





Agenda

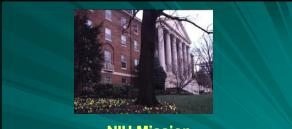
- Overview of NIH
- NICHD Research Mission & Priorities
- Research Funding Opportunities
- Career Development & Loan Repayment
- Review Process
- Some Grant Writing Tips
- Resources, Links & Contacts
- Q&A and Discussion











NIH Mission

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability.

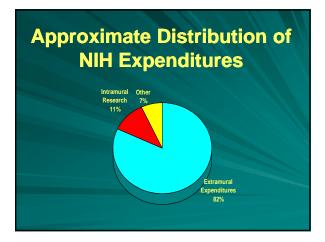
NIH Director's Five Thematic Areas

- Applying Genomics and Other High Throughput Technologies
- Translating Basic Science Discoveries into New and Better Treatments
- Using Science to Enable Health Care Reform
- Focusing on Global Health
- Reinvigorating the Biomedical Research Community

[RFA-OD-10-005]

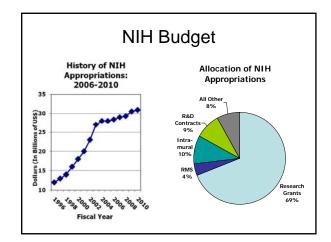
Research Support by NIH

- NIH accounts for approximately 30% of the total national support for Health R&D.
- NIH obligations account for approximately 79% of the Federal share of obligations for Health R&D.
- Approximately 80% of the NIH Budget is devoted to extramural awards.
- Over 90% of NIH's extramural awards are grants.



Annual Scope of Activities

- NIH budget of approximately \$30 billion
- Over 70,000 new or competing applications
- Over 13,000 new or competing awards
- Over 47,000 ongoing grant awards
- Approximately 3,000 study section meetings
- Approximately 80 council meetings
- Approximately 200 million pieces of paper (prior to electronic submission)



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NIA	NIAAA	NIAID	NIAMS	NCI	NICHD
NIDCD	NIDCR	NIDDK		VIEHS	NEI
NIGMS	NHLBI	NIMH			
				NINR	NHGRI
NIBIB	FIC				NLM
		cc c	IT CSR		

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

Public Law 87-838 (1962)

"...an institute for the conduct and support of research and research training related to maternal health, child health, and human development, including...the special health problems of mothers and children..."



NICHD Mission

The mission of the NICHD is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from reproductive processes, and that all children have the chance to achieve their full potential for healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.



How do we get there from here?

Contracts

Grants

Cooperative Agreements

Definitions

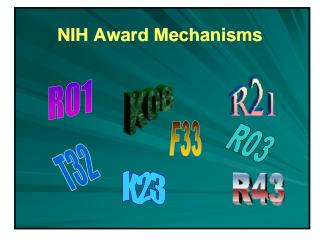
- A contract is a legal instrument used to acquire services or goods for the direct benefit or use of the Government.
- Grants and cooperative agreements are financial assistance mechanisms whereby money and/or direct assistance is provided to carry out approved activities.

Uses

- A contract is normally used when there is a need for substantial Government programmatic oversight during performance of the project.
- A grant is used whenever the awarding office anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.
- A cooperative agreement is used when substantial Federal programmatic involvement with the recipient is anticipated during performance.

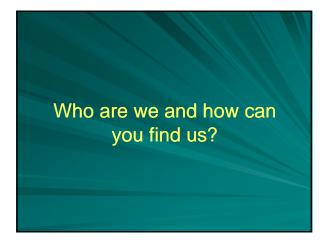
General Responsibilities

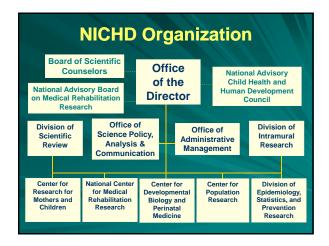
- With grants and cooperative agreements, the applicant investigators are responsible for developing concepts, methods and approaches for their research projects.
- With contracts, the awarding institute is responsible for establishing plans, protocols, and detailed requirements.

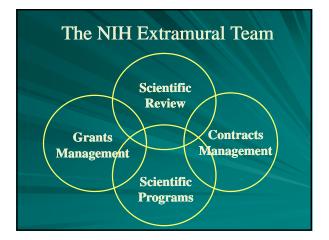


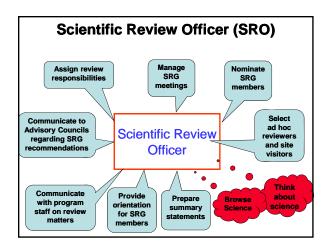
R01? RFA? FOA? SRO?

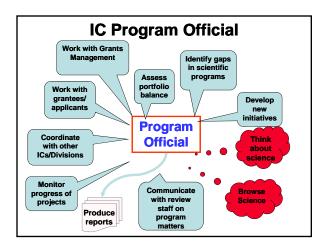
- Don't be afraid of the alphabet soup.
- Find someone to help you navigate the system.

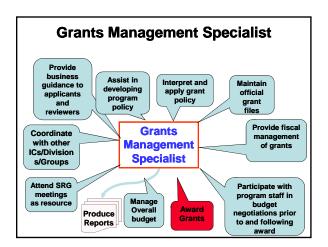
















What are our research priorities?

Center for Developmental Biology & Perinatal Medicine (CDBPM)

The CDBPM supports scientists who are advancing fundamental and clinical knowledge about maternal health and problems of child development, including preterm labor and birth, intellectual and developmental disabilities, congenital and genetic disorders, fetal growth restriction, and other conditions. The Center and its programs aim to maximize human development, prevent diseases and disorders, and improve diagnoses, therapy, and clinical care.

- Developmental Biology, Genetics & Teratology (DBGT) Branch
- Intellectual and Developmental Disabilities (IDD) Branch
- Pregnancy and Perinatology (PP) Branch

Developmental Biology, Genetics & Teratology (DBGT) Branch

The DBGT Branch supports basic and clinical research on normal and abnormal development that relates to the causes and prevention of congenital and genetic defects, as well as research training in relevant academic and medical areas. Among the Branch's high-priority research areas is basic research on elucidating the biochemical, molecular biologic, genetic, and cellular mechanisms of early development.

- Developmental Immunology
- Developmental Neurobiology
- Developmental and Clinical Genetics and Genomics
- Developmental and Reproductive Immunology
- Early Embryonic Development
- Organogenesis, Limb Development and Related Processes

Intellectual and Developmental Disabilities (IDD) Branch

The IDD Branch sponsors research and research training aimed at preventing and ameliorating intellectual and related developmental disabilities. The program supports biomedical, biobehavioral, behavioral, and translational research in etiology, pathophysiology, screening, prevention, treatment, and epidemiology.

- Behavioral, biobehavioral and social science research
- Biochemical and metabolic research
- Biomedical and genetic/genomic research
- Prenatal diagnosis, newborn screening and population screening and diagnosis

Pregnancy & Perinatology (PP) Branch

The PP Branch seeks to improve the health of mothers and children with a focus on maternal health, pregnancy, fetal well being, labor and delivery, and the developing child. The Branch supports research to: Determine basic mechanisms of normal and disease processes; identify new treatments, methodologies, and preventative strategies; assess dissemination and impact of therapeutic and preventative interventions; and increase scientific resources through recruitment and training of investigators.

- Disorders of the Newborn
- Fetal Pathophysiology
- High-Risk Pregnancy
- NICHD Neonatal Research Network (NRN): Extremely Preterm Birth Outcome Data
- Outcome Data
 Preterm Labor and Birth
- Suddent Infant Death Syndrome (SIDS)

Center for Population Research (CPR)

The CPR supports a range of population studies that aim to: understand reproductive health and biology of the male and female; establish new diagnostic and treatment methods for infertility; develop contraceptive methods that are safe, effective, inexpensive, preferably reversible, and acceptable and those that reduce the spread of sexually transmitted diseases; evaluate contraceptive methods, drugs, devices, and surgical procedures related to reproductive health; ascertain the determinants of fertility and mortality; understand the consequences of population size and distribution changes; define the antecedents and consequences of conditions that precipitate migration and immigration; examine resources and other contextual influences on family functioning and child well-being.

- Contraception and Reproductive Health (CRH) Branch
- Demographic and Behavioral Sciences (DBS) Branch
- Reproductive Sciences (RS) Branch

Contraception & Reproductive Health (CRH) Branch

The CRH Branch develops and supports research and research training programs in reproductive health, epidemiology and contraceptive technology. Major research areas include studies of: New contraceptive methods; mechanisms of action and effects of contraceptive and reproductive hormones, drugs, devices, and procedures; optimal formulations and dosages of contraceptive agents, spermicidal microbicides, and hormone replacement therapies (in animals and humans); post-marketing surveillance of reproductive products, devices, and procedures; and health and fertility effects of reproductive drugs, devices, and procedures.

- Contraception Research and Development
- Contraceptive and Reproductive Evaluation
- Prevention of HIV/AIDS and other Sexually Transmitted Infections (STIs)
- Reproductive and Gynecological Health Issues

Demographic & Behavioral Sciences (DBS) Branch

The DBS Branch supports demographic, behavioral, and social sciences research on fertility, families, population movement, morbidity and mortality, HIV/AIDS, and population composition, research on population diversity and change, studies of the consequences of population diversity and change for health and well-being, and research on the interrelationships among individual, family, group, community, and population processes are all central to this mission.

- Family, Children and Intergenerational Research
- Fertility, Infertility and Reproductive Health
- HIV/AIDS and Sexually Transmitted Infections (STIs)
- Health, Health Disparities and Mortality
- Immigrants, Migration and Population Distribution
- Population Research Infrastructure Program (PRIP)
- Race, Ethnicity, Population Composition and Change
- Research Methodologies

Reproductive Sciences (RS) Branch

The RS Branch supports research aimed at alleviating human infertility, uncovering new contraceptive leads and expanding fundamental knowledge of processes that underlie human reproduction, to include basic, clinical and translational studies that will enhance our understanding of normal reproduction and reproductive pathophysiology, as well as enable the development of more effective strategies for the diagnosis, management and prevention of conditions that compromise reproductive health.

- Fertility Preservation
- Male Reproductive Health
- Ovarian Biology
- Pre-implantation Genetics and Development
- Reproductive Endocrinology and Immunology
- Reproductive Genetics and Epigenetics
- Reproductive Medicine :Infertility and Gynecology
- Reproductive Neuroendocrinology

Center for Research for Mothers & Children (CRMC)

The CRMC supports research and research training in maternal and child health, to include gestational diabetes, antecedents of adult diseases, obesity and overweight, specific learning disabilities, mechanisms of cognition and learning, growth retardation, HIV/AIDS, and other congenital infections and diseases, and promotes research to understand the effects and effectiveness of pharmaceuticals on maternal and child health.

- Child Development and Behavior (CDB) Branch
- Endocrinology, Nutrition and Growth (ENG) Branch
- Obstetric and Pediatric Pharmacology (OPP) Branch
- Pediatric, Adolescent and Maternal AIDS (PAMA) Branch

Child Development & Behavior (CDB) Branch

The CDB Branch develops scientific initiatives and supports research and research training relevant to the psychological, psychobiological, language, behavioral, and educational development to children. The following theme characterizes all Branch programs: Development is best described and studied as a variable process in which individual differences in cognitive, social, affective, language, neurobiological maturation, environment and life experiences, and genetics interact in complex ways.

Developmental Cognitive Psychology, Behavioral Neuroscience and Psychobiology Program

- Early Learning and School Readiness Program
- Human-Animal Interaction (HAI) Research Program
- Language, Bilingualism and Biliteracy (LBB) Program Mathematics and Science Cognition and Learning: Developmental and Disorders
- NICHD Summer Research Institute in Applied Child and Adolescent Development
- Pediatric Behavior and Health Promotion Research Program
- Reading, Writing and Related Learning Disabilities Program
- Social and Affective Development/Child Maltreatment and Violence Program

Endocrinology, Nutrition & Growth (ENG) Branch

The ENG Branch provides the NICHD with a focus for research and research training in nutritional science, childhood antecedents of adult disease, developmental endocrinology, developmental neuroendocrinology, and physical growth and body composition, including bone health and obesity. Research supported in these areas is directed toward laying the groundwork for future health.

- Endocrinology
- Growth and Development
- Nutrition
- Prevention of Chronic Disease

Obstetric & Pediatric Pharmacology (OPP) Branch

The OPP Branch promotes research to improve the safety and efficacy of pharmaceuticals and to ensure centralization and coordination of research, clinical trials, and drug development activities for obstetric and pediatric populations. The Best Pharmaceuticals for Children Act (BPCA) activities at the NICHD is a major activity for the Branch, which is responsible for developing and supporting a comprehensive national effort to increase the knowledge base for understanding how to appropriately treat disease during pregnancy, infancy, and childhood using pharmaceuticals that are appropriately tested within their target populations.

- Best Pharmaceuticals for Children Act (BPCA)
- Obstetric-Fetal Pharmacology Research Unit (OPRU) Network
- Pediatric Pharmacology Research Unit (PPRU) Network

Pediatric, Adolescent & Maternal AIDS (PAMA) Branch

The PAMA Branch supports and conducts both domestic and international research into the epidemiology, natural history, pathogenesis, transmission, treatment, and prevention of HIV infection and its complications in infants, children, adolescents, pregnant women, mothers, women of childbearing age, and the family unit as a whole. The Branch seeks to maximize cooperation with other NICHD components, other federal components and agencies, and interested private organizations that share a focus on maternal, adolescent, and pediatric HIV infection and disease, while avoiding overlap with other efforts.

- Adolescent HIV Infection and Disease
- Epidemiology, Natural History and Therapeutic Research of HIV Infection in Pregnant and Non-Pregnant Women, Infants, Children and Adolescents
- Pediatric and Maternal Biomedical HIV-Related Research Issues
- Global Network

National Center for Medical Rehabilitation Research (NCMRR)

The NCMRR aims to foster development of scientific knowledge needed to enhance the health, productivity, independence, and quality-of-life of people with disabilities. A primary goal of Center-supported research is to bring the health related problems of people with disabilities to the attention of the best scientists in order to capitalize upon the myriad advances occurring in the biological, behavioral, and engineering sciences

- Behavioral Sciences and Rehabilitation Technologies (BSRT) Program
- Biological Science and Career Development (BSCD) Program
- Pediatric Critical Care and Rehabilitation (PCCR) Program
- Spinal Cord and Musculoskeletal Disorders and Assistive Devices (SMAD) Program
- Traumatic Brain Injury (TBI) Program
- Stroke Rehabilitation (TSR) Program

Division of Special Populations (DSP)

The DSP supports programs to ensure the health and well-being of children, adults, families, and communities by addressing and eliminating health disparities through the participation of diverse populations in biomedical and behavioral research within the United States and abroad. The DSP informs the public about issues related to health disparities; develops initiatives that encourage, facilitate, and increase participation of diverse populations and developing nations in biomedical and behavioral research; and develops research and scientific leadership in colleges and universities worldwide.

- Extramural Associates (EA) Program
- Research Supplements to Promote Diversity in Health-Related **Research Program**
- Academic/Community Partnership Conference Series

Division of Epidemiology, Statistics & Prevention Research (DESPR)

DESPR conducts research and supports research training in the fields of reproduction, child health, and maternal health as part of the NICHD's intramural research portfolio. The Division's research portfolio includes studies on: infant mortality; biostatistics, mathematics, and statistical methodology and consultation; epidemiology; human fecundity and fertility; pregnancy complications and adverse pregnancy outcomes; childhood injuries; teen driving; pediatric infectious diseases; birth defects; and behavioral research in health promotion and disease prevention.

How to Find Funded Projects and Potential Collaborators

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NICHD's Scientific Vision: The Next Decade

- Throughout the coming year, the NICHD will collaborate with its many stakeholders to identify the most promising scientific opportunities of the next decade across the breadth of the Institute's mission.
- The aim of this process is to develop a scientific Vision that sets an ambitious agenda and inspires the NICHD, its many partners, and the research community to achieve critical scientific goals and meet pressing public health needs.

http://www.nichd.nih.gov/vision/index.cfm

Visioning Process and Timeline

- May 2010: The NICHD convenes a group of extramural and intramural staff members to identify broad <u>scientific themes</u> that encompass the NICHD's multifaceted research portfolio.
- June 2010: Then Acting Director Dr. Alan Guttmacher, M.D., presents the proposed Vision process to the National Advisory Child Health and Human Development (NACHHD) Council, the Institute's federal advisory committee, to seek input and approval of the Vision themes.
- January—March 2011: The NICHD sponsors a series of workshops to facilitate focused discussions on the scientific opportunities and needs related to each Vision theme. White papers produced at the conclusion of the workshops form the foundation for the draft scientific Vision statement.

Visioning Process and Timeline (cont'd)

- June 2011: The NICHD holds a large multidisciplinary conference at which participants provide feedback to the draft scientific Vision statement
- September 2011: NICHD leadership presents the draft vision statement to the NACHHD Council for additional input.
- By December 2011: The NICHD completes the final version of the scientific Vision statement and prepares it for publication to inform the Institute's partners and stakeholders and to help stimulate future research activities.
- The NICHD welcomes public feedback throughout the Vision process. Please send all questions and comments to: NICHDvision@mail.nih.gov.

Overarching Questions

- In the scientific theme area, consider questions vital to the NICHD mission over the next ten years:
- What are compelling scientific research opportunities within the workshop thematic area that lie within the NICHD mission?
- To exploit these opportunities:
 - What basic, clinical, and translational research questions must be answered?
 - How would answering the questions affect public & global health? - What research tools, methods, or approaches should be developed
- to realize these scientific and public health opportunities? What innovative training and other workforce development
- activities should be pursued?

NICHD Visioning Theme Workshops

- Plasticity– January 13-14
- Reproduction– January 25-26
- Development– February 9-10
- Developmental Origins– February 14-15
- Behavior– February 17-18
- Pregnancy and Pregnancy Outcomes- February 22-23
- Diagnostics and Therapeutics March 1-2
- Environment– March 10-11
- Cognition– March 14-15

Vision Themes: Cross-cutting Issues (topics important to all scientific Vision theme areas)

- Analytical and measurement
- tools & methods
- Animal & computational models Global health
- Bioethics
- Bioinformatics
- Biotechnologies/bioengineering, Nutrition including high throughput, Prevention assistive, and other related technologies
- Developmental Trajectory
- Differences/disparities across populations
- Epigenetics/meta-genomics
- Functional status
- Implementation science,
 - including health economics
- Prevention/personalized medicina
 - Stem cells Systems biology
 - Training and mentoring

Funding Opportunity Announcements

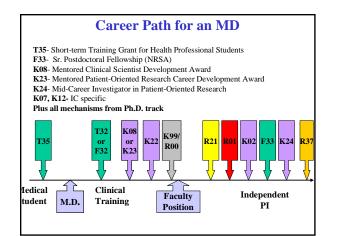
Current NICHD RFAs

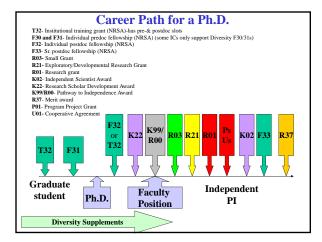
- RFA-HD-12-105: The Role of Human-Animal interactions in Child Health and Development (R03) – receipt date: 12/21/2010
- RFA-HD-10-017: Identifying and Understanding Effective Interventions for Orphans and Vulnerable Children Affected by HIV/AIDS (R01) – receipt date: 12/30/2010
- RFA-HD-10-001: Systems Oriented Pediatric Obesity Research and Training (SPORT) Center of Excellence (U54) – receipt date: 12/30/2010
- RFA-HD-12-169: Specialized Cooperative Centers
 Program in Reproduction and Fertility Research (U54) receipt date: 5/26/2011

Some Recent NICHD PAs

- PAR-11-039/040/041: Understanding and Treating Co-Morbid Conditions in Adolescents with Intellectual and Developmental Disabilities (R01/R03/R21)
- PAR-10-276: Dual Purpose with Dual Benefit: Research in Biomedicine and Agriculture Using Agriculturally Important Domestic Species (R01)
- PAR-10-230/231/232: Innovative Therapies and Tools for Screenable Disorders in Newborns (R01/R03/R21)
- PAR-10-221/222: Biophysical and Biomechanical Aspects of Embryonic Development (R01/R21)
- PAR-10-190/191/192: Vulvodynia Systematic, Epidemiologic, Etiologic or Therapeutic Studies (R01/R03/R21)
- PAR-10-154: Innovative Neuroscience K-12 Education (SBIR: R43/R44)









Fellowships (Fs)

- NRSA- National Research Service Award
- Legislated, program began in 1974 (P.L. 93-348)
- Individual awards under a mentor
- Training can be at domestic or foreign institutions
- Fund pre- and postdoc trainees in any scientific area within our scientific mission
- Can be basic or clinical most are basic
- Most awardees are for Ph.D.s
- F Kiosk: http://grants.nih.gov/training/F files nrsa.htm

Career Development Awards (Ks)

- Individual awards
- Mechanisms for basic and clinical Investigators
- Some mentored others not
- Some designed as awards for faculty investigators
- Newer programs (K22 and K99/R00) are transition awardsthese are for MDs and PhDs
- K Kiosk:
 - http://grants.nih.gov/training/careerdevelopmentawards.htm

Training Grants

- Some all predoc/some all postdoc
- Most are a mixture of slots
- Funds are mostly for tuition and trainees
- Training Related Expenses may be used to defray costs such as staff salaries, equipment, research supplies, and other expenses directly related to the training program
- Costs:
 - Tuition- 60% of requested tuition, capped at \$16,000 (\$21K for MD-PhD programs)
 - Stipends- \$20,772 pre/ postdoc \$36,996 (level 0)-\$51,036 (level 7)
 - Training Related Expenses- \$4,200 pre/\$7,850 (post); both include health insurance
 - Travel- \$400-\$1000
 - F&As- 8%

F30s and F31s Predoc Fellowships

Individual awards

- Cannot change the scope, move fellowship, or change mentor without prior NIH approval! (They do anyway)
- Predoctoral NRSA awards limited to 5 years total
- Tuition- 60% of requested tuition, capped at \$16,000 (\$21K for MD-PhD programs)
- Stipends- \$20,772 pre
- Training Related Expenses- \$4,200 includes health insurance
- Travel- \$400-\$1000

F32s Postdoc NRSA Fellowships

- Postdoc only
- Individual award
- Cannot change the scope, move fellowship, or change
- mentor without prior NIH approval! (They do anyway)
- NRSA support for up to 3 years total
- Stipends- \$36,996 (level 0)-\$51,036 (level 7)
 - Training Related Expenses- \$7,850; includes health insurance
 - Travel- \$400-\$1000

F33 Senior Postdoc Fellowships

- Not for postdocs who have been postdocs a long time
- Used for associate or full professors who want support
- for a sabbatical
- For MDs or PhDs
- Few applicants too little money
- Stipend = \$51,036
- Training Related Expenses \$7,850; includes health insurance
- Travel- \$400-\$1,000

Fellowship Review Criteria

- In addition to an Overall Impact score there are five Core Review Criteria for Fellowships:
 - Fellowship Applicant
 - Sponsors, Collaborators, and Consultants
 - Research Training Plan
 - Training Potential
 - Institutional Environment & Commitment to Training

K01- Mentored Research Scientist **Development Award**

- Support development experiences leading to research independence, training in new field or following hiatus in a research career (varies by IC)
- MDs or PhDs
- 3-5 years
- Salary Cap varies by IC + FBs
- Research Support: up to \$50,000/yr (varies by IC)
- F&As= 8%
- IC contacts and policies:
- http://grants2.nih.gov/grants/guide/pa-files/PA-10-056.html IMPORTANT: NICHD K01s limited to Medical Rehabilitation Medicine, Child Abuse and Neglect, and Population Research.

K02 Independent Scientist Award

- Best candidate is a "senior" assistant professor or "junior" associate professor
- Close to or recently promoted and tenured
- Must have independent grant support as PI, e.g., R01
 MDs (very few) and PhDs
- Salary support only
- Salary cap varies by IC + FBs for up to 5 years
- Gives up salary support from all other NIH grants!
- Relatively few applicants
- F&As= 8%

K08- Mentored Clinical Scientist Development Award K23- Mentored Patient-Oriented Research Career

- K08 supports didactic study and mentored research for individuals with clinical doctoral degrees
- K23 for clinical/patient-oriented project
- 3-5 yr award, varies by IC
- Salary cap varies by IC + FBs
- Research Support up to \$50,000/yr (varies by IC)
- F&As= 8%
- For IC Contacts and policies
 - <u>http://grants.nih.gov/grants/guide/contacts/parent_K08.html</u>
 - <u>http://grants.nih.gov/grants/guide/contacts/parent_K23.html</u>

K24 Mid-Career Investigator Award in Patient-**Oriented Research**

- Provide support for clinician investigators to allow them protected time to devote to patient-oriented research (POR) and to act as research mentors primarily for junior clinicians
- 3-5 years
- Typically MDs
- Salary cap varies by IC + FBs
- Research Support \$25,000 \$50,000 (varies by IC)
- F&As= 8%
- http://grants.nih.gov/grants/guide/contacts/parent K23.html

K25- Mentored Quantitative Research **Development Award**

- For individuals from a quantitative background (e.g., mathematics, statistics, economics, computer science, imaging science, informatics, physics, chemistry, and engineering) who want to apply their expertise to a biomedical problem and are not already working in a health or disease related topic
- 3-5 years
- Salary cap varies by IC + FBs
- Research Support: \$20,000 \$50,000 (varies by IC)
- F&As= 8%
- http://grants.nih.gov/grants/guide/contacts/parent K25.html

K99/R00 Pathway to Independence Award

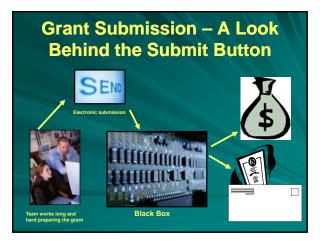
- Supported by almost all ICs with variations
- Transition award for postdocs moving to assistant professor positions (tenure track or equivalent)
- No citizenship/"green card" requirement
- K99 mentored phase (up to 2 years)
- R00 independent phase (up to 3 years; 75% effort)
- Requires mentor(s)
- *Up to \$90,000/yr total cost for K99 phase; 8% F&A
- \$249,000/yr total cost for R00 phase
- http://grants.nih.gov/grants/guide/contacts/parent K99 R00.html

Career Award Review Criteria

In addition to an Overall Impact score there are five Core Review Criteria (criterion scores) for K-award applications :

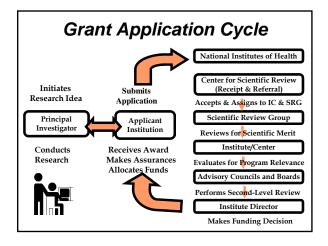
- Candidate
- Career Development Plan/Career Goals & Objectives/Plan to Provide Mentoring
- Research Plan
- Mentor(s), Consultants(s), Collaborator(s).
- Environment and Institutional Commitment to the Candidate





What's inside the "black box"?

- What happens between the time you submit an application and the time you receive either good or bad news about the outcome?
- How will this knowledge help you to guide and assist prospective applicants at your institution?



Typical Timeline for a New Individual **Research Project Grant Application** (R01)

There are three overlapping cycles per year:

- Submit in February (June, October)
 - Review in June (October, February)
 - Council in September (January, May)
 - Earliest award in December (April, July)

Cycle 1 ----Cycle 2 ---http://grants1.nih.gov/grants/funding/submissionschedule.htm

Over 80,000 applications are received each year by CSR, which checks for compliance with NIH policies and then makes 2 assignments:

- Program assignment to Institute/Center (IC) for possible funding consideration
- Review assignment to a Scientific Review Group (SRG)

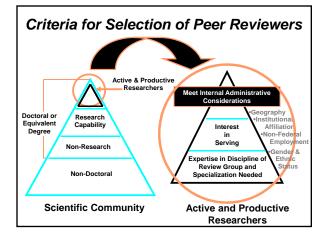


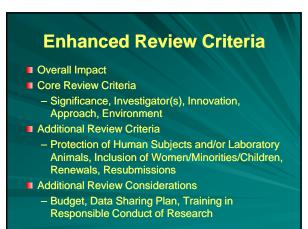
- Fellowship Grants
- [F32, F31]
- **Small Business Grants**
- Awards [K Series]
- RFAs
- Contracts

NICHD Division of Scientific **Review: Organizational Structure**

- Chartered Initial Review Group with 8 subcommittees
 - Pediatrics
 - Developmental Biology
 - Biobehavioral & Behavioral Sciences
 - Population Sciences
 - Obstetrics & Maternal-Fetal Biology

 - Reproduction, Andrology & Gynecology
 Function, Integration & Rehabilitation Sciences
- Health, Behavior and Context
- Special Emphasis Panels (as needed)





Scoring

- Applications are scored on a scale of 1 9 (1= best possible score)
- Criterion scores given by assigned reviewers
- Overall impact/priority score is given by all reviewers when the application is discussed at the meeting (usually the "upper half")
- Applications in the "bottom half" may receive a rating of "Not Discussed" – they do not receive a full discussion or numerical impact /priority score

Impact	Score	Descriptor	NIH Scoring System Additional Guidance on Strengths/Weaknesses
High	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	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	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

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

Communicating the Results

- An overall impact/priority score is calculated from the reviewers' individual scores
- The SRO prepares a summary statement:
 Verbatim written critiques by assigned reviewers
 - Criterion scores by assigned reviewers
 - Committee recommendations regarding budget, human subjects, laboratory animals, inclusion
 - "Resume and Summary of Discussion" section that captures the discussion and highlights the major strengths and weaknesses (when applications are discussed at the meeting)

Feedback on Peer Review Enhancements

- https://loop.nigms.nih.gov
- Evaluation Surveys







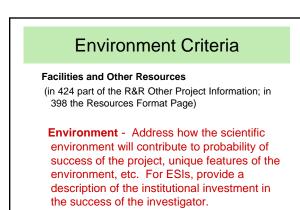
Biographical Sketch

Personal Statement – tell us why your experience and qualifications make you particularly well-suited for your role in the project

- Publications to be limited to 15
 - 5 most recent
- 5 best
- 5 most relevant to the application



Current Application	New Application
Current Application	New Application
Background and	Research Strategy
Significance	a. Significance
Research Design and	b. Innovation
Methods	c. Approach
Preliminary Studies/Progress Report	Preliminary Studies for New Applications
	 Progress Report for Renewal/Revision



Summary Resu	Its of Alignment
Core Review Criteria	Addressed in these sections of the Application
Significance	Research Strategy a. Significance
Investigator(s)	Biosketch Personal Statement
Innovation	Research Strategy b. Innovation
Approach	Research Strategy c. Approach
Environment	Resources Environment

Application Changes		
Shorter Research Strategy		
Introduction to Resubmission or Revision – all Activity Codes*	1	
Specific Aims – all Activity Codes*	1	
Research Strategy R03, R13, U13, R21, R36, SC2, SC3, R41and R43	6	
Research Strategy R01, R15, R18, U18, R33, R21/R33, R34, U34, DP3, G08, G11, G13, UH2/UH3, SC1, R42 and R44	12	
Research Strategy – all other Activity Codes	see FOA	
Combined Candidate Information and Research Strategy (K)	12	
Program Plan (K12, Kirschstein Ts, R25)		
Biographical Sketch	4	
* Except training (T and K12 – 3 pages) 104		

Some General Guidance for Grant Writing

- Understand the NIH application and review process
- Learn about IC priorities and goals
 - Not all ICs support all grant programs
 Each IC has a research training and career
- development programIdentify the grant programs offered by each IC
- Make early contact with program officers
- Find good mentors and collaborators
- Study successful grant applications
- Only propose your best and most creative ideas
- You won't get a grant if you don't apply

First Principles for Preparing a Successful Application

- Read the application instructions carefully
- Read the application instructions carefully
- Read the application instructions carefully
- Don't forget ...
 - ... read the application instructions carefully

Additional Principles

Have a Good Idea.

- Do your homework with the Institute.
- Allow plenty of time.
- Be kind to your reviewers
- Tell a good story
- Allow time for "pre-review" at your institution

Good Idea

- Does it address an important problem?
- Will scientific knowledge be advanced?
- Does it build upon or expand current knowledge?
- Is it feasible …
 - to implement?
 - to test?

5B

Homework

- Search Institute & NIH web sites.
- Contact program staff early in the process.
- Assess Institute interest and "goodness of fit" with Institute priorities.
- What are the related program announcements?
- The web is an important place to start ... but it does not replace personal contact

Be Kind to Your Reviewers

- Reviewers work late at night Help them stay alert and interested.
- Never assume that reviewers "will know what you mean."
- Make your application easy to read and understand.
- Include well-designed tables and figures.
- Present an organized, lucid write-up.
- PROOF READ!

Tell A Good Story

- Why is your area of research important public health implications?
- What is currently known in this area? What are the leading theories?
- What is not known?
- How does your research fill a gap or advance the field?

Tell A Good Story (cont'd)

- How does your theory differ from existing theories? (if relevant)
- Show how your hypotheses follow from existing knowledge and theory.
- Convince the reviewers to advocate for your research.
- Present clearly

Good Presentation

- Remember the 5 Review Criteria
- Significance
- Approach
- Innovation
- Investigator
- Environment

Good Presentation

PHS 398 and PHS 398 Component (for electronic applications):

- Organize *Items A-D* (or 1-4) of the Research Plan to answer these questions:
- What do you intend to do?
- □ Why is the work important?
- What has already been done?
- □ How are you going to do the work?

Specific Aims

- State the hypotheses clearly.
- Show that the objectives are attainable within the stated time frame.
- Don't bite off more than you can chew.
- Be clear and succinct

Background and Significance

The purpose of the background and significance section is to state the problem to be investigated, the rationale for the proposed research, the current state of knowledge relevant to the proposal and the potential contribution of this research to the problem(s) addressed.

Background and Significance

- Does this study address an important problem?
- If the aims of the application are achieved, how will scientific knowledge be advanced?
- What will be the effect of these studies on the concepts or methods that drive this field?

Background and Significance

- Is the literature review complete?
- Not just research that supports your hypotheses.
- Cast a wide net for relevant studies.
- Acknowledge inconsistencies in field.
- Showcase your knowledge of the field.

Preliminary Findings

- Build reviewer confidence you can handle the technologies, understand the methods, and interpret results.
- Interpret preliminary results critically.
- May include publications of others, but focus on your own preliminary data.
- When using results from other labs, make sure it's clear which data are yours and which emanated from others!

BUT I DON'T HAVE PRELIMINARY DATA!?!

- Not required for Exploratory/Developmental (R21) applications
- New Investigators are not expected to have as much preliminary data or prior publications

Research Design and Methods

- Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project?
- Does the applicant acknowledge potential problem areas and consider alternative tactics?

Research Design and Methods

- overview of the experimental design;
- detailed description of specific methods to accomplish the specific aims;
- How data will be collected, analyzed, and interpreted;
- timetable (work plan);

Research Design and Methods

- any new methodology used and why it represents an improvement; potential difficulties and limitations and how these will be overcome
- expected results, and alternative approaches that will be used if unexpected results are found;
- precautions to be exercised with respect to any procedures, situations, or materials that may be hazardous to personnel or human subjects.

Common Problems in Applications

- Lack of new or original ideas
- Absence of an acceptable scientific rationale
- Lack of experience in the essential methodology
- Questionable reasoning in experimental approach
- Uncritical approach

Common Problems in Applications (cont'd)

- Diffuse, superficial, or unfocused research plan
- Lack of sufficient experimental detail
- Lack of knowledge of published relevant work
- Unrealistically large amount of work
- Uncertainty concerning future directions

Good Grantsmanship

- Show your application to a colleague
- Show your application to a colleague who is naïve
- Show your application to a colleague who does not like you

Good Grantsmanship

- Your readers need to understand:
 - what you propose to do
 - how you are going to do it
 - why you believe it is important
- If they don't get it, you must revise
- Leave enough time to make revisions

There is no grantsmanship that will turn a bad idea into a good one, but......

There are many ways to disguise a good one.

William Raub, Past Deputy Director, NIH



Some Special Requirements

- Protection of Human Subjects
- Data Safety & Monitoring Plan
- Inclusion of Women and Minorities as Subjects in Clinical Research
- Inclusion of Children in Clinical Research
- Laboratory Animal Welfare
- Data Sharing Plan
- Applications Requesting \$500,000 or more (direct costs) in any budget year

Protection of Human Subjects

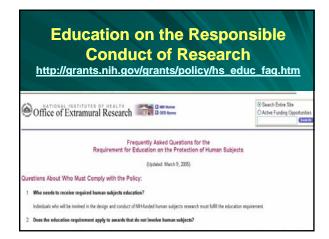
The application should address:

- Risks to the subjects
 - Human subjects involvement and characteristics
 - Sources of materials
 - Potential risks
- Adequacy of Protection against Risks
 - Recruitment and informed consent
 - Protection against risk
- Potential benefits of the proposed research to the subjects and others
- Importance of the knowledge to be gained
- Data and safety monitoring plan

Data and Safety Monitoring http://grants2.nih.gov/grants/policy/hs/data_safety.htm







Inclusion of Women and Minorities as Subjects in Clinical Research

- Required by law NIH Revitalization Act of 1993 (PL 103-43)
- Based on the ethical principle of Justice:
 - Need to share equally in both risks and benefits of research
 - · Knowledge gained from research should be generalizable to entire population
- The NIH policy is science driven designed to fill gaps in knowledge

NIH Revitalization Act of 1993

(PL 103-43)

NIH must:

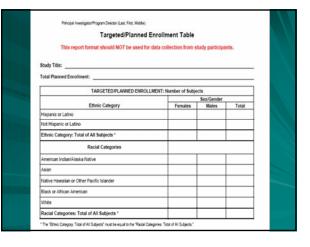
- ensure that women and members of minorities and their subpopulations are included in all human subject research:
- for Phase III clinical trials, ensure that women and minorities and their subpopulations must be included such that valid analyses of differences in intervention effect can be accomplished;
- not allow cost as an acceptable reason for excluding these groups; and
- initiate programs and support for outreach efforts to recruit these groups into clinical studies.

Inclusion of Women and Minorities as Subjects in Clinical Research

The application should address:

- The targeted/planned distribution of subjects by sex/gender and racial/ethnic groups for each proposed study or protocol using the format in the Targeted/Planned Enrollment Table
 A description of the subject selection criteria and rationale for selection of sex/gender and racial/ethnic group members in terms of the scientific objectives and proposed study design

- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
 A description of proposed outreach programs for recruiting sex/gender and racial/ethnic group members as subjects.
- If your proposed research includes an <u>NIH-Defined Phase III</u> <u>Clinical Trial</u>, the section on Inclusion of Women and Minorfiles also must address whether you expect to find clinically important sex/gender and/or race/ethnicity differences in the intervention effect



Inclusion of Children in Clinical Research

- For the purpose of implementing these guidelines, a <u>child</u> is defined as an individual under the age of 21 years.
 The application should include:

 a description of the plans to include children, or an acceptable justification if children will be excluded from the proposed research,
 a rationale for selecting a specific age range of children
- a rationale for selecting a specific age range of children
 a description of the expertise of the investigative team for dealing with children at the ages included, and of the appropriateness of the available facilities to accommodate the children
 a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study
 When children are involved in research, the Additional Protections for Children arevise as Subjects in Research (<u>45 CFR Part 46 Subpart D</u>) apply and must be addressed in the "Human Subjects Research and Protection from Risks" subheading.

Justifications for Excluding Children

- 1. The research topic to be studied is not relevant to children.
- The research logic to be studied is not netwark to children in the research.
 The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be needlessly redundant. Documentation of other studies justifying the exclusions should be provided.
- 4. A separate, age-specific study in children is warranted and preferable, when:
- 4. A separate, age-specific study in children is warranted and preferable, when:

 a. The condition is relatively rare in children, as compared to adults; or
 b. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
 c. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children

 5. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment).
 6. Study design preclude the content adult adults and previously exponent.
- 6. Study designs are alimed at collecting additional data on previously enrolled adult study subjects
 7. Other special cases can be justified by the investigator and found acceptable to the review group and the Institute Director.



Laboratory Animals

- Provide a detailed description of the proposed use of the animals (species, strains, ages, sex, and numbers of animals to be used). Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
- Provide information on the veterinary care of the animals involved. Provide information on the veterinary care of the animals involved Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

NIH Policy on Sharing of Model Organisms for Biomedical Research



Investigators submitting an NIH application/proposal beginning with the October 1, 2004 receipt date are expected to include a specific plan for sharing and distributing unique model organism research resources generated using NIH funding in the application/proposal OR state appropriate reasons for why such sharing is restricted or not possible





NIH Guide Notice: May 7, 2004 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html

FAQs and sample sharing plans available at: http://grants.nih.gov/grants/policy/model_organism/index.htm

NIH Policy on Data Sharing

Investigators submitting a research application requesting \$500,000 or more of direct costs in any single budget period to NIH on or after October 1, 2003 must include a plan for sharing final research data for research purposes, or state why data sharing is not possible.

NIH Guide Notice, February 26, 2003: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

NIH Guide Notice, October 16, 2001: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-004.html

NIH Large Grants Policy

- Pre-approval is required for investigator-initiated applications requesting \$500,000 or more (direct costs) for any year, exclusive of consortium/contractual F&A costs.
- Applies to new, competing continuation, competing supplement, or revised applications; but does not apply to FOAs that include specific budgetary limits.
- Applicants are required to contact NIH staff at least 6 weeks before submission date.
- Applications must include a cover letter indicating prior staff concurrence and identifying the program staff contacted.
- Applications without prior staff concurrence will be returned

Stem	Cell Infor I Institutes of Health of Research Topics	mation resource for steen cell re	Ansourcements	Search Tips Search	
Frequently Asker What are stem cell Can they care dise	Is7 (09) ases7 • De	DOJ Files Motion to Stay with Appeals Court (09/08/10)		hESC Toolbox Information for cell line derivers and grantees	
Are there ethical is What is the U.S. p More FAQs Links to related re	Nicy?			 NOT-OD-10-136 Amended Status of Applications and Awards Involving Human Embryonic Stem Cells, and 	
Stem Cell Researc	ch. * 190	tice of Appeal	Submissions of Stem Cell Lines for Eligibility Consideration (09/10/10)		
NIH Stees Cell Unit Current Research		 Motion to Stay - On September 7, 2010, Judge Royce C. Lamberth denied DOJs Motion to Stay. 			
Upcoming Events Funding for Resear Training Programs		U.S. Policy on Stem Cell Research On March 9, 2009, President Obama issued Executive Order 13505, entitled "Removing		 NIH Statement regarding Stay of Stem Cell Injunction (09/10/10) 	
Scientific Literatur	-	Barriers to Res Stem Cells.*	NIH Director's Response to Stem Cell Injunction (08/27/10		
Tools Site Map	_	Read About the	Executive Order •		
Glossary	* N	* NIH Guidelines on Human Stem Cell Research		 Submit a hESC line for NIH review 	
Downloads	Prop	osed Change to NI	Guidelines	and the second s	
Text size: smaller		Enderal Register announcement of proposed change to NRH Guidelines		hESC Eligibility Review Advisory Committee to the Director Working Group for	

Tracking the Status of Your Application in the eRA Commons

Status information will include:

- Receipt confirmation & application number
- NIH Institute/Center assignment & Program contact info.
- Review Group assignment, meeting date & Scientific Review Administrator (SRA) contact info.
- Priority score (when available)
- Summary statement (when available)



Things to Do Right Now Register at least 4 WEEKS IN ADVANCE of the application submission date. Familiarize yourself with the Electronic Submission of Grant Applications web site and contents, and check periodically for updates. Consult with your Authorized Organizational

- Consult with your Authorized Organizational Representative (AOR).
- Use the NIH Guide for Grants and Contracts, or search Grants.gov to find Funding Opportunity Announcements (FOAs).

Software Requirements

PureEdge viewer downloaded (free) from Grants.gov site at <u>http://www.grants.gov/DownloadViewer</u>

PDF generation software

 Grants.gov lists some available tools and software <u>http://www.grants.gov/assets/PDFConversion.pdf</u>.

MAC users will need to use PC emulation software or download free CITRIX client application to take advantage of the CITRIX service offered by Grants.gov in partnership with NIH. <u>http://www.grants.gov/MacSupport</u>

 PureEdge has committed to providing a platform independent viewer by November 2006. PureEdge viewer downloaded (free) from Grants.gov site at <u>http://www.grants.gov/DownloadViewer</u>



Important URLs

- Register in eRA Commons by following the instructions in the document at http://era.nih.gov/docs/Grantee%20Registration%20Process%20for%20Commons.pdf
- Register in Grants.gov at: : <u>http://www.grants.gov/GetStarted</u>.
- Obtain a DUNS number at: http://www.dnb.com/us/.
- Register through CCR (Central Contractor Registration) at: https://www.bpn.gov/ccr/scripts/indexconfirm.asp.
- Download PureEdge Viewer and upgrade at http://www.grants.gov/DownloadViewer.
- Download Adobe .pdf generator at: <u>http://www.grants.gov/assets/PDFConversion.pdf</u>
- Download RealPlayer to view training presentations at http://www.real.com/freeplayer/?rppr=fed

More Helpful Links

- OER Electronic Receipt Intranet Website: http://inside.era.nih.gov/ElectronicReceipt/index.htm
- Grants.gov website: http://www.grants.gov/
- For help with content questions, contact Grants Info at: <u>GrantsInfo@nih.gov</u>
- For help with registration on Grants.gov, downloading PureEdge application or forms, contact the Grants.gov help desk at: <u>support@grants.gov</u>
- For help with registration on eRA Commons, questions regarding the Commons validation process, accessing summary statements, etc, contact the NIH help desk at: <u>commons@od.nih.gov</u>
- Directions for non-windows users: http://www.grants.gov/MacSupport

