Sponsored Projects: Planning & Organizing a Research Proposal

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Course: “Funding and Grantsmanship for Research and Career Development Activities”
http://grantscourse.columbia.edu/
Topics to be Discussed

- Approaches for Competitive Applications
- Common Problems and “Why are Proposals Turned Down?”
- NIH’s Grant Review Scoring System
- NIH’s Grant Review Criteria
- Overview of the NIH R01 Funding Mechanisms
- Components of the NIH R01 Grant Application
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Approaches for Competitive Applications

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

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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)**
  - Might impact ESI status
- **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?

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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
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
- Fishing expedition
- Not hypothesis driven
- Descriptive, not mechanistic project
- Unfocused
- No or insufficient preliminary data
- Does not adequately describe access to “research resources”
- Unrealistic budget
- Methodologies beyond the expertise of investigator or research team
- Not independent of previous mentor’s research

NIH: one round of applications
Pink Sheet: Reviewers’ Comments
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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
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

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**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
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.

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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.
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- **NIH’s Grant Review Scoring System**
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### NIH's Evaluation/Scoring System

9-point rating scale (1=exceptional; 9=poor)

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<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Strengths/Weaknesses</th>
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<tr>
<td>Low Impact</td>
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<td>Fair</td>
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<td></td>
<td>8</td>
<td>Marginal</td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
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</table>


<table>
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<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
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<td>Exceptionally strong with essentially no weaknesses</td>
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<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
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<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
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<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
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<tr>
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<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
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<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
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<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
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</table>

**Minor Weakness:** An easily addressable weakness that does not substantially lessen impact

**Moderate Weakness:** A weakness that lessens impact

**Major Weakness:** A weakness that severely limits impact

Research Applications

Overall Impact:
The likelihood for a project to exert a **sustained, powerful** influence on research field(s) involved.

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<th>High</th>
<th>Medium</th>
<th>Low</th>
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<tr>
<td>Score</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
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Evaluating Overall Impact:
Consider the 5 criteria: significance, investigator, innovation, approach, environment (weighted based on reviewer's judgment) and other score influences, e.g. human subjects, animal welfare, inclusion plans, and biohazards.

- e.g. Applications are addressing a problem of **high importance/interest** in the field. May have **some or no weaknesses**.
- e.g. Applications may be addressing a problem of **high** importance in the field, but weaknesses in the criteria bring down the overall impact to medium.
- e.g. Applications may be addressing a problem of **moderate/high** importance in the field, but weaknesses in the criteria bring down the overall impact to low.
- e.g. Applications may be addressing a problem of **low or no** importance in the field, with **some or no weaknesses**.

5 is a good medium-impact application, and the entire scale (1-9) should always be considered.
NIH's Grant Review

- **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)
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>1. Significance</th>
<th>Please limit text to ¼ page</th>
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<tbody>
<tr>
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NIH's Review Criteria

(1) Significance:

- “Does the project address an important problem or a critical barrier to progress in the field?"
- Is there a strong scientific premise for the project?
- If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?
- How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?”
NIH's Review Criteria

(2) **Investigators:**

- “Are the PD/PIs, collaborators, and other researchers **well suited to the project?**

- If Early Stage Investigators or those in the early stages of independent careers, do they have **appropriate experience and training?**

- If established, have they demonstrated an **ongoing record of accomplishments** that have advanced their field(s)?

- 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?”

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

NIH's Review Criteria

(3) **Innovation:**

- “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?

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

- Is a **refinement, improvement, or new application** of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?”

https://grants.nih.gov/grants/peer/critiques/rpg_D.htm
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NIH's Review Criteria

(4) Approach:

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

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

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

(4) Approach:

- “If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?”
- Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?”
(4) **Approach:**

- “If the project involves human subjects and/or NIH-defined clinical research, are the plans to address
  - 1) the protection of human subjects from research risks, and
  - 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as
  - the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?”

“Environment:

- Will the scientific environment in which the work will be done contribute to the probability of success?
- Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed?
- Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?”
NIH's Review Criteria

**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

**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

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

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NIH's Review Criteria

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”

https://grants.nih.gov/grants/peer/critiques/rpg_D.htm
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NIH's Review Criteria

**Resource Sharing Plans:** “Reviewers will comment on whether the following Resource 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.”

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

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

NIH's Review Criteria

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

**Resubmission:** “the responses to comments from the previous scientific review group and changes made to the project”.

**Renewals:** “the progress made in the last funding period”.

**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

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Clinical Trial-Specific Review Criteria

FOAs that accept clinical trials will include additional review criteria questions in Section V. Application Review Information.

The NIH Announces New Review Criteria for Research Project Applications Involving Clinical Trials

Scored Review Criteria

Significance
Investigator(s)
Innovation
Approach
Study Design
Data Management and Statistical Analysis
Environment
Additional Review Criteria
Study Timeline

Notice Number: NOT-OD-17-118

Key Dates
Release Date: September 21, 2017

https://grants.nih.gov/policy/clinical-trials/review-criteria.htm
https://grants.nih.gov/grants/peer/critiques/rpg_D.htm

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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

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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

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<th>Element of Rigor and Transparency</th>
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<th>Additional Review Consideration</th>
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<td>Approach</td>
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</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>

<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). Describe the general strengths and weaknesses of the prior research being cited as crucial to support the application. Consider discussing the rigor of previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources. | *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. Emphasize how the experimental design and methods proposed will achieve robust and unbiased results. | *Research Strategy*  
   ➤ Approach |

*See related FAQs, blog post | *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 |
# NIH Extramural Program

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>NIH Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant</td>
<td>Patron (Assistance, encouragement)</td>
</tr>
<tr>
<td>Cooperative Agreement</td>
<td>Partner (Assistance but substantial program involvement)</td>
</tr>
<tr>
<td>Contract</td>
<td>Purchaser (Procurement)</td>
</tr>
</tbody>
</table>
Cooperative Agreements

Since cooperative agreement funding frequently involves a "network" of awards, there may be NIH Institute funding considerations [e.g., programmatic priorities, diversity of research subjects in clinical research (ethnicity, socioeconomic status, age, gender, disease-related, geographic)] that are in addition to the "usual" NIH review criteria (e.g., Significance, Investigators, Innovation, Approach, Environment).

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Cooperative Agreements

Example RFA: “Following initial peer review, recommended applications will receive a second level of review… The following will be considered in making funding decisions:

- **Scientific and technical merit** of the proposed project as determined by scientific peer review.
- Availability of **funds**.
- Relevance of the proposed project to **program priorities**.
- **Complementarity** to and **synergy** with other funded projects
- **Programmatic balance** among diseases to be studied, healthcare settings, and approaches to be implemented”
Cooperative Agreements

- “Ability to work effectively in large collaborative efforts or research consortia
- Public health importance of conditions to be studied
- Diversity of study patients, particularly with respect to inclusion of minority or underserved populations in the U.S., and relevance of proposed research questions related to diversity and health disparities
- Ability to recruit and study large sample sizes efficiently and cost-effectively
- Applicability of the proposed approach to other healthcare settings”


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Topics to be Discussed

- Approaches for Competitive Applications
- Common Problems and “Why are Proposals Turned Down?”
- NIH’s Grant Review Scoring System
- NIH’s Grant Review Criteria
- Overview of the NIH R01 Funding Mechanisms
- Components of the NIH R01 Grant Application
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
R01-Equivalent Grants:
Competing Applications, Awards, and Success Rates

![Graph showing the number of applications, awards, and success rates over fiscal years 1998 to 2017.](image-url)
<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Application Type¹ and Submission Number²</th>
<th>Number of Applications Reviewed</th>
<th>Number of Applications Awarded</th>
<th>Success Rate⁵</th>
<th>Total Funding⁵</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>New - First Submission (A0)</td>
<td>18,171</td>
<td>1,924</td>
<td>10.6%</td>
<td>$874,232,152</td>
</tr>
<tr>
<td>2015</td>
<td>New with Resubmissions (A1)</td>
<td>6,420</td>
<td>2,014</td>
<td>31.4%</td>
<td>$912,379,257</td>
</tr>
<tr>
<td>2015</td>
<td>Continuations (A0)</td>
<td>2,538</td>
<td>779</td>
<td>30.7%</td>
<td>$356,162,385</td>
</tr>
<tr>
<td>2015</td>
<td>Continuations with Resubmissions (A1)</td>
<td>1,749</td>
<td>723</td>
<td>41.3%</td>
<td>$312,440,389</td>
</tr>
<tr>
<td>2015</td>
<td>Supplements</td>
<td>92</td>
<td>27</td>
<td>29.3%</td>
<td>$6,014,041</td>
</tr>
<tr>
<td></td>
<td><strong>FY TOTAL</strong></td>
<td><strong>28,970</strong></td>
<td><strong>5,467</strong></td>
<td><strong>18.9%</strong></td>
<td><strong>$2,461,228,224</strong></td>
</tr>
<tr>
<td>2016</td>
<td>New First Submission (A0)</td>
<td>18,691</td>
<td>2,248</td>
<td>12.0%</td>
<td>$1,248,669,338</td>
</tr>
<tr>
<td>2016</td>
<td>New with Resubmissions (A1)</td>
<td>7,555</td>
<td>2,342</td>
<td>31.0%</td>
<td>$1,128,744,694</td>
</tr>
<tr>
<td>2016</td>
<td>Continuations (A0)</td>
<td>2,142</td>
<td>751</td>
<td>35.1%</td>
<td>$369,845,997</td>
</tr>
<tr>
<td>2016</td>
<td>Continuations with Resubmissions (A1)</td>
<td>1,643</td>
<td>645</td>
<td>39.3%</td>
<td>$288,385,175</td>
</tr>
<tr>
<td>2016</td>
<td>Supplements</td>
<td>75</td>
<td>24</td>
<td>32.0%</td>
<td>$6,762,600</td>
</tr>
<tr>
<td></td>
<td><strong>FY Total</strong></td>
<td><strong>30,106</strong></td>
<td><strong>6,010</strong></td>
<td><strong>20.0%</strong></td>
<td><strong>$3,042,407,804</strong></td>
</tr>
<tr>
<td>2017</td>
<td>New First Submission (A0)</td>
<td>20,131</td>
<td>2,442</td>
<td>12.1%</td>
<td>$1,624,534,972</td>
</tr>
<tr>
<td>2017</td>
<td>New with Resubmissions (A1)</td>
<td>7,658</td>
<td>2,296</td>
<td>30.0%</td>
<td>$1,165,217,451</td>
</tr>
<tr>
<td>2017</td>
<td>Continuations (A0)</td>
<td>1,991</td>
<td>703</td>
<td>35.3%</td>
<td>$340,315,993</td>
</tr>
<tr>
<td>2017</td>
<td>Continuations with Resubmissions (A1)</td>
<td>1,372</td>
<td>577</td>
<td>42.1%</td>
<td>$272,835,600</td>
</tr>
<tr>
<td>2017</td>
<td>Supplements</td>
<td>69</td>
<td>23</td>
<td>33.3%</td>
<td>$11,252,290</td>
</tr>
<tr>
<td></td>
<td><strong>FY Total</strong></td>
<td><strong>31,221</strong></td>
<td><strong>6,041</strong></td>
<td><strong>19.3%</strong></td>
<td><strong>$3,414,156,306</strong></td>
</tr>
</tbody>
</table>
Research Grant (NIH R01)

- Supports a discrete, specified project
  - Specific Aims
- “Comprehensive” funding
- Modular budgets up to $250,000/year
- Multi-year
- Flexibility
- Most NIH-supported investigator-initiated research is through this funding mechanism

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Research Grant (NIH R01)

- Funds research project
  - Salaries of PI and other research personnel
  - Supplies, reagents, etc
  - Animal costs
  - Patient care costs
  - Core facilities
  - Travel to national meetings
- Multi-Year (4yrs – 5yrs)
- Renewable
  - e.g. original grant + 2 renewals = 15yrs
Topics to be Discussed

- Approaches for Competitive Applications
- Common Problems and “Why are Proposals Turned Down?”
- NIH’s Grant Review Scoring System
- NIH’s Grant Review Criteria
- Overview of the NIH R01 Funding Mechanisms
- Components of the NIH R01 Grant Application

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RESEARCH INSTRUCTIONS FOR NIH AND OTHER PHS AGENCIES

FORMS VERSION E SERIES

Released: September 25, 2017
Revised: December 29, 2017

SF424 (R&R) APPLICATION PACKAGES
New NIH "FORMS-E" Grant Application Forms and Instructions Coming for Due Dates On or After January 25, 2018

Focus of changes:

- Consolidation of human subjects, inclusion enrollment, and clinical trial information previously collected across multiple agency forms
- Expansion and use of discrete form fields for clinical trial information to
  - provide the level of information needed for peer review;
  - lead applicants through clinical trial information collection requirements;
  - present key information to reviewers and agency staff in a consistent format; and
  - align with ClinicalTrials.gov (where possible) and position us for future data exchange with ClinicalTrials.gov
- Incorporation of recent Grants.gov changes to R&R Budget and SBIR/STTR Information forms

High-level Summary of Form Changes: FORMS-E

Changes to Agency-specific PHS Forms Included in ‘FORMS-E’ Application Packages

The majority of form changes introduced in FORMS-E packages relate to the consolidation of human subjects and inclusion enrollment report information previous collected across multiple forms into a new PHS Human Subjects and Clinical Trials Information form. The new form also expands clinical trial data collection to ensure the appropriate level of information for review and to improve oversight.

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

<table>
<thead>
<tr>
<th>Section of Application</th>
<th>Activity Codes</th>
<th>Page Limits <em>(if different from FOA, FOA supersedes)</em></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Project Summary/Abstract</strong></td>
<td>For all Activity Codes</td>
<td>30 lines of text</td>
</tr>
<tr>
<td><strong>Project Narrative</strong></td>
<td>For all Activity Codes excluding C06, UC6 and G20.</td>
<td>three sentences</td>
</tr>
<tr>
<td><strong>Introduction to Resubmission and Revision Applications</strong></td>
<td>For all Activity Codes (including each applicable component of a multi-component application)</td>
<td>1</td>
</tr>
<tr>
<td><strong>Specific Aims</strong></td>
<td>For all Activity Codes that use an application form with the Specific Aims section (including each component of a multi-component application)</td>
<td>1</td>
</tr>
<tr>
<td><strong>Biographical Sketch</strong></td>
<td>For all Activity Codes (including DP1 and DP2 which previously had special page limits)</td>
<td>5</td>
</tr>
<tr>
<td>Section of Application</td>
<td>Activity Codes</td>
<td>Page Limits * (if different from FOA, FOA supersedes)</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------</td>
</tr>
<tr>
<td>Research Strategy</td>
<td>For Activity Code DP1</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>For Activity Codes R03, R13, U13, R13, U13, R21, R35, R36, R41, R43, SC2, SC3, X01, X02, R50, UT1</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>For Activity Code DP2</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>For Activity Codes DP3, DP5, G08, G11, G13, RC2, RC4, RF1, R01, R15, R18, R21/R33, R24, R28, R33, R34, R42, R44, R61/R33, SB1, SC1, SC2, SB1, SC1, SI2, UC1, UC2, UH2, UH3, UG1, UG4, UF1, UG3/UG3, UH2/UG3, U01, U18, U24, U2C, U34, U42, U44, UT2, X01, X02</td>
<td>12</td>
</tr>
<tr>
<td></td>
<td>For all other Activity Codes</td>
<td>Follow FOA instructions</td>
</tr>
</tbody>
</table>

* FOA instructions always supersede these instructions.

https://grants.nih.gov/grants/how-to-apply-application-guide/format-and-write/page-limits.htm#car
### 14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

- **Prefix:** [Field]
- **First Name:** [Field]
- **Middle Name:** [Field]
- **Last Name:** [Field]
- **Suffix:** [Field]
- **Position/Title:** [Field]
- **Organization Name:** [Field]
- **Department:** [Field]
- **Division:** [Field]
- **Street1:** [Field]
- **Street2:** [Field]
- **City:** [Field]
- **County / Parish:** [Field]
- **State:** [Field]
- **Province:** [Field]
- **Country:** [Field]
- **USA: UNITED STATES**
- **ZIP / Postal Code:** [Field]
- **Phone Number:** [Field]
- **Fax Number:** [Field]
- **Email:** [Field]

### 15. ESTIMATED PROJECT FUNDING

| a. Total Federal Funds Requested |
| b. Total Non-Federal Funds |
| 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:** [Field]
- **b. NO**
  - PROGRAM IS NOT COVERED BY E.O. 12372; OR
  - PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW

### 17. Certification

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

21. Cover Letter Attachment


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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

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

<table>
<thead>
<tr>
<th>Awarding Component Assignment Request (optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you have a preference for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation and enter it below. All requests will be considered; however, assignment requests cannot always be honored.</td>
</tr>
<tr>
<td>Awarding Components: <a href="https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents">https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assign to Awarding Component:</th>
<th>First Choice</th>
<th>Second Choice</th>
<th>Third Choice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Do Not Assign to Awarding Component:</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Section Assignment Request (optional)</th>
</tr>
</thead>
<tbody>
<tr>
<td>If you have a preference for study section assignment, use the link below to identify the appropriate study section (e.g., NIH Scientific Review Group or Special Emphasis Panel) and enter it below. Remove all hyphens, parentheses, and spaces. All requests will be considered; however, assignment requests cannot always be honored.</td>
</tr>
<tr>
<td>Study Sections: <a href="https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection">https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection</a></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Assign to Study Section: Only 20 characters allowed</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Choice</td>
</tr>
<tr>
<td>Do Not Assign to Study Section: Only 20 characters allowed</td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>
**PHS Assignment Request Form**

**List individuals who should not review your application and why (optional)**

Only 1000 characters allowed

**Identify scientific areas of expertise needed to review your application (optional)**

*Note: Please do not provide names of individuals*

<table>
<thead>
<tr>
<th>Expertise</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
</table>

*Identify Scientific areas of expertise needed to review your application (optional)*

*Note: Please do not provide names of individuals*
# PHS 398 Cover Page Supplement

## 1. 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

<table>
<thead>
<tr>
<th>Is method consistent with American Veterinary Medical Association (AVMA) guidelines?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
</table>

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

---

[View Burden Statement](#)

[OMB Number: 0925-0001](#)

[Expiry Date: 3/31/2020](#)


Cover Page Supplement

1. 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
  - Provide a scientific justification

Will be reviewed by Office of Laboratory Animal Welfare (OLAW).
1. Vertebrate Animals Section

Are vertebrate animals euthanized? □ Yes □ No

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

3. Human Embryonic Stem Cells Section

*Does the proposed project involve human embryonic stem cells? □ Yes □ No

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: http://stemcells.nih.gov/research/registry/. Or, if a specific stem cell line cannot be referenced at this time, check the box indicating that one from the registry will be used:

□ Specific stem cell line cannot be referenced at this time. One from the registry will be used.

Cell Line(s) (Example: 0004):

X □
Project/Performance Site(s)
Where the work described in the Research Plan will be conducted

- Applicant organization (e.g., Columbia Univ.)
- Collaborating institutions (subcontracts)
  - Domestic and foreign institutions
  - e.g., Additional patient recruitment sites
- Include “Facilities and Resources” on each later in the application
- Applicant organization responsible for compliance
  - e.g., lab animals, human subjects, financial management

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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  ☐ 7  ☐ 8

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.”
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Project Summary/Abstract</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Project Narrative</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Bibliography &amp; References Cited</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Facilities &amp; Other Resources</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Equipment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Other Attachments</td>
<td></td>
<td>Add Attachments</td>
<td>Delete Attachments</td>
</tr>
</tbody>
</table>

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 the research design and methods for achieving the stated goals…”

30 lines of text
RESEARCH & RELATED Other Project Information

7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments


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R&R Other Project Information:

8. Project Narrative

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

7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments


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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)
RESEARCH & RELATED Other Project Information

7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments


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

10. Facilities & Other Resources

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

- 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 how the proposed studies will benefit from unique aspects of the scientific environment, subject populations, or collaborative arrangements.
R&R Other Project Information:

10. Facilities & Other Resources

- **Early Stage Investigators:**
  - “Describe institutional investment in the success of the investigator...”
  - 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”


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<td>10. Facilities &amp; Other Resources</td>
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<td>12. Other Attachments</td>
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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
Review specific Funding Opportunity Announcement to see if any “Other Attachments” are to be included.


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
### Research Plan Section

2. Specific Aims

3. *Research Strategy*

4. Progress Report Publication List

### Other Research Plan Section

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PD/PI Leadership Plan

8. Consortium/Contractual Arrangements

9. Letters of Support

10. Resource Sharing Plan(s)

11. Authentication of Key Biological and/or Chemical Resources

### Appendix

12. Appendix
Introduction

1. Introduction to Application (for Resubmission and Revision applications)
Research Plan Section

2. Specific Aims → 1 page


4. Progress Report Publication List
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?”
2. Specific Aims (1 page)

- State **goals** of proposed research
- Summarize expected **outcomes**
  - Impact on the fields involved
- List specific objectives
  - Describe **hypotheses** to be tested
  - Specific problem to be solved
  - Novel design to be created
  - New technology to be developed
  - Existing paradigm or clinical practice to be challenged
  - Critical barrier to research area’s progress to be addressed
- 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 **impacted** 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>
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<th>Benchmarks/ Milestones</th>
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<td>Summary of Specific Aim 3b</td>
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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.

- For trials with randomized groups/interventions, describe methods for sample size and analysis.
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

No further consideration of SABV required; not considered a weakness

¹ For research involving non-vertebrate animals, it is generally not necessary to consider sex as a biological variable.
Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)

Is strong justification provided for the single sex study?³

Are both sexes included in the study?

Does the proposal demonstrate plans to report data disaggregated by sex?⁴

Is the study intended to test for sex differences?²

Is the design/analysis adequately rigorous to test for sex differences?

Acknowledgment as a weakness in the critique and discussion and score accordingly

Acknowledgment as a strength in the critique and discussion and score accordingly

Acknowledgment as a weakness in the critique and discussion and score accordingly

Acknowledgment as a strength in the critique and discussion and score accordingly
Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)

Is the study intended to test for sex differences?²

YES

Is the design/analysis adequately rigorous to test for sex differences?

YES

Acknowledge as a strength in the critique and discussion and score accordingly

NO

Acknowledge as a weakness in the critique and discussion and score accordingly


Jaime S. Rubin, Ph.D.; http://grantascourse.columbia.edu
Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)

1. Acknowledge as a weakness in the critique and discussion and score accordingly.
2. Acknowledge as a strength in the critique and discussion and score accordingly.
3. Is strong justification provided for the single sex study?³
4. Does the proposal demonstrate plans to report data disaggregated by sex?⁴
5. Are both sexes included in the study?
6. Is the study intended to test for sex differences?²

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


- For competitive renewal applications
<table>
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<td>3. *Research Strategy</td>
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<td>4. Progress Report Publication List</td>
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- **Complete references** of all appropriate publications, manuscripts accepted for publication, patents, and other printed materials resulting from the project.

- Include the NIH Manuscript Submission reference number (NIHMS#) or the PubMed Central (PMC) reference number (PMCID#)
### Other Research Plan Section

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5. Vertebrate Animals

1) **Description of Procedures**: In addition to description of procedures, identify species, strains, ages, sex, and total numbers of animals.

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

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

### Other Research Plan Section

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6. 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
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7. 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 each of the PDs/PIs and other collaborators
- Distribution of **budget** and resources to specific components of the project or the individual PDs/PIs


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<td>2010</td>
<td>39,186</td>
<td>15.3%</td>
<td>5,318</td>
<td>16.2%</td>
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<td>2011</td>
<td>41,140</td>
<td>13.8%</td>
<td>7,258</td>
<td>13.6%</td>
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<td>2012</td>
<td>42,572</td>
<td>14.0%</td>
<td>8,300</td>
<td>13.7%</td>
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<td>2013</td>
<td>40,496</td>
<td>13.2%</td>
<td>8,275</td>
<td>14.1%</td>
<td>p&lt;0.05</td>
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<td>2010-2013</td>
<td>163,394</td>
<td>14.0%</td>
<td>29,151</td>
<td>14.2%</td>
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*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.
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8. Consortium/Contractual Agreements

- Provide a detailed explanation of programmatic, fiscal, and administrative arrangements.

- If this component is a significant portion of the overall project, explain why applicant organization, 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 as well as her/his NIH Biosketch.


Other Research Plan Section

5. Vertebrate Animals

6. Select Agent Research

7. Multiple PD/PI Leadership Plan

8. Consortium/Contractual Arrangements

9. Letters of Support

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11. Authentication of Key Biological and/or Chemical Resources


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
9. 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
### Other Research Plan Section

1. Vertebrate Animals
2. Select Agent Research
3. Multiple PD/PI Leadership Plan
4. Consortium/Contractual Arrangements
5. Letters of Support
6. Resource Sharing Plan(s)
7. Authentication of Key Biological and/or Chemical Resources

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10. Resource Sharing (I)

- **Data Sharing Plan**
  - For grants requesting >$500,000 in direct costs in any year (not including subcontract’s I.C.)
  - Brief description of how final research data will be shared or, if not possible, why not
  - Funding announcement may have additional requirements.

- **Sharing Model Organisms**
  - If developing a model organism, 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
10. Resource Sharing (II)

- **Genomic Data Sharing (GDS)**
  - 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
  - Institutional certification required before award
  - 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.

https://grants.nih.gov/grants/peer/critiques/rpg.htm
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</table>
11. 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”
- 1 page is suggested
11. Authentication of Key Biological and/or Chemical Resources (II)

- **Key biological and/or chemical resources:**
  (generated with or without NIH funds)
  - “1) May differ from laboratory to laboratory or over time
  - 2) May have qualities and/or qualifications that could influence the research data; and
  - 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”

https://grants.nih.gov/reproducibility/index.htm
Jaime S. Rubin, Ph.D.: http://grantscourse.columbia.edu
11. Authentication of Key Biological and/or Chemical Resources – FAQ’s

1. What are "key biological and/or chemical resources"?

2. What is the proper way to authenticate reagents? Are there any NIH-wide guidelines about acceptable procedures for authentication?

3. What kind of information should I include in the "Authentication of Key Biological and/or Chemical Resources" attachment?

4. Do I need to include an "Authentication of Key Biological and/or Chemical Resources" attachment?

https://grants.nih.gov/reproducibility/index.htm
https://grants.nih.gov/reproducibility/faqs.htm#V

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
11. Authentication of Key Biological and/or Chemical Resources – FAQ’s

5. If a cell line or other research resource (e.g., an antibody) is still under development, how should resource authentication be addressed in the application?

6. Do applicants have to authenticate primary cell cultures?

7. How will meritorious applications designated as inadequate for their plans for authentication of key resources be handled administratively?

https://grants.nih.gov/reproducibility/index.htm
https://grants.nih.gov/reproducibility/faqs.htm#V

Jaime S. Rubin, Ph.D.; http://grantcourse.columbia.edu
Appendix

12. Appendix

- Blank informed consent/assent forms
- Blank data collection instruments, survey forms, questionnaires,
- Sample interview questions
- Items specified in the Funding Announcement
- Clinical trial-related materials to be included in the new PHS Human Subjects and Clinical Trials Information Form – not the Appendix

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
“The PHS Human Subjects and Clinical Trials Information form is used to collect information on human subjects research, clinical research, and/or clinical trials, including

- study population characteristics,
- protection and monitoring plans, and a protocol synopsis.

This form accommodates the full spectrum of all types of clinical trials, including, but not limited to, behavioral, exploratory/development, mechanistic, pilot/feasibility, early phase, efficacy, effectiveness, group-randomized, and others.”
“All applicants must use the PHS Human Subjects and Clinical Trials Information form regardless of your answer to the question “Are human subjects involved?” on the Other Project Information Form.”

If No to Human Subjects

Does the proposed research involve human specimens and/or data?  
□ Yes  □ No

If Yes, provide an explanation of why the application does not involve human subjects research.

Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.
A separate study record is included for each protocol involving human subjects proposed in the application.

Each study record contains the following sections:

- **Section 1 - Basic Information**
  - e.g., Study title, Exemption Number, Clinical Trial Questionnaire

- **Section 2 – Study Population Characteristics**
  - Including Eligibility criteria; Inclusion of Women, Minorities, and Children; Inclusion Enrollment Report

- **Section 3 – Protection and Monitoring Plans**

- **Section 4 – Protocol Synopsis**

- **Section 5 – Other Clinical Trial-related Attachments**
NIH Definition of a 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.

https://grants.nih.gov/policy/clinical-trials/definition.htm

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Use the following four questions to determine the difference between a clinical study and a clinical trial:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?
Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if...

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

Studies intended solely to refine measures are not considered clinical trials.

Studies that involve secondary research with biological specimens or health information are not clinical trials.

https://grants.nih.gov/policy/clinical-trials/definition.htm

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
A separate study record is included for each protocol involving human subjects proposed in the application.

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- **Section 2 – Study Population Characteristics**
  - Including Eligibility criteria; Inclusion of Women, Minorities, and Children; Inclusion Enrollment Report

- **Section 3 – Protection and Monitoring Plans**

- **Section 4 – Protocol Synopsis**

- **Section 5 – Other Clinical Trial-related Attachments**
1.4. *Clinical Trial Questionnaire*

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants?  
- [ ] Yes  
- [ ] No

1.4.b. Are the participants prospectively assigned to an intervention? 
- [ ] Yes  
- [ ] No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? 
- [ ] Yes  
- [ ] No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? 
- [ ] Yes  
- [ ] No
<table>
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<th>If you answered &quot;yes&quot; to all the questions in the Clinical Trial Questionnaire</th>
<th>If you answered &quot;no&quot; to any of the questions in the Clinical Trial Questionnaire</th>
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<td>Required</td>
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<tr>
<td>Section 4 - Protocol Synopsis</td>
<td>Required</td>
<td>Do not complete</td>
</tr>
<tr>
<td>Section 5 - Other Clinical Trial-related Attachments</td>
<td>Required if specified in the FOA</td>
<td>Do not complete</td>
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</tbody>
</table>

A separate study record is included for each protocol involving human subjects proposed in the application.

Each study record contains the following sections:

- **Section 1 - Basic Information**
  - e.g., Study title, Exemption Number, Clinical Trial Questionnaire

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  - Including Eligibility criteria; Inclusion of Women, Minorities, and Children; Inclusion Enrollment Report

- **Section 3 – Protection and Monitoring Plans**

- **Section 4 – Protocol Synopsis**

- **Section 5 – Other Clinical Trial-related Attachments**
## Inclusion Enrollment Report

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# PHS Human Subjects and Clinical Trials Information

## Inclusion Enrollment Report

### Cumulative (Actual)

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</table>


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  - e.g., Study title, Exemption Number, Clinical Trial Questionnaire

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- **Section 3 – Protection and Monitoring Plans**

- **Section 4 – Protocol Synopsis**

- **Section 5 – Other Clinical Trial-related Attachments**
3.1 Protection of Human Subjects

1. Risks to Human Subjects
   a. Human Subjects Involvement, Characteristics, and Design
   b. Study Procedures, Materials, and Potential Risks

2. Adequacy of Protection Against Risks
   a. Informed Consent and Assent
   b. Protections Against Risk
   c. Vulnerable Subjects (if appropriate)

3. Potential Benefits of the Proposed Research to Research participants and Others

4. Importance of the Knowledge to be Gained
3.2 Use of single IRB for multi-site study
3.3 Data and Safety Monitoring Plan
3.4 Data and Safety Monitoring Board
3.5 Structure of study team
A separate study record is included for each protocol involving human subjects proposed in the application.

Each study record contains the following sections:

- **Section 1 - Basic Information**
  - e.g., Study title, Exemption Number, Clinical Trial Questionnaire

- **Section 2 – Study Population Characteristics**
  - Including Eligibility criteria; Inclusion of Women, Minorities, and Children; Inclusion Enrollment Report

- **Section 3 – Protection and Monitoring Plans**

- **Section 4 – Protocol Synopsis**

- **Section 5 – Other Clinical Trial-related Attachments**
4.1 Brief Summary
4.2 Study Design
4.3 Outcomes Measures
4.4 Statistical Design and Power
4.5 Subject Participation Duration
4.6 FDA-regulated intervention?
4.7 Dissemination Plan
A separate study record is included for each protocol involving human subjects proposed in the application.

Each study record contains the following sections:

- **Section 1 - Basic Information**
  - e.g., Study title, Exemption Number, Clinical Trial Questionnaire

- **Section 2 – Study Population Characteristics**
  - Including Eligibility criteria; Inclusion of Women, Minorities, and Children; Inclusion Enrollment Report

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- **Section 4 – Protocol Synopsis**

- **Section 5 – Other Clinical Trial-related Attachments**


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5.1 Other Clinical Trial-related Attachments

- Maximum of 10 PDF attachments is allowed
- Provide only if funding opportunity announcement (FOA) specifically requests
  - Use requested file names
Multiple Principal Investigators

- The contact PI is listed first
- If there is more than one Principal Investigator, all are given the role of “PD/PI”.
- NIH does not use the term co-PD/PI.

[PD = Project Director]
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

#### PROFILE - Senior/Key Person 1

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#### Attach Biographical Sketch
- Add Attachment
- Delete Attachment
- View Attachment

#### Attach Current & Pending Support
- Add Attachment
- Delete Attachment
- View Attachment
Senior/Key Personnel

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… List individuals that meet this definition… regardless of what organization they work for.”

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

“Senior/key personnel must devote measurable effort to the project whether or not salaries or compensation are requested. "Zero percent" effort or "as needed" are not acceptable levels of involvement for those designated as Senior/Key Personnel.”

List alphabetically by last name after principal investigator.

https://grants.nih.gov/grants/glossary.htm#Senior/KeyPersonnel

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
* Project Role:

- PD/PI
- Co-PD/PI
- Faculty
- Post Doctoral
- Post Doctoral Associate
- Post Doctoral Scholar
- Other Professional
- Graduate Student
- Undergraduate Student
- Technician
- Consultant
- Co-Investigator
- Other (Specify)
**RESEARCH & RELATED Senior/Key Person Profile (Expanded)**

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**Attach Biographical Sketch**

**Attach Current & Pending Support**
Other Significant Contributors

- “contribute to the scientific development or execution of the project”
- No committed measurable effort - “zero person months” or “as needed”
- Listed after Senior/Key Personnel
- Biosketch, including Research Support information
- Advisors
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

#### PROFILE - Senior/Key Person 1

<table>
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#### Attach Biographical Sketch
- [Add Attachment]
- [Delete Attachment]
- [View Attachment]

#### Attach Current & Pending Support
- [Add Attachment]
- [Delete Attachment]
- [View Attachment]
Other Support

- Do not include with research application, unless requested in the funding announcement.
- Will be requested after peer review before an award is made, part of the “Just-In-Time” submission.
- Key Personnel only.
- Not Other Significant Contributors since “overlap” is not a consideration.

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

<table>
<thead>
<tr>
<th><strong>PROFILE - Senior/Key Person 1</strong></th>
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<td>Attach Biographical Sketch</td>
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<td>Attach Current &amp; Pending Support</td>
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Biographical Sketch

- 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

Education Block: Education and Training

A. Personal Statement

- Why you have the 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)
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

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 or “research products” (e.g., abstracts, presentations, patents, databases, protocols)
  - Describe your role/contribution

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

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Biographical Sketch

D. Research Support

- Current and Completed (last three years)
- Regardless of sponsor (federal and non-federal)
- Describe overall goals of project
- Indicate responsibilities
- Do not include % effort (cal months) or $ awarded
- This section is not “Other Support”
NAME: Hunt, Morgan Casey

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

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.)

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


https://grants.nih.gov/grants/forms/biosketch.htm
## B. Positions and Honors

### Positions and Employment

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<td>Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD</td>
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<td>2000-2002</td>
<td>Lecturer, Department of Psychology, Middlebury College, Middlebury, VT</td>
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<tr>
<td>2001-</td>
<td>Consultant, Coastal Psychological Services, San Francisco, CA</td>
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<tr>
<td>2002-2005</td>
<td>Assistant Professor, Department of Psychology, Washington University, St. Louis, MO</td>
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<tr>
<td>2007-</td>
<td>Associate Professor, Department of Psychology, Washington University, St. Louis, MO</td>
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### Other Experience and Professional Memberships

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<td>Member, Gerontological Society of America</td>
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<td>1998-</td>
<td>Member, American Geriatrics Society</td>
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<tr>
<td>2000-</td>
<td>Associate Editor, Psychology and Aging</td>
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<td>2003-</td>
<td>Board of Advisors, Senior Services of Eastern Missouri</td>
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<tr>
<td>2003-05</td>
<td>NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer</td>
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### Honors

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<td>2004</td>
<td>Excellence in Teaching, Washington University, St. Louis, MO</td>
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<td>2009</td>
<td>Award for Best in Interdisciplinary Ethnography, International Ethnographic Society</td>
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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
**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

https://grants.nih.gov/grants/forms/biosketch.htm
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
- Plans 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

- A. and B. Senior/Key and Other Personnel
  - Salary and fringe; employees of the applicant organization
  - Do not include Other Significant Contributors
  - 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

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
# 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>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Project Role: P/D/FI

Add Additional Key Person

Additional Senior Key Persons:

Add Attachment  Delete Attachment  View Attachment

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</th>
<th>Requested Salary ($)</th>
<th>Fringe Benefits ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Post Doctoral Associates</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>
</tr>
<tr>
<td></td>
<td>Undergraduate Students</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>
</tr>
<tr>
<td></td>
<td>Total Number Other Personnel</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Add Additional Other Personnel

Total Other Personnel

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

- **Institutional Base Salary**
  - Prorate for budget period
  - Take into consideration yearly increases for professional and support staff
  - NIH uses a salary cap
    - $189,600/year (as of 1/7/2018)
Personnel

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

- **Fringe Benefits**
  - Government-funded sponsored projects
    - Rate may change every year
  - Non-Govt.-funded sponsored projects may have different fringe benefits rate
## 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>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Add Additional Equipment

Additional Equipment: ___________  Add Attachment  Delete Attachment  View Attachment

Total funds requested for all equipment listed in the attached file

Total Equipment

---

## D. Travel

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

2. Foreign Travel Costs

Total Travel Cost

---

## E. Participant/Trainee Support Costs

<table>
<thead>
<tr>
<th></th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuition/Fees/Health Insurance</td>
<td></td>
</tr>
<tr>
<td>Stipends</td>
<td></td>
</tr>
<tr>
<td>Travel</td>
<td></td>
</tr>
<tr>
<td>Subsistence</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

Number of Participants/Trainees

Total Participant/Trainee Support Costs
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


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E. Participant/Trainee Support Costs

- Usually not used for NIH applications
- Tuition for GRA’s is listed in “F. Other Direct Costs”
<table>
<thead>
<tr>
<th></th>
<th>F. Other Direct Costs</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Publication Costs</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Consultant Services</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>ADP/Computer Services</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Subawards/Consortium/Contractual Costs</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Equipment or Facility Rental/User Fees</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Alterations and Renovations</td>
<td></td>
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<td>8</td>
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<td>9</td>
<td></td>
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<tr>
<td>10</td>
<td></td>
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</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
- 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 involved, compensation, travel, per diem, etc.
Subawards/Consortiums

- A portion of the work will be conducted at another site, funding will "flow" from NIH to applicant organization (prime) to subcontracted institution (domestic or foreign)

- Prime institution’s budget includes Subaward’s Total Costs (Direct and Indirect Costs)

- NIH allows for the exclusion of Subcontract’s/Consortium’s Indirect Costs when determining if the application meets the funding announcement’s Direct Costs cap or limitation (if there is one)
Subawards/Consortiums

- Subaward completes similar budget forms and justification

10 YEAR R&R SUBAWARD BUDGET ATTACHMENT(S) FORM

Instructions: On this form, you will attach the 10 Year R&R Subaward Budget files for your grant application. Complete the subawardee budget(s) in accordance with the 10 Year R&R budget instructions. Please remember that any files you attach must be a PDF document.

Click here to extract the 10 Year 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.

<table>
<thead>
<tr>
<th>Attachment</th>
<th>Add Attachment</th>
<th>Delete Attachment</th>
<th>View Attachment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Please attach Attachment 1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2) Please attach Attachment 2</td>
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<td>3) Please attach Attachment 3</td>
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<td>4) Please attach Attachment 4</td>
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<td>5) Please attach Attachment 5</td>
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<tr>
<td>6) Please attach Attachment 6</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>7) Please attach Attachment 7</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Contracted Costs

- e.g., support services (e.g., testing of biological samples, clinical services)
- Provide detailed information in Budget Justification
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, costs per day, tests, treatments, costs per item, per budget period, per site
  - Expected patient accrual for each site, per budget period
  - Other available support; e.g., third party recovery, drug company
  - Role of organization’s Clinical and Translational Science Award (CTSA) program

# H. Indirect Costs

<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>
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</tr>
</tbody>
</table>

**Add Additional Indirect Cost**

**Total Indirect Costs**

**Cognizant Federal Agency**

*Agency Name, POC Name, and POC Phone Number*
Indirect Costs

- Also called Facilities and Administration (F&A)
- Federally negotiated rate
- Percentage of direct costs
- MTDC-Modified Total Direct Costs:
  - Some items (equipment, patient care costs, tuition, subaward/consortium > $25K) not included in direct costs base
- Some institution’s rate is based on “Salary & Wages”
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
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.

### RESEARCH & RELATED BUDGET - Cumulative Budget

<table>
<thead>
<tr>
<th>Section</th>
<th>Totals ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A, Senior/Key Person</td>
<td></td>
</tr>
<tr>
<td>Section B, Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Number Other Personnel</td>
<td></td>
</tr>
<tr>
<td>Total Salary, Wages and Fringe Benefits (A+B)</td>
<td></td>
</tr>
<tr>
<td>Section C, Equipment</td>
<td></td>
</tr>
<tr>
<td>Section D, Travel</td>
<td></td>
</tr>
<tr>
<td>1. Domestic</td>
<td></td>
</tr>
<tr>
<td>2. Foreign</td>
<td></td>
</tr>
<tr>
<td>Section E, Participant/Trainee Support Costs</td>
<td></td>
</tr>
<tr>
<td>1. Tuition/Fees/Health Insurance</td>
<td></td>
</tr>
<tr>
<td>2. Stipends</td>
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<tr>
<td>3. Travel</td>
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<tr>
<td>4. Subsistence</td>
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<tr>
<td>5. Other</td>
<td></td>
</tr>
<tr>
<td>6. Number of Participants/Trainees</td>
<td></td>
</tr>
<tr>
<td>Section F, Other Direct Costs</td>
<td></td>
</tr>
<tr>
<td>1. Materials and Supplies</td>
<td></td>
</tr>
<tr>
<td>2. Publication Costs</td>
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<tr>
<td>3. Consultant Services</td>
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<td>4. ADP/Computer Services</td>
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<td>7. Alterations and Renovations</td>
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<td>8. Other 1</td>
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<td>9. Other 2</td>
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<tr>
<td>10. Other 3</td>
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</tr>
<tr>
<td>Section G, Direct Costs (A thru F)</td>
<td></td>
</tr>
<tr>
<td>Section H, Indirect Costs</td>
<td></td>
</tr>
<tr>
<td>Section I, Total Direct and Indirect Costs (G + H)</td>
<td></td>
</tr>
<tr>
<td>Section J, Fee</td>
<td></td>
</tr>
<tr>
<td>Section K, Total Costs and Fee (I + J)</td>
<td></td>
</tr>
</tbody>
</table>
Budget Justification

- Must be included
- Detailed information on personnel and their expertise
- Budget calculations for other categorical items
- Discuss significant increases or decreases
- Discuss and explain budget categories that use more than the standard yearly increase
- Can include price quotes (e.g., for equipment)

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Modular Budgets: The Rationale

- Redefines the “R”-type grants as an assistance mechanism
- Detailed categorical budget information not submitted with the application
- Simplifies process
- Focuses all parties (e.g., investigators, academic institutions, peer reviewers, NIH staff) on science, rather than the details of the budget

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Modular Budgets

- Applies to all new/competing R01, R03, and R21 proposals up to $250,000 requested direct costs in any year
- $250,000 “cap” does not include Indirect Costs 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 (e.g., 10 modules = $250,000)
Modular Budgets

- If Direct Costs > $250,000 in any year, then detailed budget format (non-modular) must be used for the full application.
- For most proposals, the same number of modules are requested in each year; no modules are added for inflationary increases.
Modular Budgets

- Additional Direct Costs can be added in $25,000 modules (up to $250,000) for increases due to large, one-time equipment purchases or major changes in budget due to research needs (e.g., varying patient costs or the short term need for specific personnel).

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

- Institutes/Centers can adjust award amount as per their 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
## PHS 398 Modular Budget

**Budget Period:** 1

<table>
<thead>
<tr>
<th>Start Date:</th>
<th>End Date:</th>
</tr>
</thead>
</table>

### A. Direct Costs

<table>
<thead>
<tr>
<th>Funds Requested (§)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Direct Cost less Consortium Indirect (F&amp;A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consoritum Indirect (F&amp;A)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Direct Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.00</td>
</tr>
</tbody>
</table>

### 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>
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</tr>
</tbody>
</table>

**Add Additional Indirect Cost**

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

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

<table>
<thead>
<tr>
<th>Total Indirect (F&amp;A) Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

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

**Add Period**
### Direct Costs

- **Direct Cost less Consortium F&A**: $250,000.00
- **Consortium F&A**: $13,750.00
- **Total Direct Costs**: $263,750.00

### Indirect Costs

<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>1. MTDC</td>
<td>55.00</td>
<td>$245,000.00</td>
<td>$134,750.00</td>
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<tr>
<td>2.</td>
<td></td>
<td></td>
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<tr>
<td>3.</td>
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<tr>
<td>4.</td>
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</tbody>
</table>

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

**Name of Regional Negotiator**

**Phone Number of Regional Negotiator**

**Indirect Cost Rate Agreement Date**: 01/31/2014

**Total Indirect Costs**: $134,750.00
### Cumulative Budget Information

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

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A, Total Direct Cost less Consortium Indirect (F&amp;A) for Entire Project Period</td>
<td>$0.00</td>
</tr>
<tr>
<td>Section A, Total Consortium Indirect (F&amp;A) for Entire Project Period</td>
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</tr>
<tr>
<td>Section A, Total Direct Costs for Entire Project Period</td>
<td>$0.00</td>
</tr>
<tr>
<td>Section B, Total Indirect (F&amp;A) Costs for Entire Project Period</td>
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</tr>
<tr>
<td>Section C, Total Direct and Indirect (F&amp;A) Costs (A+B) for Entire Project Period</td>
<td>$0.00</td>
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</table>

#### 2. Budget Justifications

<table>
<thead>
<tr>
<th>Justification</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel Justification</td>
<td>Add Attachment</td>
</tr>
<tr>
<td>Consortium Justification</td>
<td>Add Attachment</td>
</tr>
<tr>
<td>Additional Narrative Justification</td>
<td>Add Attachment</td>
</tr>
</tbody>
</table>
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

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Modular Budgets: Budget Justification

- **Personnel**: List all personnel, including:
  - Names
  - Roles on the project
  - Background and expertise demonstrating that individual can accomplish their responsibilities
  - Effort - Number of calendar months
    - e.g., 6 calendar months = 50% effort
  - Do not provide individual 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:** e.g., Justification for any variation in the number of modules requested

Other Support

- Do not include with research application- will be requested after peer review before an award is to made
- Key Personnel (not Other Significant Contributors)
- “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
  - Includes research grants, cooperative agreements, and contracts, and institutional awards
  - Training awards, gifts, and prizes not required to be listed


[https://grants.nih.gov/grants/forms/othersupport.htm](https://grants.nih.gov/grants/forms/othersupport.htm)
Information requested:

- Project number (Principal Investigator)
- Title of Project (or Subproject)
- Funding agency/Source
- Major goals
- Dates of awarded/proposed project
- Annual Direct Costs
- Percent effort in Calendar months
- Overlap

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

“Scientific overlap occurs when (1) substantially the same research is proposed in more than one application or is submitted to two or more funding sources for review and funding consideration or (2) a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.”
Other Support

- **Budgetary overlap** occurs when duplicate or equivalent budgetary items (e.g., equipment, salaries) are requested in an application but already are provided by another source.

- **Commitment overlap** occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested in the application.

- **Overlap**, whether scientific, budgetary, or commitment of an individual's effort greater than 100 percent, is not permitted.”
<table>
<thead>
<tr>
<th>PROJECT</th>
<th>START DATE</th>
<th>END DATE</th>
<th>PROJECT DESCRIPTION</th>
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<tbody>
<tr>
<td>2 R01 HL 00000-13 (Anderson)</td>
<td>3/1/2017</td>
<td>2/28/2022</td>
<td>Chloride and Sodium Transport in Airway Epithelial Cells</td>
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<td>NIH/NHLBI</td>
<td>$186,529</td>
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<td>5 R01 HL 00000-07 (Baker)</td>
<td>4/1/2012</td>
<td>3/31/2017</td>
<td>Ion Transport in Lungs</td>
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<td>R000 (Anderson)</td>
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<td>Cystic Fibrosis Foundation Gene Transfer of CFTR to the Airway Epithelium</td>
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<td>$43,123</td>
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The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

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<thead>
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<th>PROJECT DESCRIPTION</th>
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<tr>
<td>DCB 950000 (Anderson)</td>
<td>12/1/2017</td>
<td>11/30/2019</td>
<td>Liposome Membrane Composition and Function</td>
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<tr>
<td>National Science Foundation</td>
<td>$82,163</td>
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The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

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.
NIH Grant Forms and Instructions

- **How to Apply - Application Guide**

- **General Application Guide for NIH and Other PHS Agencies**
  https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.100-how-to-use-the-application-instructions.htm

- **Forms Library**
  https://grants.nih.gov/grants/forms.htm

- **Format Pages**
  https://grants.nih.gov/grants/forms/format-pages.htm

Jaime S. Rubin, Ph.D.: http://grantcourse.columbia.edu
Resources for Grant Writing

- Writing a Grant Proposal
  (Application Forms and Writing Tips)
  [http://grantscourse.columbia.edu/writing.htm](http://grantscourse.columbia.edu/writing.htm)