Pre-application Webinar
PAR-13-029 “Opportunities for Collaborative Research at the NIH Clinical Center”

Friday, January 11, 2013
2:00 PM to 4:00 PM, EST
## Webinar Agenda

| I. Welcome & Overview of the Initiative | Dr. Collins |
| II. Resources, Opportunities & Working at the NIH Clinical Center | Dr. Gallin |
| III. Special Requirements for the FOA | Dr. Hayungua |
| IV. Scientific Peer Review for the FOA | Dr. Nakamura/Dr. Schneider |
| V. Budget Preparation | Ms. Joyce |
| VI. Tips for Preparing the Application | Dr. Ramsey-Ewing |
| VII. Panel Discussion/Q&A | Dr. Hayungua/Mr. Ellis |

**Meeting URL:** [https://webmeeting.nih.gov/foapreappwebinar2013/](https://webmeeting.nih.gov/foapreappwebinar2013/)

**Call-in number:** 1-866-398-2885; **Passcode:** 247071
Panel Participants:
NIH Intramural and Extramural Experts

- Francis S. Collins, MD, PhD (OD)
- Valerie Bonham, JD (OGC)
- Bryan S. Clark, MBA (NICHD)
- Joseph Ellis (OER)
- John I. Gallin, MD (CC)
- Ann Hammersla, JD (OTT)
- Della Hann, PhD (OER)
- Eugene G. Hayunga, PhD (NICHD)
- Maria D. Joyce, CPA, MBA (CC)
- Richard Nakamura, PhD (CSR)
- Frederick P. Ognibene, MD (CC)
- Anna Ramsey-Ewing, PhD (NIAID)
- Sally J. Rockey, PhD (OER)
- Mark Rohrbaugh, JD, PhD (OTT)
- Donald Schneider, PhD (CSR)
- Constantine A. Stratakis, MD, DSc (NICHD)
Questions

• We will remind you of how to pose questions frequently throughout the discussion.

• Please email any questions to: ClinicalCtrPartner@mail.nih.gov

• We have individuals monitoring incoming questions in real-time.

• Questions received today will be addressed during the panel discussion at the end of this webinar.
Welcome

Francis S. Collins, MD, PhD
Resources, Opportunities & Working at the NIH Clinical Center

John I. Gallin, M.D.
Director, NIH Clinical Center
Mission

Science

Patient Care/
Safety

Training
Clinical Center Profile

- 240 beds
- More than 450,000 patients since opening in 1953
- Every patient on research protocol
- 1,530 active protocols
  - Interventional/Clinical Trials - 723 (48%)
  - Natural History - 716 (47%)
  - Screening - 67 (4%)
  - Training - 24 (1%)
Major Emphasis

- Study of the pathophysiology of disease
- First in human with new therapeutics
- Study of patients with rare diseases

18 – 25 million people in the United States have a rare disease!
Rare Diseases at the NIH Clinical Center

The Clinical Center has the ability to assemble cohorts of patients with rare diseases

- Number of Rare Diseases 463
- Number of Protocols 692
Specialized Services and Facilities

- Phenotyping
  - Biomechanics laboratory
  - Metabolic chambers
Specialized Services and Facilities

- Cell Processing/GMP Facility
- Transfusion Medicine Department
Specialized Services and Facilities

Imaging Capabilities

• MRI Center

• PET Program
  - 3 cyclotrons
  - Radiochemistry/GMP Facility
  - 3 scanners
3T integrated simultaneous MRI-PET
Specialized Services and Facilities

Pharmaceutical Development Service GMP Facility

- Product formulation
- Analytical and quality control
- Pharmacokinetics
- Manufacturing capability (8 hour day)
  - 75,000 capsules
  - 150,000 tablets
  - 220 liters
  - 5,000 syringes
  - 8,000 vials (includes vaccines and biologics)
Collaborations Home

This site is offered to illustrate the special resources at the NIH Clinical Center and to provide information on potential opportunities for collaboration.

Why external partnerships?

In December 2010, the Congressionally mandated Scientific Management Review Board recognized the potential benefits of opening the NIH Clinical Center to external investigators and recommended doing so (4 MB). Benefits include stimulating a broader range of research, especially translational research that bridges the bedside-to-bench gap.

Based on resource availability, collaborations include the NIH Bedside-to-Bench Program, which fosters partnerships between NIH grantees and intramural clinical investigators and a new grant mechanism, "Opportunities for Collaborative Research at the NIH Clinical Center (U01)."

To support collaboration with external entities, the NIH Clinical Center has catalogued assets that may be of interest to external investigators. NIH is working diligently to make assets and opportunities for collaboration available to external investigators and to ensure that the proper infrastructure is in place for successful partnerships.

Sign up to receive email updates for Opportunities for Collaboration with Intramural Investigators at the NIH Clinical Center

http://www.cc.nih.gov/translational-research-resources/
Working at the CC

Frequently Asked Questions

- Resources
- Collaborations
- NIH Appointments for Extramural Investigators
- Credentialing for Extramural Investigators
- Conflict of Interest
- Clinical Protocols
- Building a Budget for the U01 Funding Opportunity
- Patients
- Intellectual Property
- Biospecimens
- Workspace and Lodging for Extramural Partners
- Data
PAR-13-029 Highlights

Eugene G. Hayunga, Ph.D.
Director, Office of Extramural Policy
NICHD
Purpose of the FOA

• To support collaborative research projects aligned with NIH efforts to enhance the translation of basic biological discoveries into clinical applications that improve health

• To promote partnerships between NIH intramural and (non-NIH) extramural investigator

• To provide extramural investigators an opportunity to take advantage of the unique research resources of the NIH Clinical Center
Overview

• 12 participating ICs: NICHD, NCI, NEI, NHBLI, NHGRI, NIAAA, NIAID, NIAMS, NIBIB, NIDCD, NIDA, NLM; also ORWH and ODS

• Up to $500K/year (direct costs) for up to 3 years

• U01 cooperative agreement mechanism

• Receipt dates: March 20, 2013 (also 2014 & 2015)

• Awards to be made early in FY (Nov/Dec)
Special Requirements

• Teams **must** have one extramural and one intramural investigator (“Multiple PD/PI” strongly encouraged)

• Some of the work **must** be done at the NIH Clinical Center

• Budget **must** delineate extramural, intramural and Clinical Center costs

• Application **must** include letters of support from the Clinical Center and from the appropriate IC

• Application **must** include a collaboration plan and describe the advantages of the intramural/extramural partnership and the utilization of Clinical Center resources
Letter of Intent

• Not required, but strongly encouraged

• Submit 30 days before application due date
  • No later than February 20, 2013

• Letter of Intent should include:
  • Descriptive title of proposed research
  • Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
  • Names of other key personnel
  • Participating institution(s)
  • Number and title of this funding opportunity (PAR-13-029)

• May also include:
  • Brief research plan
  • Summary of the Clinical Center services planned for utilization

• Letter of Intent can serve as your request for the Letters of collaboration/support from the Clinical Center and the relevant IC which are required
Required Letters of Support

• Letter from Clinical Center Director:
  • Clinical Center facilities will be able to accommodate the proposed research if the grant is awarded

• Letter from Participating NIH Institute/Center:
  • research project is of programmatic relevance to that Institute/Center;
  • Institute/Center has made a commitment to fund the Clinical Center and intramural investigator costs if an award is made; and
  • intramural investigator at the Institute/Center will be allowed to devote time to the research project.

• Letters of Support must be included when the application is submitted. *(Applications without both letters will be considered incomplete and will not be reviewed.)*
Questions

• Please email any questions to: ClinicalCtrPartner@mail.nih.gov

• Questions received today will be addressed during the panel discussion at the end of this webinar
Scientific Peer Review

Richard Nakamura, Ph.D.
Director, Center for Scientific Review

Don Schneider, Ph.D.
Senior Advisor to the CSR Director
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<thead>
<tr>
<th>IC Review</th>
<th>CSR Review</th>
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<tr>
<td>NCI</td>
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<td>NHLBI</td>
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Peer Review Principles

• Conflicts will be excluded

• Most reviewers will be from outside the government (Federal employees cannot exceed 25% of members)

• Standard NIH procedures will be used by all review units, and every applicant will receive written feedback (a “summary statement”)
Criteria for Review

The standard five
• Significance
• Investigators
• Innovation
• Approach
• Environment

Protections as appropriate
• Human subjects
• Vertebrate animals
• Biohazards
Additional Criteria for Review

- Does Collaborative Plan define responsibilities for the intramural and the extramural investigators?
- Is a Management Plan presented, describing roles for each participant?
- Is an advantage of the collaborative partnership evident?
- Will unique research opportunities in the NIH Clinical Center be utilized?
Questions

• Please email any questions to: ClinicalCtrPartner@mail.nih.gov

• Questions received today will be addressed during the panel discussion at the end of this webinar
Intramural Clinical Center
Budget Highlights

Maria D. Joyce, CPA, MBA
Chief Financial Officer,
NIH Clinical Center
U01 Grant Money Flow

*ICs have flexibility how these programs will be funded. Funds flow to be determined before award.
# Preparing the Budget

<table>
<thead>
<tr>
<th><strong>Extramural PI</strong></th>
<th><strong>Intramural PI</strong></th>
<th><strong>Clinical Center</strong></th>
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<tbody>
<tr>
<td>- Detailed budget required; no modular budgets.</td>
<td>- The intramural PI will create a budget request limited to the proposed work.</td>
<td>- Identify Clinical Center costs for grant as defined by the template provided.</td>
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<tr>
<td>- Budget request for the intramural investigator and the Clinical Center should be listed separately in “Section F. Other Direct Costs”.</td>
<td>- Budget may include contract staff, but not federal employees.</td>
<td>- CC to work with ICs to define resource requirements for IC services (e.g., pulmonary function tests).</td>
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<td>- Identify intramural PI before CC budget preparation begins.</td>
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**Sample Budget Template for CC Costs**

<table>
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<tr>
<th>Inpatient Services</th>
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<tbody>
<tr>
<td><strong>a) General Information:</strong></td>
</tr>
</tbody>
</table>
| PI Names:*       | Collaborating IC:*
| PI Institute:*  | Collaborating PI:*
| Grant/Study name:* |  |
| **b) Cost per Inpatient Night:**  |

- **Year 1**
  - Projected # of Patients*
  - Projected # of inpatient days/patient*
  - Total # of IP Days
  - ICD-9 Code*
  - Cost/IP Day**
  - Estimated Cost***

- **Year 2**
  - Projected # of Patients*
  - Projected # of inpatient days/patient*
  - Total # of IP Days
  - ICD-9 Code*
  - Cost/IP Day**
  - Estimated Cost***

- **Year 3**
  - Projected # of Patients*
  - Projected # of inpatient days/patient*
  - Total # of IP Days
  - ICD-9 Code*
  - Cost/IP Day**
  - Estimated Cost***

| c) Technical Services Required for the Study: |

- **Year 1**
  - Test/Procedure/Service*  
  - CPT code (if applicable)*
  - Projected # of Patients*
  - Projected # of services/patient*
  - Total # of Services
  - Cost/Service**
  - Estimated Cost**

- **Year 2**
  - Test/Procedure/Service*  
  - CPT code (if applicable)*
  - Projected # of Patients*
  - Projected # of services/patient*
  - Total # of Services
  - Cost/Service**
  - Estimated Cost**

- **Year 3**
  - Test/Procedure/Service*  
  - CPT code (if applicable)*
  - Projected # of Patients*
  - Projected # of services/patient*
  - Total # of Services
  - Cost/Service**
  - Estimated Cost**

**Template includes easy-to-follow, step-by-step instructions for completion**

**Separate tabs for:**
- Inpatient services
- Outpatient services
- Specialized research services
Sample Budget Template for CC Costs (cont)

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Drug Name*</th>
<th>HCPGS code (if applicable)*</th>
<th>Projected # of Patients*</th>
<th>Projected # of doses/patient*</th>
<th>Total # of Doses</th>
<th>Cost/Dose**</th>
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<th>Projected # of Patients*</th>
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c) Specialized Research Services*  
Program | Check box if applicable  
Rehabilitation Medicine |  
Human Motor Control Section |  
Novel Cellular Biologics for Phase III Trials |  
Penny's Development Service |  
High-Throughput Molecular Assay |  
Healthy Volunteer Program |  
Production/Banking Bone Marrow Stem Cells |  
R&D/Bluemink - Cardiovascular Imaging - Non-Invasive Imaging of Coronary Artery Disease, Heart Failure, and Atherosclerosis Imaging |  
R&D/Black - Physiological Research |  
R&D/Neumann - Nuclear Medicine/Radiopharmaceutical Research |  
R&D/PAIR - Nuclear Medicine/Radiopharmaceutical Research |  
R&D/Summers - Diagnostic Radiology |  
R&D/Wood - Interventional Oncology |  

*Specialized Research Services require completion of separate budget templates.

Specialized Research Services Required by the Study:  
Year 1 Estimated Cost** | $10,743  
Year 2 Estimated Cost** | $10,048  
Year 3 Estimated Cost** | $10,362  

Total Costs per Year:  
Year 1 Total Costs (Inpatient, Technical Services, Drugs, Specialized Research Services) | $97,709  
Year 2 Total Costs (Inpatient, Technical Services, Drugs, Specialized Research Services) | $10,048  
Year 3 Total Costs (Inpatient, Technical Services, Drugs, Specialized Research Services) | $10,362  
TOTAL Estimated Cost for Study | $27,462

- When complete, email to: ClinicalCtrPartner@mail.nih.gov.
- The Clinical Center Partner team will work with the investigator to provide accurate Clinical Center costs based on the completed template.
- Note: Applicants should allow sufficient time to identify and calculate these costs.
Preparing the Budget

Urge early contact with Clinical Center staff for assistance

Clinical Center Partnerships Mailbox: ClinicalCtrPartner@mail.nih.gov
Phone: 301.496.4121

Budget template submissions MUST be made prior to March 1, 2013 to meet project deadlines
Thank You

• Please email any questions to: ClinicalCtrPartner@mail.nih.gov

• Questions received today will be addressed during the panel discussion at the end of this webinar
Tips for Preparing the Application

Anna L. Ramsey-Ewing, Ph.D.
Director, Office of Extramural Research Policy and Operations
NIAID
Overview

• General Grantsmanship Tips
• Funding Opportunity Announcement (FOA) Structure
  – Application and Submission Information
• FOA-Specific Requirements and Considerations
  – Application Structure
  – Applications that Include Clinical Trials
  – Selection Criteria
• Electronic Submission Tips
  – Electronic Submission-General Reminders
  – FOA-Specific E-Submission Issues
• Resources
**General Grantsmanship Reminders**

- **Identify and utilize your partners**
  - Assemble a team of reviewers (SME, non-SME)
  - Your institutional officials
  - NIH staff

- **Use extensive internet resources**
  - Review funded clinical trial abstracts and public health relevance statements in NIH RePORTER
  - Review examples of funded applications
  - Review tutorials

- **Read the entire FOA!**
General FOA Structure

• Overview
  – Key Dates

• Full Text
  – Description
  – Award, Eligibility Information
    – Application and Submission Instructions
  – Application Review Information
  – Award Administration
  – Agency Contacts, Other Information
Application Structure Matters

• Components of the application are aligned with the review criteria
• Required application inclusions reflect information NIH deems necessary for high quality peer review
• All FOA-specific instructions must be followed
• Peer reviewers are required to evaluate the entire application; they may consider the appendix
IV. Application and Submission Information

FOA-specific requirements

• Collaboration Plan [Approach]
• Letters of Support (also collaboration approvals) [Approach]
• MPI Leadership Plan (include the DIR PI) [Investigator(s)]
• Resource Sharing Plan [review consideration]

Applications that lack any of these items will not be reviewed!
IV. Application and Submission Information

FOA-specific requirements:

• Budget [review consideration]
  – Budget must delineate extramural, intramural and Clinical Center costs
  – CC costs calculated using template from CC CFO
  – Intramural costs determined by discussion with intramural partner
  – Append spreadsheets as per FOA instructions
  – Non-modular only
Applications that Include Clinical Trials

• Must fully address human subjects protections issues; evaluated as a review consideration and under “Approach” scored criterion

• Require special components at the time of application submission
  – In the application
    • Clinical Protocol Synopsis
    • Statistical Analysis Plan
    • Data and Safety Monitoring Plan
    • Milestone Plan and Complete Protocol
Applications that Include Clinical Trials

-In the appendix

• The informed consent form(s) and, if applicable, assent form(s)
• Identification and qualifications of clinical trial site(s), pharmacies and laboratories
• Copies of data collection forms, questionnaires or other relevant materials
• The Investigator’s Brochure or equivalent for the study product(s)
• The Table of Contents of the Manual of Procedures
• A comprehensive Laboratory Plan
• Documentation of availability of and support for acquisition/administration of study agent(s)
• A statement addressing the need (if applicable) for IND approval from the FDA
• The Data Management Plan
• The Site Quality Management Plan
Funding Decision Considerations

• 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.

FOA-Specific

• Compliance with resource sharing policies.
• Likelihood of effective collaboration between the PD(s)/PI(s) of the applicant institution and the NIH Intramural Investigator.
• Utilization of unique research opportunities in the Clinical Center.
General E-Submission Tips

- Update eRA Commons information
- Assign delegate, if appropriate
- Identify institutional resources
- Utilize different types of reviewers
- PDF guidance
- Warnings vs. Errors
- View your application
FOA-Specific E-Submission Issues

• Multiple PI requires the intramural investigator to register in the eRA Commons

• Optional Components that are required include:

  All EXCEPT modular budget!

• SF424 (R&R) Other Project Information
  – Item 12 Other attachments
  – Filenames are important
Prefilled Header Information

Mandatory Documents
- SF424 (R & R)
- Project/Performance Site Location(s)
- Research And Related Other Project Information
- Research And Related Senior/Key Person Profile
- PHS 398 Cover Page Supplement
- PHS 398 Research Plan
- PHS 398 Checklist

Optional Documents
- PHS Cover Letter
- PHS 398 Modular Budget
- Research & Related Budget
- R & R Subaward Budget Attachment(s) Form

Select all except modular budget
# PHS 398 Research Plan

**1. Application Type:**
From SF 424 (R&R) Cover Page. The response provided on that page, regarding the type of application being submitted, is repeated for your reference, as you attach the appropriate sections of the Research Plan.

*Type of Application:*

- [ ] New
- [ ] Resubmission
- [ ] Renewal
- [ ] Continuation
- [ ] Revision

**2. Research Plan Attachments:**
Please attach applicable sections of the research plan, below.

1. Introduction to Application
   (for RESUBMISSION or REVISION only)

2. Specific Aims

3. *Research Strategy*

4. Inclusion Enrollment Report

5. Progress Report Publication List

**Human Subjects Sections**

6. Protection of Human Subjects

7. Inclusion of Women and Minorities

8. Targeted/Planned Enrollment Table

9. Inclusion of Children

**Other Research Plan Sections**

10. Vertebrate Animals

11. Select Agent Research

12. Multiple PD/PI Leadership Plan

13. Consortium/Contractual Arrangements

14. Letters of Support

15. Resource Sharing Plan(s)

16. Appendix

*Add Attachments* [Remove Attachments] [View Attachments]
PHS 398 Research Plan

2. Research Plan Attachments:

Please attach applicable sections of the research plan, below.

1. Introduction to Application

(for RESUBMISSION or REVISION only)

2. Specific Aims

3. Research Strategy

4. Inclusion Enrollment Report

5. Progress Report Publication List

Add Attachment
### PHS 398 Research Plan

**Other Research Plan Sections**

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<thead>
<tr>
<th>Section</th>
<th>Add Attachment</th>
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<tbody>
<tr>
<td>10. Vertebrate Animals</td>
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<td>11. Select Agent Research</td>
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<td>12. Multiple PD/PI Leadership Plan</td>
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<td>13. Consortium/Contractual Arrangements</td>
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<td>14. Letters of Support</td>
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<td>15. Resource Sharing Plan(s)</td>
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FOA-specific additional components
**Budget Justifications**

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th><strong>Funds Requested ($)</strong></th>
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**Total Indirect Costs**

Cognizant Federal Agency

(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs

Total Direct and Indirect Institutional Costs (G + H)

**Funds Requested ($)**

J. Fee

**Funds Requested ($)**

K. * Budget Justification

(Only attach one file)

No F & A for intramural
Grantsmanship Resources (NLM)

Grant-writing tip sheets for NIH research grants

- All About Grants - A multi-part site, including sections on Grant Application Basics, How to Plan a Grant Application, How to Write a Grant Application. These documents are in PDF form (NIAID)

- Quick Guide for Research Grant Applications (NCI)
  http://deainfo.nci.nih.gov/extra/extdocs/gntapp.htm

- Tips for New NIH Grant Applicants (NIGMS)

- Common mistakes in grant applications (NINDS)
  http://www.ninds.nih.gov/funding/grantwriting_mistakes.htm

- Writing a grant application: A Technical Checklist
  http://www.ninds.nih.gov/funding/grantsmanship_checklist.htm

- Annotated Sample R01 grant (from NIAID)
Electronic Submission of Grant Applications

- SF424, the new electronic application form that is replacing PHS 398 (slideshows and videocasts) http://era.nih.gov/ElectronicReceipt/sf424.htm
- All electronic applications require advance registration at both Grants.gov and the NIH eRA Commons. (explanation and links to both registration sites) http://era.nih.gov/ElectronicReceipt/preparing.htm
Thank You

• Please email any questions to: ClinicalCtrPartner@mail.nih.gov

• We will now address any questions.

• Video archive of today’s session and the Q+A’s will be posted on the Clinical Center website.