assesses the relationship between analgesic use and ESRD to learn if a non-contrasted CT scan can detect analgesic nephropathy. This is a case control study with detailed questionnaire and CT scan to > 200 incident ESRD patients and questionnaire to > 200 matched non-ESRD controls.
- > **The Family Investigation of Nephropathy and Diabetes (FIND)**
The FIND group recruited nearly 7,000 individuals from four ethnic groups to study the genetic determinants of susceptibility to diabetic nephropathy. Both family-based linkage and case-control strategies were used. Linkage data from 5,000 individuals are available now. GWAS data and samples will be available in 2010.

Data and/or samples are available from:

- > **Epidemiology of Diabetes Interventions and Complications (EDIC)**
EDIC is a follow-up to DCCT (Diabetes Control and Complications Trial). The DCCT demonstrated the efficacy of glycemic control for slowing the onset and progression of eye, kidney, and nerve complications and long-term diminution of CV complications. Since 1994, most DCCT participants have been enrolled in EDIC for regular observational follow-up. DCCT and EDIC family studies have collected data, DNA, and other biosamples from over 4,000 probands and relatives. In addition to phenotypic data, GWAS data from a 500K Illumina chip are available for all DCCT participants and a small number of parents.
- > **Modification of Diet in Renal Disease (MDRD)**
The multi-center MDRD study investigated whether restriction of dietary protein and phosphorus, and/or reduction of blood pressure below 140/90 reduces the rate of progression of chronic renal disease. Patients with renal disease were randomized to either normal diets, a low protein/low phosphorus diet, or a very low diet supplemented with keto amino acids. They were also randomized to a regimen to reduce blood pressure.
- > **Hemodialysis Study (HEMO)**
The HEMO study tested the effects of the dose of dialysis and the level of flux of the dialyzer membrane on mortality and morbidity among patients undergoing maintenance hemodialysis. The study randomized 1,846 patients to a standard or high dose of dialysis and to a dialyzer with a low-flux or high-flux membrane for dialysis three times a week. The primary and secondary outcome showed that patients undergoing hemodialysis three times a week had no apparent major benefit from either a higher dialysis dose than that recommended by current U.S. guidelines or from the use of a high-flux membrane.
- > **Consortium for Radiological Imaging Studies of PKD (CRISP)**
CRISP compared radiological techniques for measuring increases in renal volume during the progression of autosomal dominant polycystic kidney disease (ADPKD), testing whether magnetic resonance can detect changes in renal volume, cyst volume, or changes in % cystic involvement over a short period of time (1 to 2 years). CRISP participants had ADPKD with relatively normal renal function and creatinine clearances. Data and samples from the first five years of the CRISP study are available.
- > **Several diabetes studies, including the Diabetes Prevention Program (DPP) and the Diabetes Prevention Trial (DPT-1)**

IMPORTANT NIH CHANGES!!!

New Human Embryonic Stem Cell Guidelines

<http://stemcells.nih.gov/policy/2009guidelines.htm>

Beginning July 7, 2009, NIH funds may support research utilizing hESCs derived from donated human embryos no longer needed for reproductive purposes. Documented assurance of voluntary informed consent needs to be obtained from the donors and the hESC line needs to be included in the NIH Registry. Applicants may submit lines to the NIH Registry at <http://stemcells.nih.gov/index.asp>.