Sponsored Projects: Planning & Organizing a Research Proposal

Jaime S. Rubin, Ph.D.
Dept. of Medicine
College of Physicians and Surgeons
Columbia University

Course: “Funding and Grantsmanship for Research and Career Development Activities”

http://grantscourse.columbia.edu/
Approaches for Competitive Applications

- Identify Funding
- Prepare to Write the Grant Application
- Complete the Grant Application
Identify Funding

- Identify appropriate funding agencies
  - Government
  - Non-government

- Identify appropriate funding mechanisms
  - Research
  - Training

- Create a calendar of application deadlines for identified funding programs
Approaches for Competitive Applications

- Identify Funding
- Prepare to Write the Grant Application
- Complete the Grant Application
It’s not the will to win, but the will to prepare to win that makes the difference.

Bear Bryant, University of Alabama
Prepare to Complete the Grant Application

- Speak with Agency Program Officer
- Speak with colleagues who are/were awardees
- Review funded applications if possible
- Review agency’s review criteria
- Identify what will make the application more competitive
  - Research and/or career development arrangements
  - Access to core facilities/research resources
- Strengthen “Preliminary Work/ Pilot Data”
- Who will write confidential letters of reference?

Research and Career Development Arrangements

- **Multiple Principle Investigators** (research awards)
- **Multiple Mentors** (mentored awards)
- **Advisors** (mentored awards)
- **Co-investigators/Collaborations**
- **Subcontracts to other institutions**
- **Multidisciplinary/Interdisciplinary**
Prepare to Complete the Grant Application

- Identify and meet with Co-investigators, Collaborators, Consultants, Advisors
  - Identify roles and responsibilities
  - Administrative requirements
    (e.g. if other countries/institutions are involved)
- Identify necessary core facilities and other research resources
- Meet with research administrators
- Human subjects, lab animals and any other regulatory issues?

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Approaches for Competitive Applications

- Identify Funding
- Prepare to Write the Grant Application
- Complete the Grant Application
Complete the Grant Application

- Review the application instructions
- Identify the different components
- Create a checklist
- Create an outline
  - Content, Length of section (*vis a vis* page limits)
- Identify and delegate responsibilities for the different components
  - Technical/Scientific
  - Administrative – e.g. budget
  - Regulatory
  - Draft letters of collaboration/support

Complete the Grant Application

- Confirm page limits for each component
- Create a schedule for any required meetings
- Determine:
  - Shared computer drive/folders
  - Naming of files (dates?)
  - Track changes?
  - Font, margin, format of literature citation
- Set a **firm** time-line for each responsibility
  - Writing milestones
  - Absolute deadline date for final compilation

Complete the Grant Application

- Read **instructions**
- **Never assume** that reviewers “will know what you mean”
- Refer to **literature** thoroughly and thoughtfully
- Explicitly state the **rationale** of the proposed investigation ("the hypothesis of my study is...")
- Discuss **limitations** and potential “**challenges**” and how these will be addressed (e.g., “**alternate approaches**”)
- Include well-designed **tables and figures**
- Present an **organized**, lucid write-up (use an **outline**)
- Ask colleagues to **review** and comment
Complete the Grant Application

- Read instructions
- Never assume that reviewers “will know what you mean”
- Refer to literature thoroughly and thoughtfully
- Explicitly state the rationale of the proposed investigation (“the hypothesis of my study is…”)
- Discuss limitations and potential “challenges” and how these will be addressed (e.g., “alternate approaches”)
- Include well-designed tables and figures
- Present an organized, lucid write-up (use an outline)
- Ask colleagues to review and comment
Include Well-Designed Tables and Figures

- Include explanatory caption with the figure (not buried in text)
- Not overly complicated
- Informative, even if printed in black and white
- Easy for the reviewers to read
- Tips:
  - Bold label in text (e.g., Fig. 4) so it’s easier for reviewers to locate relevant text for individual Figure
  - Try to have Figure and relevant text on the same page
Anticipate Questions
and
Answer them before they are asked
Investigator

- Competent
- Enthusiastic
- Thorough
- Professional
Elements of a Good Proposal

- Feasible
- Relevant
- Unique
- Innovative
- Clear
- Brief
- Consistent

Common Problems with Grant Applications from New Investigators

- Does not address/follow funding agency’s mission, specific instructions, budget limits, etc.
- Overly ambitious
- Not independent of previous mentor’s research
- Fishing expedition
- Not hypothesis driven
- Descriptive, not mechanistic project
- Unfocussed
- No or insufficient preliminary data
- Unrealistic budget
- Methodologies beyond the expertise of investigator or research team
NIH: one round of applications
Pink Sheet: Reviewers’ Comments
Common Proposal Problems

- **Title**
  - Too long
  - Confusing
  - Cute but distracting
  - Not program related

- **Cover Page**
  - Does not follow format precisely
  - Does not include all necessary information
Abstract

- Not comprehensive
- Omits significant elements
- Poor grammar or spelling
- Too long
- Cut and paste job

Table of Contents

- Not included
- Inaccurate pagination
- Not informative

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
- **School Description**
  - Irrelevant information
  - Does not lead reader to proposal objectives
  - Good history: so what?
  - Too long

- **Statement of Need**
  - Deals with wants, not needs
  - No documentation
  - Unrelated to objectives/outcomes desired
  - Problem already solved
  - Not supported by current research
Objectives/Outcomes

- Not clear
- Too ambitious
- Omitted
- Procedures rather than objectives

Innovation

- Not new or innovative
- Attempt to justify new equipment/materials
- Not clearly described
Task/Activity Plan

- Insufficient detail
- Tasks not related to objectives
- Tasks not justified by needs
- Time and task charts not included
- Responsibilities not clear
- Does not address contingency plans

Evaluation of Project Progress

- Unrelated to objectives
- Unrelated to innovation
- Uses outmoded or inaccurate methods
- **Project Staffing**
  - No identification of responsibilities and roles
  - No documentation of competence (e.g. bio sketches)
  - No indication of time and effort for each individual contributing to project

- **Budget**
  - Unrelated to activities proposed
  - Little or no contribution from institution
  - Amounts not supported by proposal
  - Budget justification missing
  - Categories not those of funding agency
  - Budget cannot be sustained after project ends
- **Collaborative Efforts**
  - Names and responsibilities of all involved in proposal not identified
  - No identification of institutions involved

- **Review of Literature**
  - Unrelated to needs, objectives, innovations
  - Does not lead reader to proposed project
  - Dated material
  - Should not be a review article
NIH's Review Criteria-1

- **Overall Impact Score**
  - “Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved”

- **Core Review Criteria**
  - A separate score is given for each
NIH’s Review of Research Grants

Guidelines for Reviewers

- R01 GUIDE FOR REVIEWERS (PDF - 74 KB) (03/21/2016)
- R03 GUIDE FOR REVIEWERS (PDF - 73 KB) (03/21/2016)
- R15 GUIDE FOR REVIEWERS (PDF - 26 KB) (03/21/2016)
- R21 GUIDE FOR REVIEWERS (PDF - 74 KB) (03/21/2016)
- R34 GUIDE FOR REVIEWERS (PDF - 113 KB) (03/21/2016)
- R25 GUIDE FOR REVIEWERS (PDF - 130 KB) (03/18/2015)
- U01 BRP GUIDELINES FOR REVIEWERS (PDF - 74 KB) (03/21/2016)
- R13/U13 GUIDE FOR REVIEWERS (PDF - 74 KB) (03/21/2016)
- R41, R42, R43, R44 GUIDE FOR REVIEWERS (PDF - 128 KB) (04/05/2016) (Small Business Innovation Research and Small Business Technology Transfer Awards)
- Guide for Reviewers for 1R44 SBIR Direct Phase II applications (PDF - 191 KB) (04/23/2014)

Review Critique Fillable Templates

- RPG/R01/R03/R21/R34 Review (MS Word - 42 KB) (05/09/2016)
- R15 Review (MS Word - 41 KB) (04/21/16)
- R25 Review (MS Word - 108 KB) (03/31/2016)
- Bioengineering Research Partnership Review (MS Word - 120 KB) (03/31/2016)
- R13/U13 Review (MS Word 108 KB) (03/31/2016)
- SBIR/STTR Review (MS Word - 40 KB) (03/31/2016)

Review Criteria and Considerations

- Criteria and Considerations for Research Project Grant (RPG/R01/R03/R21/R34) Critiques (03/21/2016)
- Criteria and Considerations for R15 Critiques (03/21/2016)
- Criteria and Considerations for R25 Critiques (03/21/2016)
- Criteria and Considerations for BRP Critiques (03/21/2016)
- Criteria and Considerations for R13/U13 Critiques (03/21/2016)
- Criteria and Considerations for SBIR-STTR Critiques (03/21/2016)
(A) **Significance:**

1. “Does the project address an important problem or a critical barrier to progress in the field?

2. Is there a strong scientific premise for the project?

3. If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?

4. How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?”

https://grants.nih.gov/grants/peer/critiques/rpg_D.htm

(B) Investigators:

1. "Are the PD/PIs, collaborators, and other researchers well suited to the project?"
2. If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training?
3. If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?
4. If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?"
(C) Innovation:

(1) “Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?"

(2) Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?

(3) Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?”
(D) **Approach:**

1. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

2. Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?

3. Are potential problems, alternative strategies, and benchmarks for success presented?
NIH's Review Criteria-6

(D) Approach:
(4) If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

(5) Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?
NIH's Review Criteria-7

(E) “Environment:

(1) “Will the scientific environment in which the work will be done contribute to the probability of success?

(2) Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?

(3) Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?”

https://grants.nih.gov/grants/peer/critiques/rpg_D.htm

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
NIH's Review Criteria-8

Considered in determining merit, but not given scores

Protections for Human Subjects: For research that is not “exempt” (six categories), reviewers evaluation based on:

“1) risk to subjects,
2) adequacy of protection against risks,
3) potential benefits to the subjects and others,
4) importance of the knowledge to be gained, and
5) data and safety monitoring for clinical trials”
NIH's Review Criteria-9

Considered in determining merit, but not given scores

**Protections for Human Subjects:** For research that meets the criteria for “exempt” research (one or more of six categories), reviewers evaluation based on:

“1) the justification for the exemption

2) human subjects involvement and characteristics, and

3) sources of materials”
NIH's Review Criteria-10

Considered in determining merit, but not given scores

**Inclusion of Women, Minorities and Children:**
Reviewers evaluation based on “proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed”

https://grants.nih.gov/grants/peer/critiques/rpg_D.htm
Vertebrate Animals: “as part of the scientific assessment according to the following criteria:

1. description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used
2. justifications for the use of animals versus alternative models and for the appropriateness of the species proposed
3. interventions to minimize discomfort, distress, pain and injury; and
4. justification for euthanasia method if NOT consistent with the AVMA Guidelines”
Addressed, but not given scores or considered in overall impact score

**Budget and Period of Support:** “are fully justified and reasonable in relation to the proposed research”

**Resource Sharing Plans:** “Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genomic Data Sharing Plan”
NIH's Review Criteria-13

Addressed, but not given scores or considered in overall impact score

Authentication of Key Biological and/or Chemical Resources: if involved, “plans proposed for identifying and ensuring the validity of those resources”

Requests for Applications (RFAs) May include additional elements, relating to the specific programmatic needs of the RFA

https://grants.nih.gov/grants/peer/critiques/rpg_D.htm

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications

Notice Number: NOT-OD-16-011

These updates focus on four areas deemed important for enhancing rigor and transparency:

1) the scientific premise forming the basis of the proposed research,
2) rigorous experimental design for robust and unbiased results,
3) consideration of relevant biological variables, and
4) authentication of key biological and/or chemical resources.

Updates include:

• Revisions to application guide instructions for preparing your research strategy attachment
• Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
• Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

https://grants.nih.gov/grants/peer/critiques/rpg.htm
# Reviewer Guidance on Rigor and Transparency: Research Project Grant and Mentored Career Development Applications

## Overview: Research Project Grant (RPG) Applications

<table>
<thead>
<tr>
<th>Element of Rigor and Transparency</th>
<th>Section of Application</th>
<th>Criterion Score</th>
<th>Additional Review Consideration</th>
<th>Contribute to Overall Impact Score?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scientific Premise</td>
<td>Research Strategy</td>
<td>Significance</td>
<td>NA</td>
<td>Yes</td>
</tr>
<tr>
<td>Scientific Rigor</td>
<td>Research Strategy</td>
<td>Approach</td>
<td>NA</td>
<td>Yes</td>
</tr>
<tr>
<td>Consideration of Relevant Biological Variables, such as Sex</td>
<td>Research Strategy</td>
<td>Approach</td>
<td>NA</td>
<td>Yes</td>
</tr>
<tr>
<td>Authentication of Key Biological and/or Chemical Resources</td>
<td>New Attachment</td>
<td>NA</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>


# Rigor and Reproducibility in NIH Applications: Resource Chart

<table>
<thead>
<tr>
<th>4 AREAS OF FOCUS</th>
<th>WHAT DOES IT MEAN?</th>
<th>WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?</th>
</tr>
</thead>
</table>
| **Scientific Premise** | The **scientific premise** for an application is the research that is used to form the basis for the proposed research question(s). | Research Strategy  
➢ Significance |
| **Scientific Rigor (Design)** | **Scientific rigor** is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation and reporting of results. | Research Strategy  
➢ Approach |

*See related [FAQs](#), [blog post](#), [examples from pilots](#)
<table>
<thead>
<tr>
<th>4 AREAS OF FOCUS</th>
<th>WHAT DOES IT MEAN?</th>
<th>WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?</th>
</tr>
</thead>
</table>
| Biological Variables | Biological variables, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological variable that is frequently ignored in animal study designs and analyses, leading to an incomplete understanding of potential sex-based differences in basic biological function, disease processes and treatment response. Explain how relevant biological variables, such as the ones noted above, are factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data or other relevant considerations must be provided for applications proposing to study only one sex.  
*See related FAQs, blog posts, article | Research Strategy  
➢ Approach |
| Authentication | Key biological and/or chemical resources include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies. These resources may or may not be generated with NIH funds and:  
• may differ from laboratory to laboratory or over time;  
• may have qualities and/or qualifications that could influence the research data;  
• are integral to the proposed research. The authentication plan should state in one page or less how you will authenticate key resources, including the frequency, as needed for your research. Note: Do not include authentication data in your plan.  
*See related FAQs, blog post | Other Research Plan Section  
➢ Include as an attachment  
➢ Do not include in the Research Strategy |
Separate Scores for the 5 Individual Criteria

- All applications receive scores (even those not discussed at study section)
- Individually reported in summary statement
- Major strengths and weaknesses that influenced the overall impact/priority score - ¼ page per criterion

<table>
<thead>
<tr>
<th><strong>1. Significance</strong></th>
<th>Please limit text to ¼ page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Strengths</strong></td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td><strong>Weaknesses</strong></td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
<tr>
<td>•</td>
<td></td>
</tr>
</tbody>
</table>
Why Are Proposals Turned Down?

Research Plan

- The problem is trivial or is unlikely to produce new or useful information.
- The proposed research is based on a hypothesis that rests on doubtful, unsound or insufficient evidence.
- The proposal is more complex than the author realizes.
The problem is local in significance, production, or control, or otherwise fails to fall clearly in the mainstream of the discipline.

The problem is intellectually premature - only a pilot study.

The problem as proposed is overly involved with too many elements required to be investigated simultaneously.

The description of the research leaves the proposal nebulous, diffuse, and without a clear aim.
Investigator

- Investigator does not have experience or training for the proposed research.
- Investigator appears to be unfamiliar with pertinent literature or methods, or both.
- Investigator's previously published work in the field does not inspire confidence.
- Investigator relies too heavily, or insufficiently, on experienced associates.
- Other responsibilities prevent investigator from devoting sufficient time to this project.
Resources & Environment

- Available equipment is unsuited to the research.
- Institutional setting unfavorable.
Research Design and Methodology

- The proposed methodology, including tests and procedures, are unsuited to the objective. May be beyond the competence of the investigator.
- The over-all design is not carefully thought out.
- Statistical aspects are not given sufficient consideration.
Approach lacks imagination or originality.

Controls are either inadequately conceived or described.

Proposed material for research is unsuited of difficult to obtain.

The number of observations proposed is unsuitable.
Additional Problems

- Requirements for equipment, personnel or time are unrealistic.

- Current research grants are adequate in scope and funding to cover the proposed research.
NIH R01 Application

- Model for other NIH research (e.g. R03, R21, P01) applications
- Model for other research grant programs supported by voluntary health organizations, private foundations, and professional societies
Research Project Grants: Applications, Awards, and Success Rates

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
# NIH R01 - FY2014

- **Number of Applications, Number of Awards, Success Rate**
  - **New**
  - **Competing Renewals**

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Topic</th>
<th>Mechanism</th>
<th>Activity</th>
<th>Type</th>
<th>Statistic</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>Applications - Number</td>
<td>Research Grants</td>
<td>R01</td>
<td>Competing Renewals</td>
<td>4,241</td>
</tr>
<tr>
<td>2014</td>
<td>Success Rate</td>
<td>Research Grants</td>
<td>R01</td>
<td><strong>Competing Renewals</strong></td>
<td>34.64%</td>
</tr>
<tr>
<td>2014</td>
<td>Awards - Number</td>
<td>Research Grants</td>
<td>R01</td>
<td>Competing Renewals</td>
<td>1,467</td>
</tr>
<tr>
<td>2014</td>
<td>Awards - Number</td>
<td>Research Grants</td>
<td>R01</td>
<td>New</td>
<td>3,566</td>
</tr>
<tr>
<td>2014</td>
<td>Applications - Number</td>
<td>Research Grants</td>
<td>R01</td>
<td>New</td>
<td>23,004</td>
</tr>
<tr>
<td>2014</td>
<td>Success Rate</td>
<td>Research Grants</td>
<td>R01</td>
<td><strong>New</strong></td>
<td>15.45%</td>
</tr>
</tbody>
</table>


New (Type 1) R01 and R21 Applications over Time

R01:R21=6.62

R01:R21=1.71

Applications

Fiscal Year


https://nexus.od.nih.gov/all/2016/11/04/nih-r01-r21/

Jaime S. Rubin, Ph.D.: http://grantscourse.columbia.edu
NIH & AHRQ Announce Upcoming Changes to Policies, Instructions and Forms for 2016 Grant Applications

The planned changes focus on the following areas:

- Rigor and transparency in research
- Vertebrate animals
- Inclusion reporting
- Data safety monitoring
- Research training
- Appendices
- Font requirements
- Biosketch clarifications

NIH Grant Forms and Instructions

- **How to Apply - Application Guide**

- **Forms Library**
  [https://grants.nih.gov/grants/forms.htm](https://grants.nih.gov/grants/forms.htm)

- **Format Pages**
  [https://grants.nih.gov/grants/forms/format-pages.htm](https://grants.nih.gov/grants/forms/format-pages.htm)
### 14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix</td>
<td></td>
</tr>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>Middle Name</td>
<td></td>
</tr>
<tr>
<td>Last Name</td>
<td></td>
</tr>
<tr>
<td>Suffix</td>
<td></td>
</tr>
<tr>
<td>Position/Title</td>
<td></td>
</tr>
<tr>
<td>Organization Name</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td></td>
</tr>
<tr>
<td>Street1</td>
<td></td>
</tr>
<tr>
<td>Street2</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>County/Parish</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td>USA: UNITED STATES</td>
</tr>
<tr>
<td>ZIP/Postal Code</td>
<td></td>
</tr>
<tr>
<td>Phone Number</td>
<td></td>
</tr>
<tr>
<td>Fax Number</td>
<td></td>
</tr>
<tr>
<td>Email</td>
<td></td>
</tr>
</tbody>
</table>

### 15. ESTIMATED PROJECT FUNDING

<table>
<thead>
<tr>
<th>Category</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Total Federal Funds Requested</td>
<td></td>
</tr>
<tr>
<td>b. Total Non-Federal Funds</td>
<td></td>
</tr>
<tr>
<td>c. Total Federal &amp; Non-Federal Funds</td>
<td></td>
</tr>
<tr>
<td>d. Estimated Program Income</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. YES</td>
<td>THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON:</td>
</tr>
<tr>
<td>b. NO</td>
<td>PROGRAM IS NOT COVERED BY E.O. 12372; OR</td>
</tr>
<tr>
<td></td>
<td>PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW</td>
</tr>
</tbody>
</table>

### 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.
Cover Letter Attachment
Cover Letter Attachment

- Not usually required for R grants
- Administrative use only, not seen by peer reviewers
- Application title, PA or RFA title
- Special circumstances
  - Agency approval documentation
    - e.g., budget > $500,000
  - Subaward not active for all years
  - Proposed studies will generate large-scale genomic data
# PHS Assignment Request Form

**Funding Opportunity Number:**

**Funding Opportunity Title:**

### Awarding Component Assignment Request (optional)

If you have a preference for an Awarding Component (e.g., NIMH Institute/Center) assignment, please use the field below to identify the most appropriate assignment and enter the short abbreviation (e.g., NCI for National Cancer Institute) in “Assign to/Do Not Assign To Awarding Component” sections below. Your first choice should be in column 1. All requests will be considered; however, locus of review is predetermined for some applications and assignment requests cannot always be honored.

Information about Awarding Components can be found here: [https://grants.nih.gov/grants/phs_assignment_information.html#Awarding Components](https://grants.nih.gov/grants/phs_assignment_information.html#Awarding Components)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assign to Awarding Component:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do Not Assign to Awarding Component:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Study Section Assignment Request (optional)

If you have a preference for a study section assignment, please use the field below to identify the most appropriate study section and enter the short abbreviation for that study section in “Assign to/Do Not Assign to Study Section” sections below. Your first choice should be in column 1. All requests will be considered; however, locus of review is predetermined for some applications and assignment requests cannot always be honored.

For example, you would enter “CAMP” if you wish to request assignment to the Cancer Molecular Pathobiology study section or enter “ZRG1 HOM-R” if you wish to request assignment to the Healthcare Delivery and Methodologies SBIR/STTR panel for informatics. Be careful to accurately capture all formatting (e.g., spaces, hyphens) when you type in the request.

Information about Study Sections can be found here: [https://grants.nih.gov/grants/phs_assignment_information.html#Study Section](https://grants.nih.gov/grants/phs_assignment_information.html#Study Section)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assign to Study Section: Only 20 characters allowed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do Not Assign to Study Section: Only 20 characters allowed</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>


# PHS 398 Cover Page Supplement

**OMB Number:** 0925-0001  
**Expiration Date:** 10/31/2018

## 1. Human Subjects Section

<table>
<thead>
<tr>
<th>Clinical Trial?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

*Agency-Defined Phase III Clinical Trial?*  
☐ Yes  ☐ No

## 2. Vertebrate Animals Section

<table>
<thead>
<tr>
<th>Are vertebrate animals euthanized?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

If "Yes" to euthanasia

Is method consistent with American Veterinary Medical Association (AVMA) guidelines?  
☐ Yes  ☐ No

If "No" to AVMA guidelines, describe method and provide scientific justification

---

NIH’s definition of Clinical Trial: “A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes...”
1. Human Subjects

“a broadly based prospective Phase III clinical investigation (usually involving several hundred or more human subjects) to evaluate an experimental intervention in comparison with a standard or control intervention or to compare two or more existing treatments. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials also are included.”

https://grants.nih.gov/grants/glossary.htm

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
2. Vertebrate Animals

If:

- "Yes" to "Are vertebrate animals euthanized?" and
- "No" to "Is method consistent with AVMA guidelines?"

Then:

- Describe the method of euthanasia to be used
- With a scientific justification

Will be reviewed by Office of Laboratory Animal Welfare (OLAW).
Project/Performance Site(s)

Where the work described in the Research Plan will be conducted

- Applicant organization (CU)
- Collaborating institutions (subcontracts)
  - Domestic (e.g. NYSPI) and foreign institutions
  - Additional patient recruitment sites
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. □ 1 □ 2 □ 3 □ 4 □ 5 □ 6

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: ________________________
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:  

R&R Other Project Information:

6. Activities outside the US/
Partnerships with International Collaborators

If “Yes”, must include “**Foreign Justification**” under “12. Other Attachments”: “Describe special resources or characteristics of the research project (e.g., human subjects, animals, disease, equipment, and techniques), including the reason why the facilities or other aspects of the proposed project are more appropriate than a domestic setting.”
R&R Other Project Information:

7. Project Summary/Abstract

“Succinct and accurate description of the proposed work and should be able to stand on its own… understandable to a scientific literate reader… be concise… State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving the stated goals…”


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
R&R Other Project Information:

8. Project Narrative

“Describe the relevance of this research to public health in, at most, three sentences.”
R&R Other Project Information:

9. Bibliography/References Cited

- Full citations of all references cited in the Research Plan
- Relevant and current literature
- No page limit
- Include PMCID # or NIH Manuscript Submission Reference # as required for articles that fall under NIH’s Public Access Policy (authored/co-authored by the applicant)


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
<table>
<thead>
<tr>
<th>Section</th>
<th>Field</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Project Summary/Abstract</td>
<td></td>
<td>Add Attachment</td>
</tr>
<tr>
<td>8. Project Narrative</td>
<td></td>
<td>Add Attachment</td>
</tr>
<tr>
<td>9. Bibliography &amp; References Cited</td>
<td></td>
<td>Add Attachment</td>
</tr>
<tr>
<td>10. Facilities &amp; Other Resources</td>
<td></td>
<td>Add Attachment</td>
</tr>
<tr>
<td>11. Equipment</td>
<td></td>
<td>Add Attachment</td>
</tr>
<tr>
<td>12. Other Attachments</td>
<td></td>
<td>Add Attachments, Delete Attachments, View Attachments</td>
</tr>
</tbody>
</table>
10. Facilities & Other Resources

- Facilities to be used for the conduct of the proposed research
  - Laboratory
  - Animal
  - Computer
  - Office
  - Clinical
  - Other: Core facilities [e.g. research pharmacy, biostatistics, technical cores (microscopy, biomarkers)]

- Describe for each performance site

- Discuss how each Facility (unique features, if appropriate) will be utilized in the proposed research plan – e.g. capabilities, availability
10. Facilities & Other Resources

How will the scientific environment contribute to the probability of success (e.g., institutional support, physical resources, intellectual rapport)?

Discuss ways in which the proposed studies will benefit from unique features of the scientific environment, subject populations, or unique collaborative arrangements.
R&R Other Project Information:

10. Facilities & Other Resources

- **Early Stage Investigators:**
  - Describe institutional investment in the success of the investigator, e.g., resources for classes, travel, training; collegial support such as career enrichment programs, assistance and guidance in the supervision of trainees involved with the ESI’s project, and availability of organized peer groups.
  - Logistical support such as administrative management and oversight and best practices training.
  - Financial support such as protected time for research with salary support.

[Links to resources and further information]

R&R Other Project Information:

11. Equipment

- Major items of equipment available for project
- Relevant capabilities
- Especially important if specialized, unusual, or expensive instrumentation is involved in the study
- Core facilities “housing” equipment
<table>
<thead>
<tr>
<th>Section</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research Plan Section</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Specific Aims</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Research Strategy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Progress Report Publication List</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Human Subjects Section</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Protection of Human Subjects</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Data Safety Monitoring Plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Inclusion of Women and Minorities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Inclusion of Children</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Other Research Plan Section</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Vertebrate Animals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Select Agent Research</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Multiple PD/PI Leadership Plan</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Consortium/Contractual Arrangements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Letters of Support</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Resource Sharing Plan(s)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Authenticity of Key Biological and/or Chemical Resources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Appendix</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Appendix</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
PHS Research Plan

Section 2 [Specific Aims]: 1 page

Section 3 [Research Strategy]: 12 pages

“Answer these questions:

1. What do you intend to do?
2. Why is the work important?
3. What has already been done?
4. How are you going to do the work?”


Jaime S. Rubin, Ph.D.; http://grantcourse.columbia.edu
2. Specific Aims (1 page)

- State goals of research
- Summarize expected outcomes
  - Impact on fields involved
- List specific objectives
  - Describe hypotheses to be tested
  - Specific problem to be solved
  - Create a novel design
  - New technology to be developed
  - Challenge an existing paradigm or clinical practice
  - Address critical barrier to research area’s progress
- Can include a schematic figure relating Hypothesis and Specific Aims to scientific problem to be studied

3. Research Strategy

- (a) Significance
- (b) Innovation
- (c) Approach
  - Preliminary Studies/ Progress report

12 pages for an R01 application
3. Research Strategy - (a) Significance

- Importance of the problem/ Critical barrier to progress in the field

- Scientific premise for the project, strengths and weaknesses of published research/preliminary data that supports application

- How scientific knowledge, technical capability, and/or clinical practice will be improved

- How the concepts, methods, technologies, treatments, services, or preventative interventions will be changed if research is successful
3. Research Strategy – (b) Innovation

- How proposal changes current research and/or clinical practice paradigms
- Novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed/ used - advantages over current practice
- Improvements/ new applications of current concepts, approaches, methodologies, instrumentation, or interventions
3. Research Strategy – (c) Approach

- Overall strategy, methodology, and analyses to be used to accomplish the specific aims
- How will experimental design and methods lead to “robust and unbiased results”
- How will data be collected, analyzed, and interpreted
- Potential problems (challenges/limitations), alternative strategies/approaches
- Benchmarks (milestones) for success, strategies to establish feasibility
# Timeline for Specific Aims and Benchmarks/Milestones of Research Progress

<table>
<thead>
<tr>
<th>Benchmarks/ Milestones</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Summary of Specific Aim 1a</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 1b</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 2a</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 2b</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 3a</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Summary of Specific Aim 3b</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. Research Strategy – (c) Approach

- How relevant biological variables (e.g. sex) are incorporated into the research design and analyses. Studies with only one sex must provide strong justification.

- “Sex as a Biological Variable” is evaluated by reviewers.

- Involvement of human research subjects discussed here as well as in following appropriate sections.
Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)

Main points

- NIH expects that sex as a biological variable will be factored into research designs, analyses, and reporting in vertebrate animal and human studies.
- Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.
- This decision tree is meant to be used as a guide, but does not encompass the entire policy. See NOT-OD-15-102 for more information.

Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)

Does the study involve vertebrate animals or humans?¹

No further consideration of SABV required; not considered a weakness
3. Research Strategy – Preliminary Studies

- Included in the Approach section
- Aids reviewers in assessing the likelihood of project’s success
- Helps establishes competence and experience of PI and research team

- Complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials resulting from the project since its last competitive review.

- Include the NIH Manuscript Submission reference number (NIHMS#) or the PubMed Central (PMC) reference number (PMCID#).
<table>
<thead>
<tr>
<th>Human Subjects Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Protection of Human Subjects</td>
</tr>
<tr>
<td>6. Data Safety Monitoring Plan</td>
</tr>
<tr>
<td>7. Inclusion of Women and Minorities</td>
</tr>
<tr>
<td>8. Inclusion of Children</td>
</tr>
</tbody>
</table>
Supplemental Grant Application Instructions
For All Competing Applications and Progress Reports

PART II SUPPLEMENTAL INSTRUCTIONS FOR PREPARING THE PROTECTION OF HUMAN SUBJECTS SECTION OF THE RESEARCH PLAN, AND HUMAN SUBJECTS RESEARCH POLICY
5.-8. Human Subjects Research

- Very detailed instructions
- Pertinent even if only a subcontracted institution is involved in human subjects research
- Pertinent even if only receiving specimens
- Peer reviewers will assess protection from research risks as well as inclusion of women, minorities, and children in studies
5. Protection of Human Subjects

- **Risks to Human Subjects**
  - a. Human subjects involvement, characteristics, and design
  - b. Sources of materials
  - c. Potential risks

- **Adequacy of Protection Against Risks**
  - a. Recruitment and informed consent
  - b. Protections against risk

- **Potential Benefits of the Proposed Research to Human Subjects and Others**

- **Importance of the Knowledge to be Gained**
6. Data and Safety Monitoring Plan (DSMP)

- Required if the proposed research includes a clinical trial

- Overall framework for safety monitoring, information to be monitored, frequency of monitoring, person/group responsible for monitoring and advising, plans for interim analysis and stopping rules

- Reporting and management of Adverse Events (AEs), Serious Adverse Events (SAEs) Unanticipated Problems (UPs)

- Data and Safety Monitoring Board (DSMB)?


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
7. Inclusion of Women and Minorities

- The targeted/planned distribution of subjects by sex/gender and race and ethnicity groups
- Description of the subject selection criteria and rationale for selection of sex/gender and racial and ethnic group members
- Rationale for proposed exclusion of any sex/gender, racial, or ethnic group
- Description of proposed outreach programs for recruiting sex/gender, racial, and ethnic group members as subjects

Additional Guidance and Considerations

8. Inclusion of Children

- Description of plans to include children or acceptable justification for exclusion
- Description of and rationale for selecting specific age range
- Descriptions of investigators’ expertise for working with children at the ages included, appropriateness of available facilities, and statistically sufficient number of children
- Additional Protections for Children Involved as Subjects in Research
Inclusion Enrollment Report

Questions:

- Delayed onset study? [Yes/No]
- Enrollment Type? [Planned/Cumulative (Actual)]
- Using an Existing Dataset or Resource? [Yes/No]
- Enrollment Location? [Domestic/Foreign]
- Clinical Trial? [Yes/No]
- NIH-Defined Phase III Clinical Trial? [Yes/No]
## PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

### Study Title
*must be unique:

### Delayed Onset Study?
- Yes
- No

**If study is not delayed onset, the following selections are required:**

- **Enrollment Type**
  - Planned
  - Cumulative (Actual)

- **Using an Existing Dataset or Resource**
  - Yes
  - No

- **Enrollment Location**
  - Domestic
  - Foreign

- **Clinical Trial**
  - Yes
  - No

### Comments:

---

### Ethnic Categories

<table>
<thead>
<tr>
<th>Racial Categories</th>
<th>Not Hispanic or Latino</th>
<th>Hispanic or Latino</th>
<th>Unknown/Not Reported</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Female</td>
<td>Male</td>
<td>Unknown/Not Reported</td>
<td>Female</td>
</tr>
<tr>
<td>American Indian/Alaska Native</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Asian</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Black or African American</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>More than One Race</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Unknown or Not Reported</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**Total**
- Female
- Male
- Unknown/Not Reported

---

To ensure proper performance, please save frequently.

<table>
<thead>
<tr>
<th>Section</th>
<th>Add Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>9. Vertebrate Animals</td>
<td></td>
</tr>
<tr>
<td>10. Select Agent Research</td>
<td></td>
</tr>
<tr>
<td>11. Multiple PD/PI Leadership Plan</td>
<td></td>
</tr>
<tr>
<td>12. Consortium/Contractual Arrangements</td>
<td></td>
</tr>
<tr>
<td>13. Letters of Support</td>
<td></td>
</tr>
<tr>
<td>14. Resource Sharing Plan(s)</td>
<td></td>
</tr>
<tr>
<td>15. Authentication of Key Biological and/or Chemical Resources</td>
<td></td>
</tr>
</tbody>
</table>
9. Vertebrate Animals

- **Description of Procedures:** Identify species, strains, ages, sex, and total numbers of animals by species,

- **Justifications:** Use of species in the proposed research, why the research could not be accomplished with an alternative model (e.g. computational, human, invertebrate, *in vitro*).

- **Minimization of Pain and Distress:** Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.
10. Select Agents

“hazardous biological agents and toxins that have been identified by HHS or the U.S. Department of Agriculture (USDA) as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products…”

List of select agents:

http://www.selectagents.gov
11. Multiple PD/PI Leadership Plan

Leadership plan must be included:

- **Rationale** for choosing Multiple PDs/PIs
- **Governance and organizational structure**, communication plans, process for making joint decisions on scientific direction, and procedures for resolving conflicts
- **Roles and administrative, technical, and scientific responsibilities** for the PDs/PIs and other collaborators
- **Distribution of budget and resources** to specific components of the project or the individual PDs/PIs


<table>
<thead>
<tr>
<th>FY</th>
<th>Single PI</th>
<th>MPI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td># of</td>
<td>Award</td>
</tr>
<tr>
<td>FY</td>
<td>Applications</td>
<td>Rate</td>
</tr>
<tr>
<td>2010</td>
<td>39,186</td>
<td>15.3%</td>
</tr>
<tr>
<td>2011</td>
<td>41,140</td>
<td>13.8%</td>
</tr>
<tr>
<td>2012</td>
<td>42,572</td>
<td>14.0%</td>
</tr>
<tr>
<td>2013</td>
<td>40,496</td>
<td>13.2%</td>
</tr>
<tr>
<td>2010-2013</td>
<td>163,394</td>
<td>14.0%</td>
</tr>
</tbody>
</table>

*includes all research project grant activities. Two-tailed proportion z-test with the null hypothesis that single PI and MPI award rates are equal. P-values less than 0.05 are significant at the 95% confidence level. One test is statistically significant at the 95% confidence level.
12. Consortium/Contractual Agreements

- Provide a detailed explanation of programmatic, fiscal, and administrative arrangements.
- If this component constitutes a significant portion of the overall project, explain why applicant organization and not the subcontract should be grantee.
- In addition to administrative and budgetary documentation, a Letter of Support/ Collaboration from the lead subcontracted investigator is included.

13. Letters of Support

e.g. Consultants, Subcontracted PI’s, Collaborators, Individuals providing special research resources, access to core facilities, Advisory Board member

All letters in one single PDF file
14. Resource Sharing (I)

- **Data Sharing Plan**
  - For grants requesting >$500,000 in direct costs in any year
  - Brief description of how final research data will be shared or, if not possible, why not

- **Sharing Model Organisms**
  - If development of a model organism is anticipated, describe a plan for sharing and distributing this unique research resource
  - If sharing is impossible or restricted, provide reasons

- Not dependent of $ value of grant

14. Resource Sharing (II)

- **Genomic Data Sharing**
  
  - For research that generates large-scale human or non-human genomic data
  
  - Includes genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data
  
  - If data sharing is not possible, provide explanation
  
  - NIH Genomic Data Sharing Policy
    
    [https://gds.nih.gov/03policy2.html](https://gds.nih.gov/03policy2.html)
Implementing Rigor and Transparency in NIH & AHRQ Research Grant Applications

Notice Number: NOT-OD-16-011

These updates focus on four areas deemed important for enhancing rigor and transparency:

1) the scientific premise forming the basis of the proposed research,
2) rigorous experimental design for robust and unbiased results,
3) consideration of relevant biological variables, and
4) authentication of key biological and/or chemical resources.

Updates include:

- Revisions to application guide instructions for preparing your research strategy attachment
- Use of a new "Authentication of Key Biological and/or Chemical Resources" attachment
- Additional rigor and transparency questions reviewers will be asked to consider when reviewing applications

https://grants.nih.gov/grants/peer/critiques/rpg.htm
15. Authentication of Key Biological and/or Chemical Resources

- Briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposed studies

15. Authentication of Key Biological and/or Chemical Resources (II)

- Key biological and/or chemical resources:
  (generated with or without NIH)
  - 1) May differ from lab to lab or over time
  - 2) May have qualities and/or qualifications that could influence the research data;
  - 3) Integral to the proposed research (e.g., cell lines, specialty chemicals, antibodies, and other biologics)

- Standard laboratory reagents (e.g., common biologicals/chemicals) that are not expected to vary do not need to be included
Applications proposing clinical trials:
- Clinical trial protocols
- Investigator's brochure from Investigational New Drug (IND)

All applications:
- Blank informed consent/assent forms
- Blank surveys, questionnaires, data collection instruments

Items specified in the Funding Announcement
**PROFILE - Project Director/Principal Investigator**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix</td>
<td></td>
</tr>
<tr>
<td>First Name</td>
<td></td>
</tr>
<tr>
<td>Middle Name</td>
<td></td>
</tr>
<tr>
<td>Last Name</td>
<td></td>
</tr>
<tr>
<td>Suffix</td>
<td></td>
</tr>
<tr>
<td>Position/Title</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td></td>
</tr>
<tr>
<td>Organization Name</td>
<td></td>
</tr>
<tr>
<td>Division</td>
<td></td>
</tr>
<tr>
<td>Street1</td>
<td></td>
</tr>
<tr>
<td>Street2</td>
<td></td>
</tr>
<tr>
<td>City</td>
<td></td>
</tr>
<tr>
<td>County/Parish</td>
<td></td>
</tr>
<tr>
<td>State</td>
<td></td>
</tr>
<tr>
<td>Province</td>
<td></td>
</tr>
<tr>
<td>Country</td>
<td></td>
</tr>
<tr>
<td>Zip / Postal Code</td>
<td></td>
</tr>
<tr>
<td>Phone Number</td>
<td></td>
</tr>
<tr>
<td>Fax Number</td>
<td></td>
</tr>
<tr>
<td>E-Mail</td>
<td></td>
</tr>
<tr>
<td>Credential, e.g., agency login</td>
<td></td>
</tr>
<tr>
<td>Project Role</td>
<td>PD/PI</td>
</tr>
<tr>
<td>Other Project Role Category</td>
<td></td>
</tr>
<tr>
<td>Degree Type</td>
<td></td>
</tr>
<tr>
<td>Degree Year</td>
<td></td>
</tr>
</tbody>
</table>

*Attach Biographical Sketch* [Add Attachment] [Delete Attachment] [View Attachment]

*Attach Current & Pending Support* [Add Attachment] [Delete Attachment] [View Attachment]
### Project Role:

<table>
<thead>
<tr>
<th>Option</th>
</tr>
</thead>
<tbody>
<tr>
<td>PD/PI</td>
</tr>
<tr>
<td>Co-PD/PI</td>
</tr>
<tr>
<td>Faculty</td>
</tr>
<tr>
<td>Post Doctoral</td>
</tr>
<tr>
<td>Post Doctoral Associate</td>
</tr>
<tr>
<td>Post Doctoral Scholar</td>
</tr>
<tr>
<td>Other Professional</td>
</tr>
<tr>
<td>Graduate Student</td>
</tr>
<tr>
<td>Undergraduate Student</td>
</tr>
<tr>
<td>Technician</td>
</tr>
<tr>
<td>Consultant</td>
</tr>
<tr>
<td>Co-Investigator</td>
</tr>
<tr>
<td>Other (Specify)</td>
</tr>
</tbody>
</table>

RESEARCH & RELATED Senior/Key Person Profile (Expanded)
Senior/Key Personnel “are defined as all individuals who contribute in a substantive, meaningful way to the scientific development or execution of the project, whether or not salaries are requested. Consultants should be included… if they meet this definition… regardless of what organization they work for.”
Senior/Key Personnel (2)

Key Personnel must devote measurable effort to the project whether or not salaries are requested. “Zero calendar months” effort or “as needed” are not acceptable levels of involvement for those designated as Key Personnel.

List alphabetically by last name after principal investigator.

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Other Significant Contributors

- “contribute to the scientific development or execution of the project”
- No committed effort - “zero person months” or “as needed”
- Listed after Senior/Key Personnel
- Biosketch, including Research Support information
- e.g., Consultants, Advisors on career development awards/fellowships

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix</td>
<td></td>
</tr>
<tr>
<td>* First Name</td>
<td></td>
</tr>
<tr>
<td>* Last Name</td>
<td></td>
</tr>
<tr>
<td>Middle Name</td>
<td></td>
</tr>
<tr>
<td>Suffix</td>
<td></td>
</tr>
<tr>
<td>Position/Title</td>
<td></td>
</tr>
<tr>
<td>Department</td>
<td></td>
</tr>
<tr>
<td>Organization Name</td>
<td></td>
</tr>
<tr>
<td>Division</td>
<td></td>
</tr>
<tr>
<td>* Street1</td>
<td></td>
</tr>
<tr>
<td>Street2</td>
<td></td>
</tr>
<tr>
<td>* City</td>
<td></td>
</tr>
<tr>
<td>County/Parish</td>
<td></td>
</tr>
<tr>
<td>* State</td>
<td></td>
</tr>
<tr>
<td>Province</td>
<td></td>
</tr>
<tr>
<td>* Country</td>
<td></td>
</tr>
<tr>
<td>* Zip/Postal Code</td>
<td></td>
</tr>
<tr>
<td>* Phone Number</td>
<td></td>
</tr>
<tr>
<td>Fax Number</td>
<td></td>
</tr>
<tr>
<td>* E-Mail</td>
<td></td>
</tr>
<tr>
<td>Credential, e.g., agency login</td>
<td></td>
</tr>
<tr>
<td>* Project Role</td>
<td>PD/PI</td>
</tr>
<tr>
<td>Other Project Role Category</td>
<td></td>
</tr>
<tr>
<td>Degree Type</td>
<td></td>
</tr>
<tr>
<td>Degree Year</td>
<td></td>
</tr>
<tr>
<td>* Attach Biographical Sketch</td>
<td></td>
</tr>
<tr>
<td>Attach Current &amp; Pending Support</td>
<td></td>
</tr>
</tbody>
</table>

[Image of a PDF form](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/research-forms-d.pdf)
Biographical Sketch (I)

- For Key Personnel, Other Significant Contributors, and Consultants
- Used by reviewers to assess each investigator’s qualifications for their proposed role in addition to the overall competence of the entire research team
- [https://grants.nih.gov/grants/forms/biosketch.htm](https://grants.nih.gov/grants/forms/biosketch.htm)
- 5 pages in length total

Biographical Sketch (II)

- **Education Block: Education and Training**

  - **A. Personal Statement**
    - Why you have the background expertise for your role in the proposed project (e.g. training, previous relevant experimental work, technical expertise; collaborations, scientific environment, etc.)
    - Relevant “Contributions to Science”
    - Up to four publications/“research products” relevant to proposed project
    - “Impediments” to past productivity (e.g. family responsibilities, illness, disability, military service) (optional)
Biographical Sketch (III)

■ **B. Positions and Honors** (chronological order)
  ■ Professional experience
  ■ Previous positions/employment
  ■ Honors, awards, professional achievements
  ■ Advisory/review committees
  ■ Professional memberships
  ■ Clinical licensures, specialty board certifications
Biographical Sketch (IV)

C. Contributions to Science

- Describe most significant contributions to science (up to five) Include:
  - Historical background of scientific problem
  - Central finding(s) - Influence of these finding(s) on the progress of science or the application of these finding(s)
  - Your specific role

- Reference up to 4 publications/“research products”
  - Describe your role/contribution

- May include URL to a full list of your published work
  - Must be a federal website (e.g., My Bibliography)

Biographical Sketch (V)

D. Research Support

- Selected
- Current
- Completed - last three years
- Regardless of sponsor (federal and non-federal)
- Describe overall goals of project
- Indicate responsibilities of key personnel
- Do not include % effort (cal months) or $ awarded
- This section is not “Other Support”
BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

**NAME:** Hunt, Morgan Casey

**eRA COMMONS USER NAME** (credential, e.g., agency login): huntmc

**POSITION TITLE:** Associate Professor of Psychology

**EDUCATION/TRAINING** *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Completion Date MM/YYYY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of California, Berkeley</td>
<td>B.S</td>
<td>05/1990</td>
<td>Psychology</td>
</tr>
<tr>
<td>University of Vermont</td>
<td>Ph.D.</td>
<td>05/1996</td>
<td>Experimental Psychology</td>
</tr>
<tr>
<td>University of California, Berkeley</td>
<td>Postdoctoral</td>
<td>08/1998</td>
<td>Public Health and Epidemiology</td>
</tr>
</tbody>
</table>
A. Personal Statement

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-Investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

### B. Positions and Honors

#### Positions and Employment

<table>
<thead>
<tr>
<th>Year</th>
<th>Position</th>
<th>Institution and Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>1998-2000</td>
<td>Fellow, Division of Intramural Research</td>
<td>National Institute of Drug Abuse, Bethesda, MD</td>
</tr>
<tr>
<td>2000-2002</td>
<td>Lecturer, Department of Psychology</td>
<td>Middlebury College, Middlebury, VT</td>
</tr>
<tr>
<td>2001-</td>
<td>Consultant, Coastal Psychological Services</td>
<td>San Francisco, CA</td>
</tr>
<tr>
<td>2002-2005</td>
<td>Assistant Professor</td>
<td>Department of Psychology, Washington University, St. Louis, MO</td>
</tr>
<tr>
<td>2007-</td>
<td>Associate Professor</td>
<td>Department of Psychology, Washington University, St. Louis, MO</td>
</tr>
</tbody>
</table>

#### Other Experience and Professional Memberships

<table>
<thead>
<tr>
<th>Year</th>
<th>Membership</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995-</td>
<td>Member, American Psychological Association</td>
</tr>
<tr>
<td>1998-</td>
<td>Member, Gerontological Society of America</td>
</tr>
<tr>
<td>1998-</td>
<td>Member, American Geriatrics Society</td>
</tr>
<tr>
<td>2000-</td>
<td>Associate Editor, Psychology and Aging</td>
</tr>
<tr>
<td>2003-</td>
<td>Board of Advisors, Senior Services of Eastern Missouri</td>
</tr>
<tr>
<td>2003-05</td>
<td>NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer</td>
</tr>
<tr>
<td>2007-11</td>
<td>NIH Risk, Adult Addictions Study Section, members</td>
</tr>
</tbody>
</table>

#### Honors

<table>
<thead>
<tr>
<th>Year</th>
<th>Award</th>
</tr>
</thead>
<tbody>
<tr>
<td>2003</td>
<td>Outstanding Young Faculty Award, Washington University, St. Louis, MO</td>
</tr>
<tr>
<td>2004</td>
<td>Excellence in Teaching, Washington University, St. Louis, MO</td>
</tr>
<tr>
<td>2009</td>
<td>Award for Best in Interdisciplinary Ethnography, International Ethnographic Society</td>
</tr>
</tbody>
</table>
C. Contribution to Science

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.


Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PgT7IEFIAJBtGMRDdWFmjWAO/?sort=date&direction=ascending
D. Research Support

Ongoing Research Support
R01 DA942367  Hunt (PI)  09/01/08-08/31/16
Health trajectories and behavioral interventions among older substance abusers
The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.
Role: PI

R01 MH922731  Merryle (PI)  12/15/07-11/30/15
Physical disability, depression and substance abuse in the elderly
The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.
Role: Co-Investigator

Faculty Resources Grant, Washington University  08/15/09-08/14/15
Opiate Addiction Database
The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.
Role: PI

Completed Research Support
R21 AA998075  Hunt (PI)  01/01/11-12/31/13
Community-based intervention for alcohol abuse
The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.
Role: PI
Budget Justification

- Complete
- Comprehensive
- Concise
- Calculated correctly
NIH and other agencies require detailed budgets and justifications.

Make sure that the requested funding ‘matches’ the scientific project proposed.

Peer reviewers will be able to detect if:
- The budget is ‘padded’
- The budget is insufficient to support the project, evoking questions concerning how well the investigator understands scope of project.

Describe additional funding for project, if any.
Budget - overview

- Most categories are usually increased 2%-3% per year
- Equipment is usually purchased in the 1st year
- Plan for unusual changes in future years (e.g. additional personnel, reduction in the number of patient care costs) should be built into the budget and explained in the budget justification
Budget-categories (I)

- A. and B. Senior/Key and Other Personnel
  - Salary and fringe; employees of the University
  - Budget Justification: Role on Project
    - Identify role, does not have to be official university title
    - Justify and describe specific functions
    - Describe background and expertise as they pertain to role in this project
# RESEARCH & RELATED BUDGET

- **Budget Period 1**

## ORGANIZATIONAL DUNS:

Enter name of Organization: 

## Budget Type:

- [ ] Project
- [ ] Subaward/Consortium

**Budget Period:** 1  **Start Date:**  **End Date:**

### A. Senior/Key Person

<table>
<thead>
<tr>
<th>Prefix</th>
<th>First</th>
<th>Middle</th>
<th>Last</th>
<th>Suffix</th>
<th>Base Salary ($)</th>
<th>Months</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Cal.</td>
<td>Acad.</td>
<td>Sum.</td>
<td></td>
</tr>
</tbody>
</table>

**Project Role:**

**Total Funds requested for all Senior Key Persons in the attached file**

**Total Senior/Key Person**

### B. Other Personnel

<table>
<thead>
<tr>
<th>Number of Personnel</th>
<th>Project Role</th>
<th>Months Cal.</th>
<th>Acad.</th>
<th>Sum.</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Post Doctoral Associates</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Graduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Undergraduate Students</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Secretarial/Clerical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Number Other Personnel**

**Total Other Personnel**

**Total Salary, Wages and Fringe Benefits (A+B)**
Personnel (I)

- **Institutional Base Salary**
  - Includes base salary + A1 salary
  - Prorate for budget period
  - Take into consideration 7/1 and 1/1 increases for professional and support staff
  - Current NIH salary cap of $185,100/year (as of 1/10/16)
Personnel (II)

- **Salary Requested**
  - Usually institutional base salary x effort on grant
  - Usually based on calendar months (federal grants)
  - Special instructions for GRAs

- **Fringe Benefits**
  - Government-funded sponsored projects
    - Rate may change every year
  - Non-Govt.-funded sponsored projects
### C. Equipment Description

List items and dollar amount for each item exceeding $5,000

<table>
<thead>
<tr>
<th>Equipment item</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
</table>

Additional Equipment: [Add Attachment] [Delete Attachment] [View Attachment]

Total funds requested for all equipment listed in the attached file

<table>
<thead>
<tr>
<th>Total Equipment</th>
</tr>
</thead>
</table>

### D. Travel

1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)  
2. Foreign Travel Costs

<table>
<thead>
<tr>
<th>Total Travel Cost</th>
</tr>
</thead>
</table>

### E. Participant/Trainee Support Costs

1. Tuition/Fees/Health Insurance  
2. Stipends  
3. Travel  
4. Subsistence  
5. Other

<table>
<thead>
<tr>
<th>Number of Participants/Trainees</th>
<th>Total Participant/Trainee Support Costs</th>
</tr>
</thead>
</table>
C. Equipment

- Items costing $5,000 or more with a “service life” of at least one year
- List each item separately
- Justify each item
- May include price quote
D. Travel

- Itemize in budget justification
- Justify purpose, destination of each trip, no. of individuals traveling, length of trip
- Special consideration for foreign travel
<table>
<thead>
<tr>
<th>F. Other Direct Costs</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3. Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4. ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5. Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6. Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7. Alterations and Renovations</td>
<td></td>
</tr>
<tr>
<td>8.</td>
<td></td>
</tr>
<tr>
<td>9.</td>
<td></td>
</tr>
<tr>
<td>10.</td>
<td></td>
</tr>
</tbody>
</table>

**Total Other Direct Costs**

F. Other Direct Costs

Material and Supplies

- Glassware, chemicals and reagents, radioisotopes, tissue culture/molecular biology supplies

Animals:

- Number, species
- Animal care: Number of days, cost per day
Budget-categories

- Publication Costs
- Consultant Costs
- Subawards/Consortiums
- Patient Care Costs
- Service Agreements
- GRA Tuition/Fees
- Core Facilities
Consultants

- Individuals involved in project who are not employees of applicant organization or those involved in subcontracts
- Include names and organizational affiliations
- Describe role and services to be performed (e.g. member of advisory committee, consulting physician)
- Describe no. of days involvement, compensation, travel, per diem, etc.
Subawards/Consortiums

- A portion of the work will be conducted at another site, funding will “flow” from NIH to CU (prime) to subcontracted institution (domestic or foreign)
- Prime institution’s budget includes Subaward’s Direct and Indirect Costs
- Subaward completes similar budget forms and justification
R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the R&R Subaward Budget Attachment

Important: Please attach your subawardee budget file(s) with the file name of the subawardee organization. Each file name must be unique.

1) Please attach Attachment 1
2) Please attach Attachment 2
3) Please attach Attachment 3
4) Please attach Attachment 4
5) Please attach Attachment 5
6) Please attach Attachment 6
7) Please attach Attachment 7
Patient Care Costs

- Inpatient and/or outpatient costs

- Budget Justification:
  - Names of hospitals and/or clinics
    - Amounts for each, per budget period
    - Do they have a current HHS-negotiated research patient care rate agreement?
    - If not, how were the costs calculated?
  - Number of patient days, tests, treatments, costs per item, per budget period
  - Expected patient accrual for each site, per budget period
  - Other available support; e.g., third party recovery, drug company
  - Role of institution’s CTSA

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Indirect Costs**
Indirect Costs

- Also called Facilities and Administration (F&A)
- Percentage of direct costs
- Federally negotiated rate: 60% (on campus)
- MTDC-Modified Total Direct Costs:
  
  Some items (equipment, patient care costs, tuition, subaward consortia > $25K) not included in direct costs base
Indirect Costs

- Some NIH programs have a lower rate: 8% on training grants (T) and career development awards (K)

- Non-government, non-profit agencies (e.g., voluntary health organizations, professional societies, foundations) may have lower rates (e.g. 25%, 10%, 0%)

- Non-federal agencies may use total direct costs as the base to calculate I.C.

- Industry-sponsored research contracts and clinical trials have other rates.

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Budget - Future Years

- Some agencies may require composite, not detailed, budgets for future years.
- Most categories are usually increased 2%-3% per year.
- Equipment is usually purchased in the 1st year.
- Plan for unusual changes in future years (e.g., additional personnel, use of core facility, reduction in the number of patient care costs), and “build” that into the budget and explain in the budget justification.

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
## RESEARCH & RELATED BUDGET - Cumulative Budget

### Section A, Senior/Key Person

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section B, Other Personnel

<table>
<thead>
<tr>
<th>Total Number Other Personnel</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section C, Equipment

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section D, Travel

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Domestic
2. Foreign

### Section E, Participant/Trainee Support Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Tuition/Fees/Health Insurance
2. Stipends
3. Travel
4. Subsistence
5. Other
6. Number of Participants/Trainees

### Section F, Other Direct Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. Materials and Supplies
2. Publication Costs
3. Consultant Services
4. ADP/Computer Services
5. Subawards/Consortium/Contractual Costs
6. Equipment or Facility Rental/User Fees
7. Alterations and Renovations
8. Other 1
9. Other 2
10. Other 3

### Section G, Direct Costs (A thru F)

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section H, Indirect Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section I, Total Direct and Indirect Costs (G + H)

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Section J, Fee

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Totals ($):

<table>
<thead>
<tr>
<th>Total</th>
<th>Amount ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Modular Budgets: The Rationale

- Redefines the “R”-type grants as an assistance mechanism
- Simplifies process and minimizes budget negotiation
- Focuses all parties on science

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Modular Budgets

- Applies to all new/competing R01, R03, and R21 proposals up to $250,000 requested direct costs in any year
  - Does not include F&A of subaward/consortium
- RFAs with budgets of more than $250,000 may be modular at NIH Institute/Center’s discretion
- Direct costs requested in module amounts of $25,000

Modular Budgets

- For most proposals, the same number of modules should be requested in each year; no modules are added for inflationary increases.

- Only the Direct Costs of a subaward/ consortium should be included in the Direct Cost modules.
Modular Budgets

- Additional direct costs can be added in $25,000 modules for increases due to large, one-time equipment purchases or major changes in budget due to research needs (for example, varying patient costs or the short term need for specific personnel).

- Yearly variations in the number of modules must be justified in narrative form.

- If Direct Costs > $250,000 in any year, then detailed budget format (non-modular) must be used for the application.
Modular Budgets

- Applicant will provide personnel and other budget information in narrative format only
- NIH may adjust number of modules and Institutes/Centers can adjust to cost management plan

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
How to Determine the Standard Number of Modules

- Determine the total project direct costs. Divide by $25,000 and by number of years. Round to a whole number.

- Example:
  - Year 01: $150,000, Year 02: $153,000, Year 03: $156,060, Year 04: $159,181, and Year 05: $162,365 (2% yearly increase)
  - Total for the five years: $780,606
  - Divided by $25,000: 31.22
  - Divided by 5 years: 6.24
  - 6 modules: $150,000; 7 modules: $175,000
Modular Budgets: Budget Justification

- Information, in narrative form:
  - All Personnel
  - Subaward/Consortium arrangements, when applicable
  - Significant budget items that result in a change in the number of $25,000 modules

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Modular Budgets: Budget Justification

- Personnel: List **all** personnel, including:
  - Names
  - Roles on the project
  - Background and expertise demonstrating that individual can accomplish their responsibilities
  - Number of calendar months
    - e.g. 6 cal months = 50% effort
  - Do not provide salary information

Modular Budgets: Budget Justification

- **Consortium/Contractual costs:**
  - Name(s) of participating institution(s) and whether foreign or domestic
  - Estimate of total costs (direct plus indirect) for each year rounded to nearest $1,000
  - List all personnel
    - Role on the project
    - Effort on project

- **Additional: Justification for any variation in the number of modules requested**
## PHS 398 Modular Budget

### Budget Period: 1

<table>
<thead>
<tr>
<th>Start Date</th>
<th>End Date</th>
<th>Next Period</th>
</tr>
</thead>
</table>

### A. Direct Costs

| Direct Cost less Consortium Indirect (F&A) | 0.00 |
| Consortium Indirect (F&A) | |
| Total Direct Costs | 0.00 |

### B. Indirect (F&A) Costs

<table>
<thead>
<tr>
<th>Indirect (F&amp;A) Type</th>
<th>Indirect (F&amp;A) Rate (%)</th>
<th>Indirect (F&amp;A) Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Add Additional Indirect Cost**

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

**Indirect (F&A) Rate Agreement Date**

**Total Indirect (F&A) Costs**

### C. Total Direct and Indirect (F&A) Costs (A + B)

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
<th>0.00</th>
</tr>
</thead>
</table>

---


### Cumulative Budget Information

1. **Total Costs, Entire Project Period**

   - **Section A, Total Direct Cost less Consortium Indirect (F&A) for Entire Project Period**: $0.00
   - **Section A, Total Consortium Indirect (F&A) for Entire Project Period**: 
   - **Section A, Total Direct Costs for Entire Project Period**: $0.00
   - **Section B, Total Indirect (F&A) Costs for Entire Project Period**: 
   - **Section C, Total Direct and Indirect (F&A) Costs (A+B) for Entire Project Period**: $0.00

2. **Budget Justifications**

   - **Personnel Justification**: 
   - **Consortium Justification**: 
   - **Additional Narrative Justification**: 

PART III POLICIES, ASSURANCES, DEFINITIONS, AND OTHER INFORMATION
# PART III POLICIES, ASSURANCES, DEFINITIONS, AND OTHER INFORMATION

<table>
<thead>
<tr>
<th>Section</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Policy</td>
</tr>
<tr>
<td>1.1 Applications That Include Consortium/Contractual Facilities and Administrative Costs</td>
</tr>
<tr>
<td>1.2 Resubmission of Unfunded RFA Applications</td>
</tr>
<tr>
<td>1.3 NIH Policy on Resubmission Applications</td>
</tr>
<tr>
<td>1.4 Policy on the Acceptance for Review of Unsolicited Applications That Request $500,000 or More in Direct Costs</td>
</tr>
<tr>
<td>1.5 Sharing Research Resources</td>
</tr>
<tr>
<td>1.5.1 Data Sharing Policy</td>
</tr>
<tr>
<td>1.5.2 Sharing Model Organism Policy</td>
</tr>
<tr>
<td>1.5.3 NIH Genomic Data Sharing (GDS) Policy</td>
</tr>
<tr>
<td>1.6 Inventions and Patents</td>
</tr>
<tr>
<td>1.7 Just-In-Time Policy</td>
</tr>
<tr>
<td>1.8 Other Support</td>
</tr>
<tr>
<td>1.9 Graduate Student Compensation</td>
</tr>
<tr>
<td>1.10 DUNS Number &amp; SAM Registration</td>
</tr>
<tr>
<td>1.11 Public Access Policy</td>
</tr>
<tr>
<td>1.12 PHS Metric Program</td>
</tr>
<tr>
<td>1.13 Transition to the SF424 (R&amp;R) Application and Electronic Submission through Grants.gov</td>
</tr>
<tr>
<td>1.14 Multiple Program Director/Principal Investigator Policy</td>
</tr>
<tr>
<td>1.15 New, Including Early Stage, Investigators</td>
</tr>
<tr>
<td>1.16 Policy on Instruction in the Responsible Conduct of Research</td>
</tr>
<tr>
<td>1.17 Transparency Act Reporting</td>
</tr>
<tr>
<td>1.18 Encouragement for Institutions to Develop Individual Development Plans for Graduate Students and Postdoctoral Researchers</td>
</tr>
<tr>
<td>1.19 Recruitment Plan to Enhance Diversity</td>
</tr>
</tbody>
</table>
Other Support

- Do not include with research application- will be requested after peer review before an award is to be made.

- Key Personnel only (not Other Significant Contributors, Consultants)

- “All financial resources …available in direct support of an individual’s research endeavors”

- Active and pending support
  - Includes Federal, non-government, non-profit, commercial, and institutional funding
  - Research grants, cooperative agreements, and contracts
  - Training awards, gifts, and prizes not required to be listed

https://grants.nih.gov/grants/forms/othersupport.htm

Jaime S. Rubin, Ph.D; http://grantscourse.columbia.edu
Other Support

Information requested:

- Project number
- Funding agency/Source
- Major goals
- Dates of awarded/proposed project
- Annual Direct Costs
- Percent effort/Calendar months
- Overlap


Jaime S. Rubin, Ph.D.: http://grantscourse.columbia.edu
Other Support

“Overlap, whether scientific, budgetary, or commitment of an individual’s effort greater than 100 percent (i.e., 12 person months), is not permitted.”

“to ensure

that sufficient and appropriate levels of effort are committed to the project;
that there is no duplication of funding for scientific aims, specific budgetary items, or an individual’s level of effort; and
that only funds necessary to the conduct of the approved project are included in the award.”
ANDERSON, R.R.

ACTIVE
2 R01 HL 00000-13 (Anderson) 3/1/2012 – 2/28/2017 3.60 calendar
NIH/NHLBI $186,529
Chloride and Sodium Transport in Airway Epithelial Cells

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) 4/1/2001 – 3/31/2012 1.20 calendar
NIH/NHLBI $122,717
Ion Transport in Lungs

The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

R000 (Anderson) 9/1/2014 – 8/31/2017 1.20 calendar
Cystic Fibrosis Foundation $43,123
Gene Transfer of CFTR to the Airway Epithelium

The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING
DCB 950000 (Anderson) 12/1/2014 – 11/30/2016 2.40 calendar
National Science Foundation $82,163
Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

OVERLAP
There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

RICHARDS, L.
NONE
Resources for Grant Writing

- Writing a Grant Proposal
  
  http://grantscourse.columbia.edu/writing.htm