Pre-application Webinar Agenda
“Opportunities for Collaborative Research at the NIH Clinical Center”
X02 (PAR-15-286) and U01 (PAR-15-287)

Monday, November 9, 2015
10:00 AM – 11:30 AM, EST
| I. Welcome & Overview of the Initiative | Dr. Lauer |
| II. Resources, Opportunities & Working at the NIH Clinical Center | Dr. Gallin |
| III. Special Requirements for the FOA | Dr. Hayunga |
| IV. Scientific Peer Review for the FOA | Drs. Schneider and Bhagavan |
| V. Budget Preparation | Ms. Joyce |
| VI. Tips for Preparing the Application | Dr. Santora |
| VII. Panel Discussion/Q&A | Dr. Hayunga |
Panelists

Dr. Michael Lauer  
NIH Deputy Director for Extramural Research

Dr. John Gallin  
Director, NIH Clinical Center

Dr. Eugene Hayunga  
Director of NICHD Office of Extramural Policy, NIH

Dr. Seetha Bhagavan  
Scientific Review Officer, CSR, NIH

Dr. Donald Schneider,  
Senior Scientific Advisor to the Director, CSR, NIH

Ms. Maria Joyce, Chief  
Financial Officer, Clinical Center, NIH

Dr. Ken Santora, Chief,  
Extramural Science Policy Section  
Office of Extramural Research Policy and Operations
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

Michael Lauer, MD
NIH Deputy Director for Extramural Research
Thursday, March 13, 2014

NIH opens research hospital to outside scientists

New program tackles disease on many fronts.

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Learn More About Collaborating with NIH’s Clinical Center

In 2012, NIH created a unique opportunity for extramural researchers to collaborate with our intramural scientists and use the exceptional resources of the NIH Clinical Center. I want to
“This initiative will provide top scientists outside NIH the opportunity to utilize the sizeable resources of our clinical center. The collaborative process they undertake with researchers here on campus will set a framework for important biomedical discoveries and needed treatments.”

Dr. Francis Collins
Projects Include

- Trial of treatment of Nieman Pick C
- Trial of treatment of relapsed leukemia
- New cardiac catheter
- Malaria vaccine trial
- Follow-up of Cryptococcus infection
# Update: Cycles 1-3
Opening CC to Extramural

<table>
<thead>
<tr>
<th>LOI’s /X02’s</th>
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<th>CYCLE 2</th>
<th>CYCLE 3</th>
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<td>Publication FOA for X02 and U01</td>
<td>June 2015</td>
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<td>Webinar</td>
<td>November 9, 2015</td>
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<tr>
<td>Due Date for X02 Pre-applications</td>
<td>December 15, 2015</td>
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<td>Evaluation of X02 Pre-applications</td>
<td>Dec 2015 - Jan 2016</td>
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<tr>
<td>Due Date for U01 Applications</td>
<td>April 11, 2016</td>
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<tr>
<td>Scientific Peer Review of U01 Applications</td>
<td>June-July 2016</td>
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<td>Second-level Review by Institute/Center Advisory Councils</td>
<td>October 2016</td>
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<tr>
<td>Start Date for Awarded U01 Grants</td>
<td>Nov-December 2016</td>
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Collaborating with NIH Intramural Investigators at the Clinical Center

Welcome to the NIH Clinical Center's Collaboration Website. This site features the special resources at the NIH Clinical Center and provides information on opportunities for research collaborations. The Clinical Center has a rich history of supporting the NIH portfolio of clinical studies, with talented investigators and specialized infrastructure responsible for the many medical breakthroughs that have happened here. Our nurses say there is "no other hospital like it," and I have to agree. Here you will find unique patient cohorts, state-of-the-art equipment, and one-of-a-kind services.

In December 2010, the congressionally mandated Scientific Management Review Board recommended that the NIH Clinical Center be more accessible to external investigators.

These collaborations represent an extraordinary opportunity to broaden research opportunities, stimulate research, and ultimately improve public health. Please explore current research at the NIH Clinical Center and consider how your research could benefit from one of our opportunities for collaboration.

U01 Pre-Application Webinar - November 9th

Current Intramural NIH Research

What We Have to Offer

Get Your Questions Answered
Resources, Opportunities & Working at the NIH Clinical Center

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

Science

Training

Patient Care/Safety
Clinical Center Profile

- ~509,000 patients since opening in 1953
- 240 beds; FY 2015 Budget $409.0 M
- Hospital surrounded by research labs
- Every patient is on a research protocol
- Care is free
- Patient travel/housing provided as needed
- 2,800 CC employees + ~4,000 employees from 18 ICs that use hospital
- 1,255 credentialed physicians
- 1,611 active protocols
  - Interventional/Clinical Trials – 773 (48%)
  - Natural History – 744 (46%)
  - Screening – 67 (4%)
  - Training – 27 (2%)
The NIH Clinical Center is the largest hospital in the world totally dedicated to clinical research.
Selected CC Accomplishments
First 50 Years

• Chemotherapy for cancer
• Use of blood lipid levels as biomarkers of cardiovascular disease
• Enzyme replacement therapy for Gaucher’s Disease leading to founding of the Genzyme Corporation
• Immunosuppressive therapy for nonmalignant diseases
• Fluoride to prevent dental caries
• Lithium for depression
Selected CC Accomplishments
Last Decade

• Identification of genes for stuttering
• Immune therapy for metastatic melanoma and other cancers
• New imaging approaches for diagnosis and management of prostate cancer
• Application of microbial whole genome sequencing in hospital epidemiology
• First in human candidate Ebola vaccines
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!
Specialized Services and Facilities
“Deep” Phenotyping

- Biomechanics laboratory
Specialized Services and Facilities

• Phenotyping
  o Biomechanics laboratory
  o Metabolic chambers

• Cell Processing/GLP Facility
  o Immunotherapy and cell therapy for cancer
Specialized Services and Facilities

Imaging Capabilities

• MRI Center

• PET Program
  o 3 cyclotrons
  o Radiochemistry/cGMP Facility
  o 3 scanners, including MRI-PET
Study of Infectious Diseases

Isolation unit for

• study of patients harboring potentially infectious pathogens such as Ebola
• first in human vaccines studies (malaria, Ebola)
Collaborating with NIH Intramural Investigators at the Clinical Center

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Opportunities for Collaborative Research at the Clinical Center (U01)

Current Intramural NIH Research

What We Have to Offer

Get Your Questions Answered

NOTE: PDF documents require the free Adobe Reader.

This page was last updated: 07/15/2016

http://www.cc.nih.gov/translational-research-resources/index.html
PAR-15-286 and PAR-15-287
Highlights

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

• 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 investigators

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

• 15 participating ICs: NICHD, NCI, NEI, NHBLI, NIAAA, NIAID, NIAMS, NIBIB, NIDA, NIDCD, NIDCR, NIDDK, NIMH, NINDS, NCCIH; also ORWH and ODS

• Up to $500K/year (direct costs) for up to 4 years

• Application process:
  o X02 pre-application, due December 15, 2015, 2016, 2017
  o U01 cooperative agreement, due April 11, 2016, 2017, 2018

• 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 must describe the advantages of the intramural/extramural partnership and the utilization of Clinical Center resources
Considerations when Applying

- Intramural partner
- Clinical Center resources
- Research interests of participating ICs
- Application instructions and FAQs
  http://clinicalcenter.nih.gov/translational-research-resources/faq-2-applying.html
Research Areas of Interest  
(Section I of the FOAs)

Specific Areas of Interest
Awards for high quality science demonstrating the potential to result in understanding an important disease process or lead to a new therapeutic intervention will be available in topics relevant to the research interests and priorities of the participating NIH Institutes/Centers (ICs), to include:

NCI
The National Cancer Institute (NCI) invites applications in research areas relevant to the Institute’s mission, which is to provide global leadership for research, training, health information dissemination, and other programs with respect to the cause, prevention, diagnosis, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients. The NCI encourages bench-to-bedside research to: increase understanding of the molecular and physiological basis of health and disease; stimulate clinical discoveries about the mechanisms underlying disease to develop improved prevention, diagnosis, and treatment; enable the translation of basic discoveries into clinical practice for the benefit of personal and public health; foster training and mentoring of emerging scientists and physicians; and communicate research advances to the public. The NCI Vision and Priorities are found at http://www.cancer.gov.

NEI
The National Eye Institute’s mission is to “conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual function, preservation of sight, and the special health problems and requirements of the blind.” Specific areas of interest include:

- Eye movement recording facility including stimuli presentation, video and eye coil recording equipment, and software to analyze the recordings is available for collaborative research in eye movement research;
- Collaborative genetic research through eyeGENE;
- Collaborative research using cohorts of children and adults with inherited eye diseases and ocular malformations including but not limited to: uveal coloboma, Stargardt disease/ABCA4 retinopathy, for spinocerebellar ataxia, type 7 (SCA7), albinism, and modeling disease pathogenesis using induced pluripotent (iPS) cells derived from patients;
- Collaboration in ongoing studies with a focus on retinal vascular diseases and uveitis.
- Examples can be found at: http://clinicalstudies.info.nih.gov/cgi/protinstitute.cgi?NEI0.html
- Collaborative research using cohorts of children with ocular inflammatory disease, including juvenile idiopathic arthritis (JIA) as well as monogenic disorders
- Collaboration in evaluating African Americans with ocular inflammatory disease with a particular emphasis on Sarcoidosis. In addition, studying the role of the immune system in African American patients with age-related macular degeneration (AMD);
- Collaboration with those interested in investigating autoimmune retinopathy, the underlying pathophysiology and treatment;
- Evaluating patients with ocular toxoplasmosis.
X02 Pre-application (PAR-15-286)

• Recommended first step in the process
• Due dates: December 15, 2015, 2016, 2017
• Requires collaboration plan and brief research plan
• Does not require budget info, appendix or attachments
• Reviewed administratively by NIH staff
• Enables staff to determine whether the proposed research can be supported by the resources of the NIH Clinical Center and is relevant to the research mission of one of the participating ICs
• Serves as request for the required Letters of Support from the Clinical Center and the relevant IC
• No awards made for the X02
Review Criteria for the X02 Pre-application

• Is there a collaborative team of at least one NIH intramural investigator and one (non-NIH) extramural investigator?
• Does the NIH intramural investigator plan to devote an appropriate amount of time/effort to the research project?
• Is the Collaboration Plan well defined with identifiable responsibilities for the NIH intramural investigator and the (non-NIH) extramural applicant?
• Is a plan for management of the collaboration presented, as well as descriptions of what each participant proposes to provide to the collaborative partnership?
• Is there a clear and well described advantage to bringing the intramural and extramural investigators together in a collaborative partnership?
• Does the research plan clearly describe the work that will be performed at the NIH Clinical Center?
• Is it clear which unique research opportunities in the NIH Clinical Center will be utilized?
• Can the NIH Clinical Center facilities accommodate the proposed research?
• Does the research project address an important problem that is of programmatic relevance to one of the participating Institutes/Centers?
• If the research project includes a clinical trial are regulatory requirements in place?
• Can the proposed objectives be accomplished within the 4-year project period?
U01 Application (PAR-15-287)

• Due dates: April 11, 2016, 2017, 2018
• Requires collaboration plan, full research plan, and letters of support from Clinical Center and relevant IC
• Requires detailed budget information
• Requires appropriate attachments (e.g., Clinical Protocol, Milestones, Data & Safety Monitoring Plan, etc.)
• Scientific Peer Review as per usual NIH practices
• Award decisions as per usual NIH practices
• The X02 pre-application serves as Letter of Intent and request for the required Letters of Support
Required Letters of Support for U01 Application

- **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 able to devote time to the research project.

- Letters of Support must be included when the application is submitted. *(U01 Applications without both letters will be considered incomplete and will not be reviewed.)*
Key Changes for the Upcoming Cycle

- **Four Year Project Period**
  - In past cycles, the maximum project period grantees could request was 3 years. The new FOA increases that to 4 years.

- **New Budget Template**
  - When planning for CC costs, please be sure to use the new version of the template (available online) rather than a previously utilized version.

- **IC Participation**
  - As noted previously, new ICs have joined the program. Consult the FOAs for details on participating ICs.

- **Foreign Awards/Components**
  - Eligibility criteria allow applications from foreign (non-U.S.) organizations and domestic (U.S.) applications with foreign components.

- **Competing Continuation Awards**
  - Awardees from the first cycle will be eligible to compete for Renewal (Type 2) awards this year.
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.
Scientific Peer Review

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

Don Schneider, Ph.D.
Seetha Bhagavan, Ph.D.
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”)
Deadline Alerts

• “December 15, 2015” Optional/recommended Pre-application due
• “March 1” Confirm/initiate registrations for SAM etc.
• April 11, 2016 Error-free application due
• Peer review June-August 2016
• Council October 2016
Criteria for Review

The standard five (with additions)

• Significance
• Investigators
• Innovation
• Approach
• Environment

Protections as appropriate

• Human subjects
• Vertebrate animals
• Biohazards
Additional Criteria for Review

• Is the Collaborative Plan well defined with identifiable responsibilities for the NIH intramural investigator and the extramural applicant?

• Is a plan for management of the collaboration clearly presented, with well-defined descriptions of what each participant proposes to provide to the collaborative partnership?

• Is there a clear and well described advantage to bringing the intramural and extramural investigators together in a collaborative partnership?

• Is it clear which unique research opportunities in the NIH Clinical Center will be utilized?
Criteria for comment (not scored)

• Select agent research
• Resource sharing plans
• Budget and period of support
Questions

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Intramural Clinical Center
Budget Highlights

Maria D. Joyce, CPA, MBA
Chief Financial Officer,
NIH Clinical Center
ICs have flexibility how these programs will be funded. Funds flow to be determined before award.
## Preparing the Budget

<table>
<thead>
<tr>
<th>Extramural PI</th>
<th>Intramural PI</th>
<th>Clinical Center</th>
</tr>
</thead>
<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>
</tr>
<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>
</tr>
<tr>
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<td>• Identify intramural PI before CC budget preparation begins.</td>
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</table>
Sample Budget Template for CC Costs

**Clinical Center Budget Template**

### Inpatient Services

#### a) General Information:
- Extramural PI Name:*
- Intramural PI Name:*
- Extramural PI Institute:*
- Intramural IC:*
- Study Name:*  

#### b) Cost per Inpatient Night:

<table>
<thead>
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<th>Year</th>
<th>Projected # of Patients*</th>
<th>Projected # of inpatient days/patient*</th>
<th>Total # of IP Days</th>
<th>ICD-9 Code*</th>
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#### c) Technical Services Required for the Study:

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<th>Year 2</th>
<th>Year 1 SUBTOTAL</th>
<th>Year 2 SUBTOTAL</th>
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<tbody>
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</table>

- Template includes easy-to-follow, step-by-step instructions for completion
- Separate tabs for:
  - Inpatient services
  - Outpatient services
  - Specialized research services

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*Input by Extramural Applicant

**Input by Clinical Center**
**Sample Budget Template for CC Costs (cont)**

### (d) Drugs Required for the Study:

<table>
<thead>
<tr>
<th>Year 1</th>
<th>Drug Name*</th>
<th>HCPCS code (if applicable)*</th>
<th>Projected # of Patients*</th>
<th>Projected # of doses/patient*</th>
<th>Drug Dosage</th>
<th>Total # of Doses</th>
<th>Cost/Dose**</th>
<th>Estimated Cost**</th>
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**Year 1 SUBTOTAL**: $0

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<th>Total # of Doses</th>
<th>Cost/Dose**</th>
<th>Estimated Cost**</th>
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**Year 2 SUBTOTAL**: $0

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<th>Total # of Doses</th>
<th>Cost/Dose**</th>
<th>Estimated Cost**</th>
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**Year 3 SUBTOTAL**: $0

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<th>HCPCS code (if applicable)*</th>
<th>Projected # of Patients*</th>
<th>Projected # of doses/patient*</th>
<th>Drug Dosage</th>
<th>Total # of Doses</th>
<th>Cost/Dose**</th>
<th>Estimated Cost**</th>
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**Year 4 SUBTOTAL**: $0

**Total Costs per Year:**

- Year 1 Total Costs (Inpatient): $0
- Year 2 Total Costs (Inpatient): $0
- Year 3 Total Costs (Inpatient): $0
- Year 4 Total Costs (Inpatient): $0

**TOTAL Estimated Cost for Study**: $0

*Input by Extramural Applicant

**Input by Clinical Center

Return template to: ClinicalCtrPartner@mail.nih.gov
Sample Budget Template for CC Costs (cont)

<table>
<thead>
<tr>
<th>Clinical Center Budget Template</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialized Research Services</td>
</tr>
</tbody>
</table>

**a) General Information:**
- Extramural PI Name:*  
- Intramural PI Name:*  
- Extramural PI Institute:*  
- Intramural IC:*  
- Study name:*  

**b) Specialized Research Services**

<table>
<thead>
<tr>
<th>Program</th>
<th>Check box if applicable</th>
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<tbody>
<tr>
<td>Rehabilitation Medicine</td>
<td></td>
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<tr>
<td>Human Motor Control Section</td>
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<tr>
<td>Novel Cellular Biologics for Phase I/II Trials</td>
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<td>Healthy Volunteer Program</td>
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<td>Patient Recruitment Program</td>
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<tr>
<td>R&amp;IIS Bluemke - Cardiovascular Imaging - Non-Invasive Imaging of Coronary Artery Disease, Heart Failure and Atherosclerosis Imaging</td>
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</tr>
<tr>
<td>R&amp;IIS Frank - Stem Cell Images</td>
<td></td>
</tr>
<tr>
<td>R&amp;IIS Neumann - Nuclear Medicine/Radiopharmaceutical Research</td>
<td></td>
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<tr>
<td>R&amp;IIS Paik - Nuclear Medicine/Radiopharmaceutical Research</td>
<td></td>
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<tr>
<td>R&amp;IIS Summers - Diagnostic Radiology</td>
<td></td>
</tr>
<tr>
<td>R&amp;IIS Wood - Interventional Oncology</td>
<td></td>
</tr>
<tr>
<td>Other - Clinical Research Informatics</td>
<td></td>
</tr>
<tr>
<td>Other - Contract Nursing Support</td>
<td></td>
</tr>
</tbody>
</table>

*Specialized Research Services require completion of separate budget templates.*

**Specialized Research Services Required by the Study:**

<table>
<thead>
<tr>
<th>Year 1 Estimated Cost**</th>
<th>$0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 2 Estimated Cost**</td>
<td>$0</td>
</tr>
<tr>
<td>Year 3 Estimated Cost**</td>
<td>$0</td>
</tr>
<tr>
<td>Year 4 Estimated Cost**</td>
<td>$0</td>
</tr>
</tbody>
</table>

**TOTAL Estimated Cost for Study**  
$0

*Input by Extramural Applicant

**Input by Clinical Center

Return template to: ClinicalCtrPartner@mail.nih.gov

- 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.
Lessons Learned

• Applicants should provide complete and detailed information for requested services in the Budget Template (procedure, test, service names with CPT codes, drug names and dosages, etc). This will aid the Clinical Center and reduce turnaround time with the mandatory Budget Template reviews.

• Timely submission of the grant budget template to the Clinical Center is required to allow adequate time for coding/costing review.

• The Clinical Center streamlined the Budget Templates to improve the user experience. Example revisions include: fields added/removed where necessary and cost summary table added.

• The Clinical Center has coordinated a method to address IC supported services.
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, 2016 to meet project deadlines
Tips for Preparing the Application

Kenneth E. Santora, Ph.D.
Chief, Extramural Science Policy
Office of Extramural Research Policy and Operations
DEA, 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 (X02 vs U01)
• Resources
General Grantsmanship Reminders

• Identify and utilize your partners
  – Assemble a team of reviewers (SME, non-SME)
  – Your institutional officials: *Internal Deadlines*!
  – NIH staff

• Use extensive internet resources
  – NIH RePORTER: Review funded clinical trial abstracts and public health relevance statements
  – Review examples of funded applications
  – Review tutorials

• *Read the entire FOA!*
General FOA Structure

• Part I. Overview
  – Key Dates
  – Related Notices

• Part 2. Full Text
  – Description (Purpose, IC-specific Areas of Interest)
  – Award, Eligibility Information (Foreign allowable)
  – Application and Submission Instructions
  – Application Review Information
  – Award Administration
  – Agency Contacts, Other Information
Application Structure Matters

• Need ALL Components: may be considered incomplete and returned
• 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
Submitting the Pre-Application (X02) and Application (U01)
IV. Application and Submission Information

FOA-specific requirements

• Collaboration Plan [Approach]
• Letters of Support [Approach] *U01 only*
  – Director of the NIH CC
  – IC specific support letter
• MPI Leadership Plan (include the DIR PI) [Investigator(s)] *recommended; not required*
• Resource Sharing Plan [review consideration]
• Consortium Contractual Arrangements (*U01*)

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

FOA-specific requirements:

• Budget [review consideration] *U01 only*
• [http://www.cc.nih.gov/translational-research-resources/U01/index.html](http://www.cc.nih.gov/translational-research-resources/U01/index.html)
  – Budget cap of $500K direct costs!
  – Budget *must* delineate extramural, intramural and Clinical Center costs
  – Read FOA for Allowable costs
  – Intramural costs determined by discussion with intramural partner- *start early!*
  – **Must** include an **Extramural Collaborations Budget Template** (Other Attachment)
  – Modular budget **NOT** allowed
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 (Other Attachments)
    - Clinical Protocol Synopsis
    - Statistical Analysis Plan
    - Data and Safety Monitoring Plan
    - Milestone Plan and Complete Clinical Protocol/justification
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 products(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
• Identify institutional resources
• ASSIST (U01 only) vs Grants.gov submission
• New FORMS D
• PDF guidance
• Warnings vs. Errors (*validation steps*)
• View your application
# New ‘Forms D’ and NIH Policies

<table>
<thead>
<tr>
<th>Policy Area</th>
<th>Guide Notice</th>
<th>Quick Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Rigor and Transparency</strong></td>
<td>NOT-OD-16-011</td>
<td>New research strategy language; new &quot;Authentication of Key Biological and/or Chemical Resources&quot; attachment.</td>
</tr>
<tr>
<td><strong>Vertebrate Animals</strong></td>
<td>NOT-OD-16-006</td>
<td>Simplifies required criteria, descriptions, justifications.</td>
</tr>
<tr>
<td><strong>Definition of Child</strong></td>
<td>NOT-OD-16-010</td>
<td>“Child” under inclusion policy is now under 18 years old.</td>
</tr>
<tr>
<td><strong>Inclusion Forms</strong></td>
<td>TBA</td>
<td>Adding optional PHS Inclusion Enrollment Report form to FORMS-D application packages</td>
</tr>
<tr>
<td><strong>Data Safety Monitoring Plans</strong></td>
<td>see NOT-OD-16-004</td>
<td>New “Data Safety Monitoring Plan” attachment, required for all applications involving clinical trials (box checked for CT)</td>
</tr>
<tr>
<td><strong>PHS Assignment Request Form</strong></td>
<td>NOT-OD-16-008</td>
<td>Asks for assignment preference (IC, study section), potential conflicts, and needed expertise. NIH will no longer honor requests for study section assignment in the cover letter only in assignment request form.</td>
</tr>
<tr>
<td><strong>Font Guidelines</strong></td>
<td>NOT-OD-16-009</td>
<td>Added flexibility for fonts allowed in PDF attachments</td>
</tr>
<tr>
<td><strong>Biosketch Clarifications</strong></td>
<td>NOT-OD-16-004</td>
<td>Rules for URL to publication list; cite work in both personal statement and contributions to science sections; graphics, figures and tables are not allowed</td>
</tr>
</tbody>
</table>
How Are the X02 and U01 Submission Packages Similar?

Like the U01 application, the X02 pre-application:

• includes a research plan that comprises **specific aims** and a **research strategy** and **requires a collaboration plan** (Other Attachments)

• must **address resource sharing**

• is subject to special organizational and individual **eligibility** requirements

• must propose projects covered under IC-specific guidelines and should request assignment to an IC in the cover letter

• undergoes **electronic submission** and is subject to the same required registrations and timelines
How Do the X02 and U01 Submission Packages Differ?

The X02 pre-application has special requirements:

• **No funds** associated with the application (SF424 Cover; $0 Budget)
• Indicate “No” for involvement of human subjects and vertebrate animals (SF424 Other Project Information)...
  
  ...but remember to provide information about any human subjects/patients in the Research Strategy section of the application (PHS398 Research Plan).

• Research strategy is limited to **6 pages**, instead of 12, and should address special review criteria instead of standard review criteria
• Appendices and letters of support **not** required
• Additional documentation and information for clinical trials **not** required (protocol synopsis, informed consent forms, etc.)
X02-Specific E-Submission Instructions

SF424(R&R) Cover

- **Type of Submission**: Select "Pre-application".
- **Total Federal Funds Requested**: Enter "0".
- **Total Federal and Non-Federal Funds**: Enter "0".
- **Estimated Program Income**: Enter "0".
- **Cover Letter**: Applicants are encouraged to indicate the appropriate NIH Institute/Center in the cover letter (new assignment request form).

SF424 Other Project Information

- **Are Human Subjects Involved**: Answer "No".
- **Are Vertebrate Animals Used**: Answer "No".
- **Other Attachments**: *Collaboration Plan*
U01 FOA-Specific E-Submission Issues

• Multiple PI requires the intramural investigator to register in the eRA Commons
  – Find the IC contact (usually the AOR/SO)
  – Need for Agency Login under PROFILE
• SF424 (R&R) Other Project Information
  – Item 12 Other attachments
  – Filenames are important
Grant Application Package

Opportunity Title: Opportunities for Collaborative Research at the NIH
Offering Agency: National Institutes of Health
CFDA Number: PAR-15-287
CFDA Description: 
Opportunity Number: 
Competition ID: FORMS-C
Opportunity Open Date: 03/11/2016
Opportunity Close Date: 04/11/2016
Agency Contact: eRA Commons Help Desk Monday to Friday 7 am to 8 pm ET
http://grants.nih.gov/support/

This opportunity is only open to organizations, applicants who are submitting grant applications on behalf of a company, state, local or tribal government, academia, or other type of organization.

Application Filing Name: 

Select Forms to Complete

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

Optional
R & R Subaward Budget Attachment(s) Form 5 YR 30 ATT
Planned Enrollment Report
PHS 398 Cumulative Inclusion Enrollment Report
PHS 398 Modular Budget
Research & Related Budget

Pre-filled Header Will change to Forms D

U01 only; except Modular Budget
**APPLICATION FOR FEDERAL ASSISTANCE**

**SF 424 (R&R)**

1. **TYPE OF SUBMISSION:**
   - Pre-application
   - Application
   - Changed/Corrected Application

2. **DATE SUBMITTED:**

3. **DATE RECEIVED BY STATE:**

4. **a. Federal Identifier**
5. **b. Agency Routing Identifier**
6. **c. Previous Grants.gov Tracking ID**

5. **APPLICANT INFORMATION**
   - **Legal Name:**
   - **Department:**
   - **Division:**
   - **Street1:**
   - **Street2:**
   - **City:**
   - **County / Parish:**
   - **Province:**
   - **Country:**
   - **USA: UNITED STATES**
   - **ZIP / Postal Code:**

6. **PERSON TO BE CONTACTED ON MATTERS INVOLVING THIS APPLICATION**
   - **Prefix:**
   - **First Name:**
   - **Last Name:**
   - **Position/Title:**
   - **Street1:**
   - **Street2:**
   - **City:**
   - **County / Parish:**
   - **Province:**
   - **Country:**
   - **USA: UNITED STATES**
   - **ZIP / Postal Code:**
   - **Phone Number:**
   - **Fax Number:**
   - **Email:**

7. **EMPLOYER IDENTIFICATION (EIN) OR (TIN):**

8. **TYPE OF APPLICANT:**
   - Please select one of the following:
   - [ ] Small Business
   - [ ] Organization Type
   - [ ] Women Owned
   - [ ] Socially and Economically Disadvantaged
   - Other (Specify):

9. **TYPE OF APPLICATION:**
   - [ ] New
   - [ ] Resubmission
   - [ ] Renewal
   - [ ] Continuation
   - [ ] Revision

10. **If Revision, mark appropriate box(es):**
    - [ ] A. Increase Award
    - [ ] B. Decrease Award
    - [ ] C. Increase Duration
    - [ ] D. Decrease Duration
    - [ ] Other (specify):

11. **Is this application being submitted to other agencies?**
    - [ ] Yes
    - [ ] No
    - What other Agencies?

12. **NAME OF FEDERAL AGENCY:**
    - National Institutes of Health

13. **CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:**
    - TITLE:

14. **DESCRIPTIVE TITLE OF APPLICANT’S PROJECT:**

15. **PROPOSED PROJECT:**
    - **Start Date:**
    - **Ending Date:**

16. **CONGRESSIONAL DISTRICT OF APPLICANT**
15. ESTIMATED PROJECT FUNDING

a. Total Federal Funds Requested
   "0"

b. Total Non-Federal Funds
   X02

c. Total Federal & Non-Federal Funds

d. Estimated Program Income

16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?

a. YES
   □ THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:
   DATE:

b. NO
   □ PROGRAM IS NOT COVERED BY E.O. 12372; OR
   □ PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

17. By signing this application, I certify (1) to the statements contained in the list of certifications* and (2) that the statements herein are true, complete and accurate to the best of my knowledge. I also provide the required assurances* and agree to comply with any resulting terms if I accept an award. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)

   [ ] I agree

   *The list of certifications and assurances, or an Internet site where you may obtain this list, is contained in the announcement or agency specific instructions.

18. SFLLL (Disclosure of Lobbying Activities) or other Explanatory Documentation

19. Authorized Representative

Prefix: [ ] First Name: [ ] Middle Name: [ ]

Last Name: [ ]

Position/Title: [ ]

Organization: [ ]

Department: [ ] Division: [ ]

Street1: [ ]

Street2: [ ]

City: [ ] County / Parish: [ ]

State: [ ] Province: [ ]

Country: [ ] USA: UNITED STATES ZIP / Postal Code: [ ]

Phone Number: [ ] Fax Number: [ ]

Email: [ ]
Item 12: Other Attachments

1. Are Human Subjects Involved? [Yes, No]
   1.a. If YES to Human Subjects
       Is the Project Exempt from Federal regulations? [Yes, No]
       If yes, check appropriate exemption number.
       If no, is the IRB review Pending? [Yes, No]
       IRB Approval Date:
       Human Subject Assurance Number:

2. Are Vertebrate Animals Used? [Yes, No]
   2.a. If YES to Vertebrate Animals
       Is the IACUC review Pending? [Yes, No]
       IACUC Approval Date:
       Animal Welfare Assurance Number:

3. Is proprietary/privileged information included in the application? [Yes, No]

4. Does this project have an actual or potential impact on the environment? [Yes, No]
   4.a. If yes, please explain:
   4.b. If yes, please explain:
   4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? [Yes, No]
   4.d. If yes, please explain:

5. Is the research performance site designated, or eligible to be designated, as a historic place? [Yes, No]
   5.a. If yes, please explain:

6. Does this project involve activities outside of the United States or partnerships with international collaborators? [Yes, No]
   6.a. If yes, identify countries:
   6.b. Optional Explanation:

7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments

[Add Attachment, Delete Attachment, View Attachment]
# PHS 398 Research Plan

Please attach applicable sections of the research plan, below.

<table>
<thead>
<tr>
<th>Section</th>
<th>Attachment Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Introduction to Application (for RESUBMISSION or REVISION only)</td>
<td>Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>2. Specific Aims</td>
<td>X02 and U01 Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>3. *Research Strategy</td>
<td>X02 and U01 Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>4. Progress Report Publication List</td>
<td>Add Attachment Delete Attachment View Attachment</td>
</tr>
</tbody>
</table>

**Human Subjects Sections**

<table>
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<th>Section</th>
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<tr>
<td>5. Protection of Human Subjects</td>
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<tr>
<td>6. Inclusion of Women and Minorities</td>
<td>U01 only Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>7. Inclusion of Children</td>
<td>U01 only Add Attachment Delete Attachment View Attachment</td>
</tr>
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</table>

**Other Research Plan Sections**

<table>
<thead>
<tr>
<th>Section</th>
<th>Attachment Options</th>
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<tbody>
<tr>
<td>8. Vertebrate Animals</td>
<td>U01 only Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>9. Select Agent Research</td>
<td>X02 and U01 Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>10. Multiple PD/PI Leadership Plan</td>
<td>Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>11. Consortium/Contractual Arrangements</td>
<td>U01 only Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>12. Letters of Support</td>
<td>U01 only Add Attachment Delete Attachment View Attachment</td>
</tr>
<tr>
<td>13. Resource Sharing Plan(s)</td>
<td>X02 and U01 Add Attachment Delete Attachment View Attachment</td>
</tr>
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</table>

**Appendix (if applicable)**

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<td>Appendix</td>
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# Comparison

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<tr>
<th>Application Information</th>
<th>X02</th>
<th>U01</th>
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<tbody>
<tr>
<td>Multiple-PI allowed (MPI Leadership Plan)</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Foreign applicants, components allowed</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>NIH Clinical Center component required</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Collaboration Plan</td>
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<td>Y</td>
</tr>
<tr>
<td>Resource Sharing Plan(s)</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Funding request included</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Specific Aims</td>
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<td>Y</td>
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<tr>
<td>Research Strategy page limit</td>
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<tr>
<td>Clinical Trial Documents</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Enrollment/Inclusion Tables</td>
<td>N</td>
<td>Y</td>
</tr>
<tr>
<td>Appendix, Letters of Support required</td>
<td>N</td>
<td>Y</td>
</tr>
</tbody>
</table>
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)

• 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)
E-Submission Resources (NLM)

Electronic Submission of Grant Applications

• eRA Modules, User Guides, and Documentation
  https://era.nih.gov/modules_user-guides_documentation.cfm/

• All electronic applications require advance registration at both
  Grants.gov and the NIH eRA Commons. (explanation and links to both
  registration sites)
  https://era.nih.gov/registration_accounts.cfm

• Training and communication tools to make your experience with the eRA
  system easier, including web-based tutorials, presentations and other
  resources
  https://era.nih.gov/era_training/index.cfm
Working at the CC: Frequently Asked Questions

• Planning a Collaboration:
  • Intramural research Resources
  • Collaborations

• Applying for the “Opportunities for Collaborative Research at the NIH Clinical Center (X02) Pre-application and (U01)”
  • Eligibility to Apply for the U01 Funding Opportunity
  • X02 Pre-application to Apply to the U01 Funding Opportunity
  • Building a Budget for the U01 Funding Opportunity
  • Applying for the U01 Funding Opportunity

• Implementing a Collaboration:
  • NIH Appointments for Extramural Investigators
  • Credentialing for Extramural Investigators
  • Conflict of Interest
  • Clinical Protocols
  • Patients
  • Intellectual Property
  • Biospecimens
  • Workspace and Lodging for Extramural Partners
  • Data
Webinar slides posted later today at:
http://www.cc.nih.gov/translational-research-resources/webinar.html