

Pre-Application Technical Assistance Webinar for  
NICHD Program Announcements for “Vulvodynia -  
Systematic Epidemiologic, Etiologic or Therapeutic  
Studies”

***Overview of the Research Program, Grant  
Mechanisms, and Grant Application Basics***

July 22, 2011

Estella C. Parrott, M.D., M.P.H.

Reproductive Sciences Branch, Center for Population Research  
*Eunice Kennedy Shriver* National Institute of Child Health  
and Human Development, National Institutes of Health



# Meeting Overview

- Overview of the Vulvodynia Research Program
- Grant Mechanisms
- Grant Application Basics
- Highlights of the NIH Peer Review Process
- Grant Writing for Success: Your Funded NIH Application

**Health Information**

[A to Z health & human development topics](#)

[Clinical research & clinical trials](#)

[Health education](#)

[Publications & materials](#)

## Vulvodynia

### What is vulvodynia?

Vulvodynia is a term used to describe chronic pain or discomfort of the [vulva](#).

Health care providers do not know what causes vulvodynia. It is diagnosed when other causes of vulvar pain, such as infection or skin diseases, are ruled out.

NICHD-funded research estimates that as many as 16 percent of women suffer from chronic vulvar pain at some time in their lives.

### What are the symptoms of vulvodynia?

The main symptom of vulvodynia is pain. The type of pain can be different for each woman.

Vulvodynia can cause burning, stinging, irritation, or rawness of the vulva. Pain may move around or always be in the same place. It can be constant, or come and go.

### What is the treatment for vulvodynia?

There is currently no cure for vulvodynia. But there are treatments for some of the symptoms. Some current treatments include local pain relievers (medications), physical therapy, changes in diet, and drug treatment.

Because each woman's symptoms may be different, no one treatment works all the time or is right for everyone. If you have chronic vulvar pain or discomfort, talk to your health care provider about possible treatments.



#### For More Information:

##### Clinical Trials

- [NICHD Related Clinical Trials](#)
- [All Related Clinical Trials](#)

##### News Releases

- [Roughly One Quarter of U.S. Women Affected By Pelvic Floor Disorders](#)
- [All Related News](#)

##### Publications/Materials

- [Vulvodynia Packet](#)
- [Fibromas Uterinos](#)
- [All Related Publications](#)

##### Web Sites

- [National Vulvodynia Association](#)
- [ORWH - Vulvodynia](#)
- [Pelvic Floor Disorders Network](#)

##### Contact Information:

NICHD Information Resource Center  
Address:  
P.O. Box 3006  
Rockville, MD 20847  
Phone: 1-800-370-2943  
984-1473

[NICHD@ mail.nih.gov](#)

[All Contacts](#)

<http://www.nichd.nih.gov/health/topics/Vulvodynia.cfm>

- [Vulvodynia: Toward Understanding a Pain Syndrome](#)

# Vulvodynia Program Objectives

- Purpose: To invite investigator-initiated applications that address basic, clinical, translational, epidemiological and/or behavioral research on vulvodynia and related symptom-based conditions.
- Goal: To facilitate new research on diagnostic, prevention, and therapeutic approaches to vulvodynia, a chronic pelvic pain condition in women.
- Expected Outcome: To provide findings useful for development of future prevention or treatment strategies. It is anticipated that these studies will increase our understanding of the pathophysiology, biologic and behavioral risk factors, natural history, and genetics of vulvodynia.

# Overall Research Scope

- To increase our knowledge about the underlying mechanisms.
- To stimulate studies in this underresearched area.
- To build a foundation for assessing improved clinical applications and future research needs that complement our overall commitment to support research important to women's health.

# Funding Opportunity Announcements (FOA)

- Program Announcement (PA)
  - Identifies areas of increased priority and/or emphasis on particular funding mechanisms for a specific area of science
  - Usually accepted on standard dates
  - Remains active for three years from date of release unless the announcement indicates a specific expiration date or the NIH Institute/Center (I/C) inactivates sooner
  - Special Types
    - **PAR: A PA with special receipt, referral and/or review considerations, as described in the PAR announcement**
    - **PAS: A PA that includes specific set-aside funds as described in the PAS announcement**

# **Grant Mechanisms**

# **Vulvodynia - Systematic Epidemiologic, Etiologic or Therapeutic Studies (R03)**

**PAR-10-191**

**Application Submission Dates:**

**September 21, 2010, September 21, 2011, September 21, 2012**

**<http://grants.nih.gov/grants/guide/pa-files/PAR-10-191.html>**

# R03 Mechanism of Support

- Small Research Grant R03 award mechanism
- The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project

# NIH Small Research Grant (R03)

## R03 Grant Mechanism:

- Specific Aims limited to 1 page
- The Research Strategy may not exceed 6 pages, including tables, graphs, figures, diagrams, and charts
- No preliminary data are required, but may be included if available
- One resubmission (A1) is allowed
- Introduction required for a resubmission is limited to one page
- No renewal applications (formally competing continuation)
- Ideal support for new investigators to generate sufficient data for R01 submission

# R03 Research Projects

## Types of Projects:

- Pilot or Feasibility Studies
- Small self-contained research projects
- Development of research methodology
- Development of new research technology
- Secondary analysis of existing datasets
- High risk/high payoff studies

# R03 Funds Available

- NICHD primary sponsor
- ORWH co-sponsor
- A project period of up to two years
- Budget for direct costs of up to two \$25,000 modules, or \$50,000 per year, may be requested (i.e., a maximum of \$100,000 over two years in four modules of \$25,000 each)
- Commensurate Facilities and Administrative (F&A) costs are allowed

# **Vulvodynia - Systematic Epidemiologic, Etiologic or Therapeutic Studies (R21)**

**PAR-10-192**

**Application Submission Dates:**

**September 21, 2010, September 21, 2011, September 21, 2012**

**<http://grants.nih.gov/grants/guide/pa-files/PAR-10-192.html>**

# R21 Mechanism of Support

- NIH Exploratory/Developmental Research Grant (R21) award mechanism
- The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project

# NIH Exploratory/Developmental Research Grant (R21)

## R21 Grant Mechanism:

- Specific Aims limited to 1 page.
- The Research Strategy may not exceed 6 pages, including tables, graphs, figures, diagrams, and charts.
- No preliminary data are required, but may be included if available
- One resubmission (A1) is allowed
- Introduction required for a resubmission is limited to one page
- No renewal applications (formally competing continuation)
- Direct costs are limited to \$275,000 over a two-year period, with no more than \$200,000 in direct costs allowed in any single year

# R21 Research Projects

## Types of Projects:

- Feasibility of a novel scientific area of investigation
- New experimental system with potential to enhance health-related research
- Development of novel techniques, agents, model systems, methodologies or applications that could have a major impact
- Studies may involve considerable risk but may lead to a breakthrough in a particular area
- No preliminary data are required, but is highly advised

# R21 Research Objectives

- By using the R21 grant mechanism, the NIH seeks to foster the introduction of novel scientific ideas, model systems, tools, agents, targets, and technologies that have the potential to substantially advance biomedical research
- R21 mechanism is intended to encourage new exploratory and developmental research projects
- Projects could assess the feasibility of a novel area of investigation or a new experimental system that has the potential to enhance health-related research
- Unique and innovative use of an existing methodology to explore a new scientific area
- Studies may involve considerable risk but may lead to a breakthrough in a particular area, or to the development of novel techniques, agents, methodologies, models, or applications that could have a major impact on a field of biomedical, behavioral, or clinical research

# R21 Research Objectives

- Applications for R21 awards should describe projects distinct from those supported through the traditional R01 mechanism
- Long-term projects, or projects designed to increase knowledge in a well-established area, will not be considered for R21 awards
- Applications submitted under this mechanism should be exploratory and novel
- Studies should break new ground or extend previous discoveries toward new directions or applications
- Projects that use widely accepted approaches and methods within well established fields are better suited for the R03 or R01 mechanism depending on their scope and budget

# R21 Available Funds

- NICHD primary sponsor
- ORWH co-sponsor
- Direct costs are limited to \$275,000 over a two-year period, with no more than \$200,000 in direct costs allowed in any single year
- Applicants may request direct costs in \$25,000 modules, up to the total direct costs limitation of \$275,000 for the combined two-year award period.

# R21 Budget Component

- U.S. applicants submitting an application with direct costs in each year of \$250,000 or less (excluding consortium Facilities and Administrative [F&A] costs) must use the PHS398 Modular Budget component
- U.S. applicants requesting more than \$250,000 in annual direct costs and all foreign applicants must complete and submit budget requests using the Research & Related Budget component

# **Vulvodynia - Systematic Epidemiologic, Etiologic or Therapeutic Studies (R01)**

**PAR-10-190**

**Application Submission Dates:**

**September 21, 2010, September 21, 2011, September 21, 2012**

**<http://grants.nih.gov/grants/guide/pa-files/PAR-10-190.html>**

# R01 Mechanism of Support

- This FOA will use the R01 (Research Project Grant) award mechanism.
- The R01 is the original and historically oldest grant mechanism used by NIH.
- The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project.

# NIH Research Project Grant (R01)

## R01 Grant Mechanism:

- Specific Aims limited to 1 page
- The Research Strategy may not exceed 12 pages, including tables, graphs, figures, diagrams, and charts
- Preliminary data are required
- Project period from 1 to 5 years
- One resubmission (A1) is allowed
- Introduction required for a resubmission is limited to one page
- Renewal applications are permitted (formally competing continuation)

# R01 Research Objectives

- The R01 provides support for health-related research and development based on the mission of the NIH.
- R01s can be investigator-initiated or can be in response to a program announcement or request for application.
- The R01 is an award made to support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing the investigator's specific interest and competencies, based on the mission of the NIH.

# R01: Funds Available

- NICHD primary sponsor
- ORWH co-sponsor
- The R01 uses the modular as well as the non-modular budget formats
- Specifically, a U.S. organization submitting an application with direct costs in each year of \$250,000 or less (excluding consortium Facilities and Administrative [F&A] costs) should use the PHS398 Modular Budget component
- U.S. applicants requesting more than \$250,000 in annual direct costs and all foreign applicants must complete and submit budget requests using the Research & Related Budget component
- Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary

## **Section I.**

# **Funding Opportunity Description**

# Vulvodynia Research Initiative

- This initiative is expected to increase our knowledge about the underlying mechanisms and stimulate studies in this underresearched area that will build a foundation for assessing improved clinical applications and future research needs that complement our overall commitment to support research important to women's health.
- The objective of these FOAs is to support outstanding research projects and investigators who are willing to communicate in a collaborative fashion about a chronic pain condition that poses a reproductive burden to many women.

# Vulvodynia Research Initiative

- New and experienced basic scientists, epidemiologists, and clinical investigators are invited to submit research grant applications on the epidemiology, etiology, prevalence, criteria for accurate diagnosis, underlying pathophysiology of chronic pain mechanisms, and treatment strategies for vulvodynia.
- Successful applicants will be invited to a meeting to share recent findings, current knowledge, and engage in dialogue about future research directions.

**Section II.**  
**Award Information**

# R01 Mechanism of Support

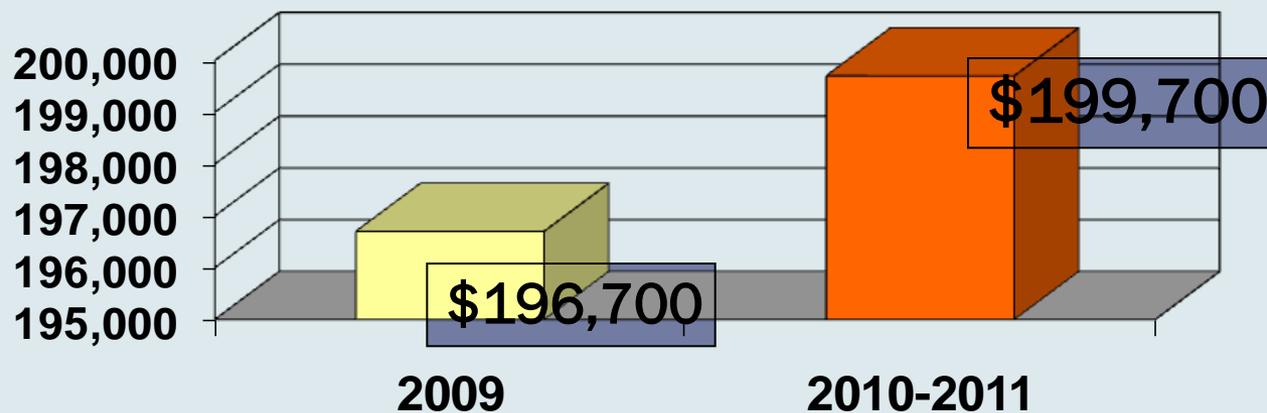
- This FOA will use the R01 (Research Project Grant) award mechanism
- The Project Director/Principal Investigator (PD/PI) will be solely responsible for planning, directing, and executing the proposed project
- It also uses the modular as well as the non-modular budget formats

# R01: Funds Available

- NICHD primary sponsor
- ORWH co-sponsor
- It also uses the modular as well as the non-modular budget formats
- Specifically, a U.S. organization submitting an application with direct costs in each year of \$250,000 or less (excluding consortium Facilities and Administrative [F&A] costs) should use the PHS398 Modular Budget component.
- U.S. applicants requesting more than \$250,000 in annual direct costs and all foreign applicants must complete and submit budget requests using the Research & Related Budget component.
- Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary.

# Salary Cap

- Restricts the amount of **direct salary** under a grant or contract to Executive Level I of the Federal Executive Pay Scale
- Executive Level I increase effective January 1, 2010



May 4, 2011 NIH Guide Notice:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-073.html>

**Section III.**  
**Eligibility Information**

# Eligible Applicants

- Eligible Institutions
- Eligible Individuals
  - Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are encouraged to apply
  - More than one PD/PI (i.e., multiple PDs/PIs), may be designated on the application for projects that require a “team science” approach
- Other Special Eligibility Criteria
  - Number of Applications: Applicants may submit more than one application, provided that each application is scientifically distinct.

# Other Eligibility Criteria

- **Number of Applications:** Applicants may submit more than one application, provided that each application is scientifically distinct.
- **Resubmissions:** Applicants may submit a resubmission application (revised or amended), but such application must include an Introduction addressing the previous peer review critique (Summary Statement).
  - ❖ **Reminder:** An A2 application is allowed until January 7, 2011, if the A0 was submitted before January 25, 2009  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-080.html>
- **Renewal:** R01 applicants may submit a competing application requesting additional years of funding to continue project.

**Section IV.**  
**Application and Submission**  
**Information**

# Eligible Applicants: eRA Commons

- One-time registration, if required, for organizational/Institutional Registration in [Grants.gov/Get Registered](http://www.grants.gov/GetRegistered) (<http://www.grants.gov/>) and eRA Commons
- Project Director/Principal Investigator (PD/PI) Registration in the NIH eRA Commons is required
  - Individual(s) designated as PDs/PIs on the application must be registered in the NIH eRA Commons
  - Multiple PDs/PIs: all PDs/PIs must be registered individually and be assigned the PI role in the eRA Commons prior to the submission of the application

# Application Information

- Applicants must download the SF424 (R&R) application forms and SF424 (R&R) Application Guide for this FOA through [Grants.gov/Apply](http://www.grants.gov/Apply) (<http://www.grants.gov/>)
- Note: Only the forms package directly attached to a specific FOA can be used

<http://grants.nih.gov/grants/funding/424/>**Forms & Deadlines**[Forms & Applications](#)[Submission Dates /  
Deadlines](#)[Submitting Your  
Application](#)**Global OER Resources**[Glossary & Acronyms](#)[Frequently Used Links](#)[Frequent Questions](#)

## SF424 (R&R) Application and Electronic Submission Information

This page provides application guides for preparing electronic grant applications using the SF424 (R&R) application forms. Free Adobe Reader software is required. For minimum system requirements and download instructions, go to [http://www.grants.gov/help/download\\_software.jsp](http://www.grants.gov/help/download_software.jsp). See the [Electronic Submission of Grant Applications](#) page for more information on the NIH electronic submission process.

**Table of Contents for this Page:**

- [SF424 \(R&R\) Application Guides](#)
- [Additional Format Pages](#)
- [Data Tables](#) (for Institutional Training Grant Applications)
- [Other Information](#) (eRA Assembly guides and Person-Months information)
- [Notable Changes Made to SF424 \(R&R\) Application Guides](#)

**Latest News:**

- [Now Available: SF424 \(R&R\) Individual Fellowship Application for NIH and AHRQ](#) (02/05/2010)
- [Now Available: SF424 \(R&R\) SBIR/STTR Application Guide for NIH and other PHS Agencies](#) (01/15/2010)
- [Now Available: Restructured Application Forms and Instructions for Application Due Dates on or after January 25, 2010](#) (11/23/2009)

**Instructions During Transition to Restructured Application Forms**

NIH and other PHS agencies are transitioning to Restructured Application Forms with new page limits. For a period of time between November, 2009 and the beginning of February, 2010, applicants must carefully select which version of the FOA and application package they should be using, and during this period all active funding opportunities will be clearly noted in the "Competition ID" field of the forms package. All applications intended for due dates on or after January 25, 2010 must use the current application packages and instructions (Competition ID of **ADOBE-FORMS-A**). All applications intended for due dates before January 25, 2010 must use the previous application packages and instructions (Competition ID of **ADOBE-FORMS-B**).

# Foreign Organizations (Non-domestic [non-U.S.] Entities)

- NIH policies concerning grants to foreign (non-U.S.) organizations can be found in the NIH Grants Policy Statement at: <http://grants.nih.gov/grants/foreign/>
  - ❖ Indicate how the proposed project has specific relevance to the mission and objectives of the NIH/IC and has the potential to significantly advance the health sciences in the United States
  - ❖ Describe unusual talent, resources, populations, or environmental conditions in other countries that are not readily available in the U.S. or that augment existing U.S. resources

# Multiple PD/PI: Eligible Projects/Grant Mechanisms

- Projects or activities that clearly require a “team science” approach and which do not fit the single-PI model. Selection of single or multiple PI option should always be based on the research proposed
- Not synonymous with “big science”
- No upper limit on number of PIs allowed. Could include as few as two PIs jointly responsible for the scientific and technical direction of the project
- The multiple-PI option requires the designation of a single “Contact PI”
- Contact PI is the liaison to NIH, and is responsible for:
  - all communication between the PIs and the NIH
  - coordinating progress reports for the project

# Multiple PD/PI: Leadership Plan

- Describe governance and organizational structure of the leadership team and research project, including:
  - Rationale for choosing a multiple PD/PI approach
  - Framework to facilitate and enhance scientific productivity
  - Communication plans, including reporting to the NIH funding component
  - Process for making decisions on scientific direction
  - Allocation of resources
  - Publications
  - Intellectual property issues
  - Procedures for resolving conflicts; PDs/Pis roles and administrative, technical, and scientific responsibilities for the project, including responsibilities for human subjects or animal studies as appropriate
- Leadership Plan will follow the Research Plan as a new section

# Applications Involving Multiple Institutions

- One institution must be designated as the prime institution and funding for the other institution(s) must be requested via a subcontract to be administered by the prime institution.
  - When submitting a detailed budget, the prime institution should submit its budget using the Research & Related Budget component.
  - All other institutions should have their individual budgets attached separately to the Research & Related Subaward Budget Attachment(s) Form.
- When submitting a modular budget, the prime institution completes the PHS398 Modular Budget component only.
  - Information concerning the consortium/subcontract budget is provided in the budget justification.
  - Separate budgets for each consortium/subcontract grantee are not required when using the Modular budget format.

# PAR Submission, Review, and Anticipated Start Dates

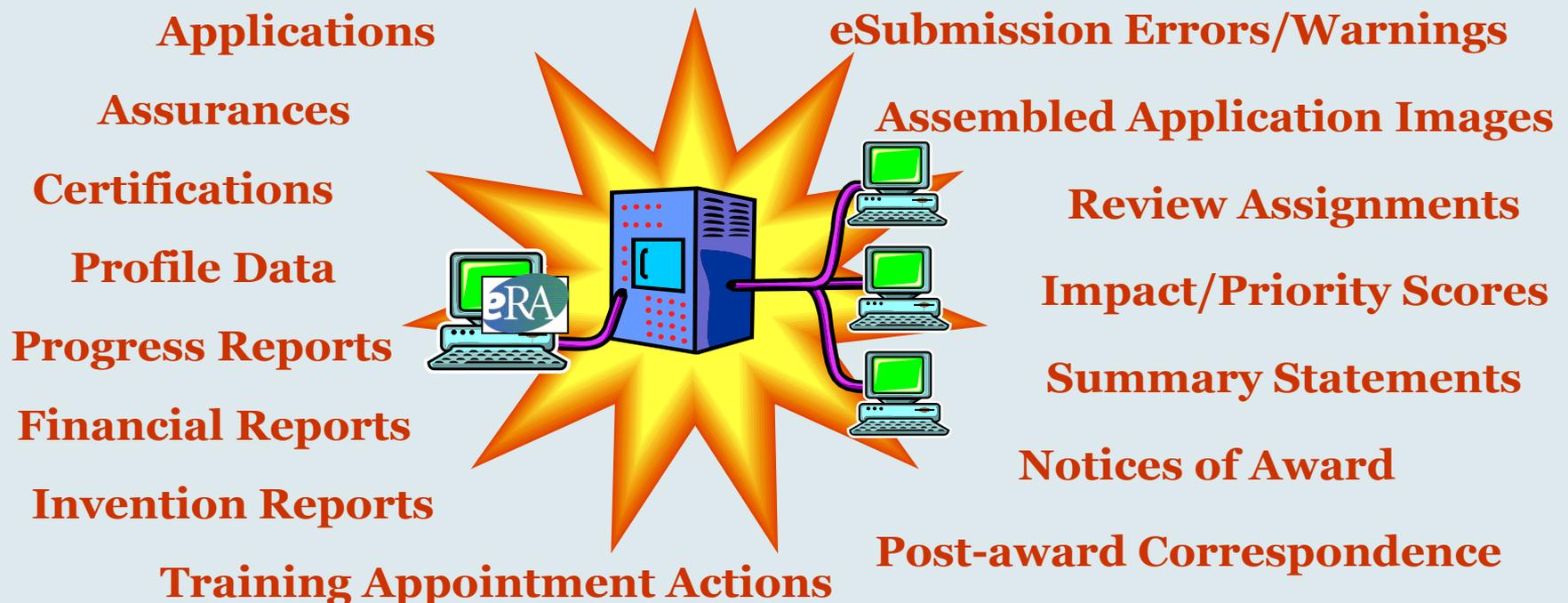
- ❖ **Letters of Intent Receipt Dates:** August 20, 2010, August 20, 2011, August 20, 2012
- ❖ **Application Due Dates:** September 21, 2010, September 21, 2011, September 21, 2012
- ❖ **Peer Review Dates:** February/March 2011, February/March 2012, February/March 2013
- ❖ **Council Review Dates:** May 2011, May 2012, May 2013
- ❖ **Earliest Anticipated Start Dates:** July 2011, July 2012, July 2013

# Letter of Intent

- Prospective applicants are asked to submit a letter of intent that includes the following information:
  - ❖ Descriptive title of proposed research
  - ❖ Name, address, and telephone number of the PD(s)/PI(s)
  - ❖ Names of other key personnel
  - ❖ Participating institutions
  - ❖ Number and title of this funding opportunity
- The letter of intent is not required, is not binding, and does not enter into the review of a subsequent application. The information that it contains allows IC staff to estimate the potential review workload and plan the review.

# What is eRA Commons?

- The eRA Commons is an online interface where grant applicants, grantee organizations, grantees and federal staff can access, share, and transmit administrative information related to their applications and grants



# Investigator Meeting

## Investigator Meeting :

- After initiation of the program, the NICHD will sponsor one meeting each year to stimulate discussion and encourage the exchange of information among investigators who participate in this program
- In the budget for the grant application, applicants should include travel funds for the meeting to be held in Bethesda, Maryland
- Travel funds may be requested for the Principal Investigator/Program Director, co-investigators, collaborators, and trainees associated with the grant
- The applicants should also include a statement in the application indicating their willingness to participate in such a meeting

# R01 Budget Component: Large Grants

- Specific Instructions for Applications Requesting \$500,000 (direct costs) or More per Year
- Applicants requesting \$500,000 or more in direct costs for any year (excluding consortium F&A costs) must carry out the following steps:
  - Contact the IC program staff at least 6 weeks before submitting the application, i.e., as plans are being developed for the study
  - Obtain agreement from the IC staff that the IC will accept the application for consideration for award; and,
  - Include a cover letter with the application that identifies the staff member and IC who agreed to accept assignment of the application
- This policy applies to all new, renewal, revision, or resubmission applications

<http://grants.nih.gov/grants/guide/notice-files/NOT-HD-06-003.html>

# Resource Sharing Plans

- Data Sharing Plan: Include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible.  
[http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)
- Sharing Model Organisms: All applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and related resources or state appropriate reasons why such sharing is restricted or not possible.  
[http://grants.nih.gov/grants/policy/model\\_organism/index.htm](http://grants.nih.gov/grants/policy/model_organism/index.htm)

# Resource Sharing Plans

- Genome-Wide Association Studies (GWAS): Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible.
  - A genome-wide association study is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (e.g., blood pressure or weight) or the presence or absence of a disease or condition.
  - Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies.  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html>

**Section V.**  
**Application Review Information**

# Review and Selection Process

- Overall Impact Score
- Scored Review Criteria
  - Significance
  - Investigator(s)
  - Innovation
  - Approach
  - Environment
- Additional Review Criteria
  - Protections for Human Subjects
  - Vertebrate Animals
  - Biohazards

# Application Selection Process

- Applications submitted in response to this funding opportunity will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:
  - Scientific and technical merit of the proposed project as determined by scientific peer review
  - Availability of funds
  - Relevance of the proposed project to program priorities

# Review System for Grant Applications

## Scientific Review Group (SRG)

- Independent outside review
- Evaluate scientific merit, significance
- Recommend length and level of funding

1st level

Output: Priority Score and Summary Statement

3 - 7 months

## Advisory Council

- assess quality of SRG process
- offers recommendation to Institute Staff
- evaluates program priorities and relevance
- advises on policy

2nd level

Output: Funding Recommendations

1 - 3 months

## Institute Director

- makes final decision based on Council input, programmatic priorities
- Must also Pass Administrative Review

Output: Awards or Resubmission

## **Section VI.**

# **Award Administration Information**

# Administration Information

- Award Notices
- Policy Requirements
- Reporting

**Section VII.**  
**Agency Contacts**

# Scientific/Research Contact

## Section VII. Agency Contacts

---

We encourage your inquiries concerning this funding opportunity and welcome the opportunity areas: scientific/research (program), peer review, and financial or grants management issues:

### **1. Scientific/Research Contact(s):**

Estella Parrott, M.D., M.P.H.  
Reproductive Sciences Branch  
Center for Population Research  
*Eunice Kennedy Shriver* National Institute of Child Health and Human Development  
6100 Executive Boulevard, Room 8B01, MSC 7510  
Bethesda, MD 20892-7510  
Telephone: (301) 435-6971  
Fax: (301) 496-0962  
Email: [ep61h@nih.gov](mailto:ep61h@nih.gov)

**Section VIII.**  
**Other Information**

# Required Federal Citations

- Review all required federal citations, selected examples include:
  - Use of Animals in Research
  - Human Subjects Protection
  - Data and Safety Monitoring Plan
  - Sharing Research Data
  - Policy for Genome-Wide Association Studies (GWAS)
  - Sharing of Model Organisms
  - Required Education on the Protection of Human Subjects
  - Human Embryonic Stem Cells (hESC)
  - NIH Public Access Policy
  - Loan Repayment Program

# **Receipt and Referral of Applications**

# Receipt and Referral of Applications

Electronic SF424 R&R  
submitted through  
[grants.gov](https://www.grants.gov)

CSR Referral Office  
assigns the  
application...

to an NIH Institute (IC)

a unique identifier  
(application number)

to Integrated Review  
Groupa (IRG) and then a  
study section (SRG)

Application assessed  
for completeness &  
eligibility

Notice of assignment  
available in eRA  
Commons in 4 weeks

**1<sup>st</sup> Month**

**2<sup>nd</sup> Month**

# **Revised Application Format**

# Application Format Revised in Three Sections

## ➤ **Research Plan:**

### Specific Aims

- Includes new language about the impact of the proposed research

### Research Strategy

- New section, includes current *Background and Significance, Preliminary Studies/Progress Report, and Research Design and Methods*

### Select Agents Research

- Reflects the Environment criterion

## ➤ **Resources:**

- Reflect the Environment criterion

## ➤ **Biographical Sketch:**

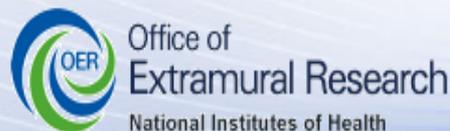
- Requires a Personal Statement and provide guidelines for the inclusion of references

# Shorter Page Limit Guide

Section of Application	Page Limits
<b>Introduction for Resubmission Application</b>	<b>1</b>
<b>Specific Aims</b>	<b>1</b>
<b>Research Strategy:</b> R03, R13/U13, R21, R36, R41, R43, Fellowships (F), SC2, SC3	<b>6</b>
<b>Research Strategy:</b> R01, single project U01, R10, R15, R18, U18, R33, R24, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1	<b>12</b>
<b>Biographical Sketch</b>	<b>4</b>

\* Page limits may vary for other funding mechanisms.  
Check Funding Opportunity Announcement (FOA):  
[http://grants.nih.gov/grants/forms\\_page\\_limits.htm#other](http://grants.nih.gov/grants/forms_page_limits.htm#other)

**New and Early  
Stage Investigators (ESIs)**



### Funding Opportunities

[Funding Opportunities \(RFAs, PAs\) & Notices](#)

[Unsolicited Applications \(Parent Announcements\)](#)

[Research Training & Career Development](#)

[Small Business \(SBIR/STTR\)](#)

[Contract Opportunities](#)

### NIH-Wide Initiatives

[Stem Cell Information](#)

[New and Early Stage Investigators](#)

[Genome-Wide Association Studies \(GWAS\)](#)

[NIH Roadmap for Medical Research](#)

### Award Data

[NIH Reports \(RePORT\)](#)

## New and Early Stage Investigator Policies

### On This Page:

- [Statement of Commitment](#)
- [Pathway to Independence Awards](#)
- [Definition of New Investigator](#)
- [NIH Director's New Innovator Award](#)
- [Early Stage Investigator Policies](#)
- [Links to Institute and Center Policies](#)
- [Frequently Asked Questions](#)
- [New and Early Stage Investigator Policies Archives and Resources](#)

## Statement of Commitment to New and Early Stage Investigators

[New investigators](#) are the innovators of the future - they bring fresh ideas and technologies to existing biomedical research problems, and they pioneer new areas of investigation. Entry of new investigators into the ranks of independent, NIH-funded researchers is essential to the health of this country's biomedical research enterprise. NIH's interest in the training and research funding of new investigators is understandably deep and longstanding. Over the years, special programs to assist new investigators in obtaining independent research funding have been created (see [History of Commitment](#) on these pages). In spite of these concerted efforts, the [average age](#) at which an investigator first obtains R01 funding increased by five to six years between 1980 and 2001 (PowerPoint - 44 KB). During the doubling of the NIH between FY 1998 and 2003, the [number of new](#) R01 investigators increased from about 1,500 to more than 1,680. New Investigators accounted for approximately [25 percent](#) of all competing R01 recipients during this period. After the doubling, the number and percentage of [new investigators declined](#) reaching a low of 1,365 in FY 2006 and then responding to renewed NIH efforts, increased in FY 2007 and 2008.

In order to address both the duration of training and to protect the flux of new investigators, the NIH announced a

# New and Early Stage Investigator Status

## New Investigator:

- PD/PI who has not yet competed successfully for a substantial NIH research grant
- Multiple PD/PIs: All PD/PIs must meet requirements

## Early Stage Investigator (ESI):

- PD/PI who qualifies as a New Investigator AND is within 10 years of completing the terminal research degree or is within 10 years of completing medical residency (or equivalent)

# New and Early Stage Investigator Status

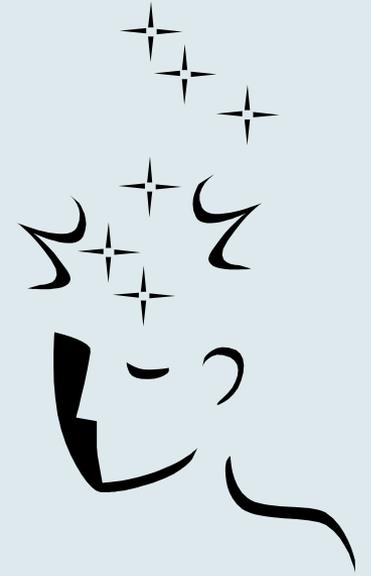
- Self designation of new investigator status
- “New” investigators cannot have successfully competed as a PD/PI for most research grants.
- Except a PI on the following mechanisms: e.g., R03, R15, R21, R34, K08, K23, and K12 may be considered a new investigator when applying for research grants
- Get special considerations during peer review and IC funding decisions
- Applies only to R01 applications

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-134.html>

[http://grants.nih.gov/grants/new\\_investigators/](http://grants.nih.gov/grants/new_investigators/)

**For more information  
Please visit the following web sites:**

**NIH Web Site: <http://www.nih.gov>  
NICHD Web Site: <http://www.nichd.nih.gov>**



Thank you