Extramurally-Funded Sponsored Projects to Support Research Activities: Best Practices for Competitive Applications

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Course: “Funding and Grantsmanship for Research and Career Development Activities”
http://grantscourse.columbia.edu/
Course Policies:

Please, No:

- Recording of Presentation
- Screen Shots of Presentation
- Posting to Social Media
- Sharing of Course Material with those Outside of Course

Thanks, Jaime Rubin
## Research (R) Announcements

<table>
<thead>
<tr>
<th>Activity Code(s)</th>
<th>Title</th>
<th>Announcement Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>R01</td>
<td>NIH Research Project Grant <em>(Parent R01 Clinical Trial Not Allowed)</em></td>
<td>PA-20-185</td>
</tr>
<tr>
<td>R01</td>
<td>Research Project Grant <em>(Parent R01 Basic Experimental Studies with Humans Required)</em></td>
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</tr>
<tr>
<td>R01</td>
<td>Research Project Grant <em>(Parent R01 Clinical Trial Required)</em></td>
<td>PA-20-183</td>
</tr>
</tbody>
</table>
**Parent Announcements (For Unsolicited or Investigator-Initiated Applications)**

Not all NIH Institutes and Centers participate on all parent announcements. Before submitting your application, make sure the NIH Institute or Center that might be interested in your research is listed as a participating organization in the announcement.

### Research (R) Announcements

<table>
<thead>
<tr>
<th>R21</th>
<th>NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)</th>
<th>PA-20-195</th>
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<td>NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)</td>
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<tr>
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<td>PA-20-196</td>
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</tbody>
</table>

https://grants.nih.gov/grants/guide/parent_announcements.htm
Topics to be Discussed

- 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
Topics to be Discussed

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- Components of the NIH R01 Grant Application
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
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

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• Project Staffing
  • No identification of responsibilities and roles
  • No documentation of competence (e.g., biosketches)
  • 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* (rigor of prior research).
- The proposal is *more complex* than the applicant 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** – **not focused**.
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.
- Access to **core facility** or “special” **research resource** is **not documented**.
- Institutional setting **unfavorable**.
Research Design and Methodology

- The proposed methodology, including tests and procedures, are unsuited to the objective.
- The proposed methodology is 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.

**Study design** is **not rigorous**.

Proposed **material for research** is unsuited of difficult to obtain.

The **number of observations** proposed is unsuitable.

“**Rigor and Reproducibility”**
Additional Problems

- **Requirements** for equipment, personnel or time are **unrealistic**.
- **Current research grants** are adequate in scope and funding to cover the proposed research.
- Poor previous **research productivity**.
Topics to be Discussed

- 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's Evaluation/Scoring System

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

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
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<tr>
<td>High Impact</td>
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<tr>
<td></td>
<td>3</td>
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<tr>
<td>Moderate Impact</td>
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<td>Good</td>
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<td></td>
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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>
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<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths/Weaknesses</th>
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<tbody>
<tr>
<td>High</td>
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<td>Exceptional</td>
<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>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
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<tr>
<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>
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<td>A few strengths and a few major weaknesses</td>
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<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</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

<table>
<thead>
<tr>
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<th>High</th>
<th>Medium</th>
<th>Low</th>
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</thead>
<tbody>
<tr>
<td>Score</td>
<td>1 2 3</td>
<td>4 5 6</td>
<td>7 8 9</td>
</tr>
</tbody>
</table>

#### 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.

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Impact Score

- **Preliminary Impact Scores** determine which applications discussed at study section

- **Impact Score given by each member of the study section**

- **Overall Impact Score** (for discussed applications): Mean of reviewers’ Impact Scores \( \times 10 \)

- 81 possible overall Impact Scores
  
  \((10 – 90, \text{ whole numbers})\)

http://enhancing-peer-review.nih.gov/timelines.html
http://www.niaid.nih.gov/researchfunding/grant/strategy/pages/7payline.aspx
## Calculating Percentile

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<th>Percentile</th>
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<tr>
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</tr>
<tr>
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<td>15</td>
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<td>//</td>
<td>//</td>
<td></td>
</tr>
<tr>
<td>80</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Percentile Value Calculation

- Relative rank for each priority score on a scale from 10 to 90.
- Follows NIH convention: Inverse relationship of priority score to scientific merit - \[\text{lowest percentile value represents the highest scientific merit}\]
- Specifies the percent of applications with scores equal to or better than (lower impact score) the application \[P = 100/N \times (k^{-1/2})\]

\[P = \text{Percentile Value}\]
\[k = \text{Numerical Rank of Impact Score}\]
\[N = \text{Total number of applications}\]
Calculating Percentile

80 applications*, 14 of which were not recommended for further consideration

<table>
<thead>
<tr>
<th>Rank</th>
<th>Impact Score</th>
<th>Percentile</th>
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</thead>
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<tr>
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<td>3</td>
<td>20</td>
<td>3.1</td>
</tr>
<tr>
<td>4</td>
<td>21</td>
<td>4.4</td>
</tr>
</tbody>
</table>

Rank = 3

\[ P = \frac{100}{80} \times (3-\frac{1}{2}) = 3.1 \]

* Study section’s last three review cycles

# NIAID: Payline

## NIAID Paylines for FY 2023

These paylines are for investigator-initiated applications reviewed for the September 2022, January 2023, and June 2023 Council meetings.

<table>
<thead>
<tr>
<th>Grant Type</th>
<th>Payline</th>
<th>Status</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>R01 (non-new PIs)</td>
<td>10 percentile</td>
<td>Interim</td>
<td>Research Projects for established investigators</td>
</tr>
<tr>
<td>R01 (new PIs)</td>
<td>14 percentile</td>
<td>Interim</td>
<td>Research Projects for new and early-stage investigators</td>
</tr>
</tbody>
</table>


Topics to be Discussed

- 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
Initial Review Group or Study Section

Actions

- **Discussed applications:**
  - Receives Impact/Priority Scores
  - Receives Scores for individual core review criteria

- **Not Discussed:**
  - Receives Scores for individual core review criteria

- Not Recommended for Further Consideration (NRFC)

- Other: e.g., Deferred
current criteria derive from multiple regulations; changes that conform to them well are more feasible than those that don’t. The Code of Federal Regulations (42 C.F.R. Part 52h.8) requires that research project applications be evaluated based on significance, investigators, innovation, approach, and environment. Protections for humans, animals, and the environment, adequacy of inclusion plans, and budget must be evaluated. The “21st Century Cures” Act (Public Law 114-255) requires attention to rigor and reproducibility and aspects of clinical trials. That said, there is room for improved implementation.”
NIH's Review Criteria

- **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*”
    
    (using five core review criteria, and additional review criteria)
  - “An application does not need to be strong in all categories to be judged likely to have *major scientific impact*.”

- **Core Review Criteria**
  A separate score is given for each

---

For Research Project Grant (Parent R01 Clinical Trial Not Allowed) (PA-20-185)
Check individual funding announcement if applying to another


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NIH's Review Criteria

Core Review Criteria
A separate score is given for each for each.

(A) Significance
(B) Investigators
(C) Innovation
(D) Approach
(E) Environment
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>
<td>Strengths</td>
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<td>Weaknesses</td>
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**NIH Research Grant Applications: Changes**

- Applications deadlines **on/after January 25, 2019**

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<tr>
<th>Form</th>
<th>Section</th>
<th>Heading</th>
<th>Current language</th>
<th>Revised language</th>
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<tbody>
<tr>
<td>Research Plan</td>
<td>Research Strategy</td>
<td><strong>Significance</strong></td>
<td>Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.</td>
<td>Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.</td>
</tr>
<tr>
<td>Research Plan</td>
<td>Research Strategy</td>
<td><strong>Approach</strong></td>
<td>Not Applicable</td>
<td>Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project.</td>
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<tr>
<td>Human Subjects and Clinical Trials Information</td>
<td>Section 2 – Study Population Characteristics</td>
<td>2.4 Inclusion of Women, Minorities, and Children</td>
<td>2. Inclusion of Children [References to the Inclusion of Children in Clinical Research policy]</td>
<td>2. Inclusion Across the Lifespan [References to Inclusion of Children replaced with Inclusion Across the Lifespan]</td>
</tr>
</tbody>
</table>

**Notice Number: NOT-OD-18-228**


(A) **Significance:**

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

2. Is the **prior research** that serves as the key support for the proposed project **rigorous**?

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

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

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(B) Investigators:

(1) “Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project?

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

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

(4) If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?”
NIH's Review Criteria

(C) Innovation:

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

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

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

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NIH's Review Criteria

(D) Approach:

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

(2) Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?

(3) Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?"
NIH's Review Criteria

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


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NIH's Review Criteria

(D) 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) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?”

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NIH's Review Criteria

(E) “Environment:

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

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

(3) Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?”
**Additional Review Criteria & Considerations**

**Additional Review Criteria** – Evaluated for the overall impact score, but not given an individual score

- Protections for Human Subjects
- Inclusion on the basis of Sex/Gender, Race, Ethnicity and Age in Clinical Research; Clinical Trials, Single IRB
- Vertebrate Animals
- Human Embryonic Stem Cells
- Biohazards
- Resubmissions
  - Response to previous reviewers’ comments and subsequent changes made to the proposal
- Renewals
  - Progress made in the last funding period


Additional Review Criteria & Considerations

Additional Review Considerations - Not given an individual score and not considered for the overall impact score

- Authentication of Key Biological and/or Chemical Resources
  - Plans for identifying and ensuring the validity of resources

- Budget and Period of Support

- Select Agent Research

- Resource Sharing Plans
  - 1) Data Sharing Plan; 2) Sharing Model Organisms; and 3) Genomic Data Sharing Plan (GDS)
Guidance for NIH Reviewers

- Rigor and Transparency
- Sex as a Biological Variable
- Vertebrate Animals
- Human Subjects Section
- Clinical Trials
- Single IRB for multi-site studies
- Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research
- Human Embryonic Stem Cells
- Authentication of Key Biological and/or Chemical Resources
- Select Agents
- Resource Sharing Plans
- Budget Information
- Revision Applications


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# Guidance for NIH Reviewers

https://grants.nih.gov/grants/policy/review-guidelines.htm

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<th>Description</th>
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<tr>
<td>R</td>
<td>R and U Awards (Research Project Grants; R01, R03, R21, SBIR/STTR, etc. and Cooperative Agreements: U01, etc.).</td>
</tr>
<tr>
<td>K</td>
<td>K Awards (Career Development)</td>
</tr>
<tr>
<td>F</td>
<td>F Awards (Fellowships)</td>
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<tr>
<td>S</td>
<td>S10 Awards (Shared Instrumentation)</td>
</tr>
<tr>
<td>T</td>
<td>T Awards (Training)</td>
</tr>
<tr>
<td>R</td>
<td>R and U Awards (Research Project Grants; R01, R03, R21, SBIR/STTR, etc. and Cooperative Agreements: U01, etc.)</td>
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<td>-----------------</td>
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<tr>
<td>KATZ R01 GUIDE FOR REVIEWERS (01/19/2021)</td>
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### NIH Research Grant Review Criteria: Changes

- **Application deadlines on/after January 25, 2019**

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<th>Section</th>
<th>Criteria</th>
<th>Current language</th>
<th>Revised language</th>
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<tr>
<td>Scored Review Criteria</td>
<td>Significance</td>
<td>Is there a strong scientific premise for the project?</td>
<td>Is the prior research that serves as the key support for the proposed project rigorous?</td>
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<tr>
<td>Scored Review Criteria</td>
<td>Approach</td>
<td>Not Applicable</td>
<td>Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project?</td>
</tr>
</tbody>
</table>

**Notice Number:** NOT-OD-18-228


# NIH Research Grant Review Criteria: Changes

**Application deadlines on/after January 25, 2019**

<table>
<thead>
<tr>
<th>Scored Review Criteria</th>
<th>Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>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?</td>
</tr>
</tbody>
</table>

**Notice Number: NOT-OD-18-228**


**NIH Research Grant Review Criteria: Changes**

- **Applications deadlines** on/after January 25, 2019

| Additional Review Criteria | Inclusion of Women, Minorities, and Individuals Across the Lifespan | When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the 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. | When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the 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 individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. |

**Notice Number:** NOT-OD-18-228


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

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

Notice Number: NOT-OD-16-011

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

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

Updates include:

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

https://grants.nih.gov/grants/peer/critiques/rpg.htm
NIH research grant and career development award application instructions and review language focus on four key areas:

1. The rigor of the prior research
2. Rigorous experimental design for robust and unbiased results
3. Consideration of relevant biological variables
4. Authentication of key biological and/or chemical resources
# Reviewer Guidance on Rigor and Transparency:
Research Project Grant and Mentored Career Development Applications

## Overview: Research Project Grant (RPG) Applications

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


### Rigor and Reproducibility in NIH Applications: Resource Chart

<table>
<thead>
<tr>
<th>4 AREAS OF FOCUS</th>
<th>WHAT DOES IT MEAN?</th>
<th>WHERE SHOULD IT BE INCLUDED IN THE APPLICATION?</th>
</tr>
</thead>
</table>
| Rigor of the Prior Research | A careful assessment of the rigor of the prior research that serves as the key support for a proposed project will help applicants identify any weaknesses or gaps in the line of research. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project. Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project. *See related FAQs, blog post* | Research Strategy  
- Significance  
- Approach |
| 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. *See related FAQs, blog post, examples from pilots* | Research Strategy  
- Approach |
<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>
<tbody>
<tr>
<td>Biological Variables</td>
<td>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. <em>See related FAQs, blog posts, article</em></td>
<td>Research Strategy ➢ Approach</td>
</tr>
</tbody>
</table>
| 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 have been 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, examples* | Other Research Plan Section ➢ Include as an attachment ➢ **Do not include** in the Research Strategy. |
“The proposed changes will allow peer reviewers to focus on scientific merit by evaluating 1) the **scientific impact, research rigor, and feasibility** of the proposed research without the distraction of administrative questions and 2) whether or not appropriate expertise and resources are available to conduct the research, thus mitigating the undue influence of the reputation of the institution or investigator.”
<table>
<thead>
<tr>
<th>CURRENT</th>
<th>PROPOSED</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Main Review Criteria</strong> (will affect Overall Impact Score)</td>
<td><strong>Factor 1: Importance of the Research</strong> (individually scored)</td>
</tr>
<tr>
<td></td>
<td><em>Significance, Innovation</em></td>
</tr>
<tr>
<td>Individually scored:</td>
<td><strong>Factor 2: Rigor and Feasibility</strong> (individually scored)</td>
</tr>
<tr>
<td>1. Significance</td>
<td><em>Approach</em></td>
</tr>
<tr>
<td>2. Investigator(s)</td>
<td><strong>Factor 3: Expertise and Resources</strong> (not individually scored; affects Overall Impact Score)</td>
</tr>
<tr>
<td>3. Innovation</td>
<td><em>Investigators, Environment</em></td>
</tr>
<tr>
<td>4. Approach</td>
<td></td>
</tr>
<tr>
<td>5. Environment</td>
<td></td>
</tr>
<tr>
<td><strong>Additional Review Criteria</strong> (can affect Overall Impact Score)</td>
<td></td>
</tr>
<tr>
<td>Human Subject Protections; Inclusion of Women; Minorities, and Children; Vertebrate Animal: Biohazards; Resubmission/Renewal/Revisions - some modifications expected for review of clinical trials RPGs</td>
<td></td>
</tr>
<tr>
<td><strong>Additional Review Considerations</strong> (no effect on Overall Impact Score)</td>
<td><strong>• Authentication of Key Biological and/or Chemical Resources</strong></td>
</tr>
<tr>
<td>• Application from Foreign Organizations</td>
<td><strong>• Budget and Period of Support</strong></td>
</tr>
<tr>
<td>• Select Agent Research</td>
<td></td>
</tr>
<tr>
<td>• Resource Sharing Plans</td>
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<tr>
<td>• Authentication of Key Biological and/or Chemical Resources</td>
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<tr>
<td>• Budget and Period of Support</td>
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<tr>
<td>Mechanism</td>
<td>NIH Role</td>
</tr>
<tr>
<td>-----------------</td>
<td>----------------------------------------------</td>
</tr>
<tr>
<td>Grant</td>
<td>Patron</td>
</tr>
<tr>
<td></td>
<td>(Assistance, encouragement)</td>
</tr>
<tr>
<td>Cooperative Agreement</td>
<td>Partner</td>
</tr>
<tr>
<td></td>
<td>(Assistance but substantial program involvement)</td>
</tr>
<tr>
<td>Contract</td>
<td>Purchaser</td>
</tr>
<tr>
<td></td>
<td>(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).

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

Topics to be Discussed

- 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 New (Type 1) Grants: Competing Applications, Awards, and Success Rates

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
# NIH R01-Equivalent Grants Success Rates - FY2021

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Competing Status (Type) and Submission Number</th>
<th>Number of Applications Reviewed</th>
<th>Number of Applications Awarded</th>
<th>Success Rate $^5$</th>
<th>Total Funding $^6$</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>New First Submission (A0)</td>
<td>26,352</td>
<td>3,704</td>
<td>14.1%</td>
<td>$2,541,143,257</td>
</tr>
<tr>
<td>2021</td>
<td>New with Resubmissions (A1)</td>
<td>8,422</td>
<td>2,559</td>
<td>30.4%</td>
<td>$1,512,299,217</td>
</tr>
<tr>
<td>2021</td>
<td>Continuations (A0)</td>
<td>2,001</td>
<td>858</td>
<td>42.9%</td>
<td>$509,860,668</td>
</tr>
<tr>
<td>2021</td>
<td>Continuations with Resubmissions (A1)</td>
<td>1,086</td>
<td>487</td>
<td>44.8%</td>
<td>$281,445,853</td>
</tr>
<tr>
<td>2021</td>
<td>Supplements</td>
<td>126</td>
<td>19</td>
<td>15.1%</td>
<td>$31,167,676</td>
</tr>
<tr>
<td><strong>2021</strong></td>
<td><strong>FY Total</strong></td>
<td><strong>37,987</strong></td>
<td><strong>7,627</strong></td>
<td><strong>20.1%</strong></td>
<td><strong>$4,875,916,671</strong></td>
</tr>
</tbody>
</table>

### NIH R01-Equivalent Grants Success Rates - FY2021

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<thead>
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### NIH R01-Equivalent Grants Success Rates - FY2021

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<tr>
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<td><strong>FY Total</strong></td>
<td><strong>20.1%</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

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

- 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
New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023

Notice Number: NOT-OD-22-195


High-level Grant Application Form Change Summary: FORMS-H


NIH will require the use of the updated Biographical Sketch and Other Support format pages for submissions on or after January 25, 2022. See NOT-OD-21-073, NOT-OD-21-110, and NOT-OD-21-122 for more information.
Key Changes:

- For NIH, as part of the implementation of the 2023 NIH Data Management and Sharing Policy, a new “Other Plan(s)” attachment field has been added to the PHS 398 Research Plan Form and the PHS 398 Career Development Award Supplemental Form. Applicants must attach the required Data Management and Sharing Plan in this new field in FORMS-H applications. See NOT-OD-21-013 and NOT-OD-22-189 for more information. Note: Although the 2023 NIH Data Management and Sharing Policy is not applicable to fellowship and institutional training grant applications, the new attachment field was added for potential future use with other plans.
The PHS 398 Research Training Program Plan Form is used only for Training applications and Multi-project applications with an "NRSA Training" Component.

This form includes fields to upload several attachments including the Program Plan, Faculty Biosketches, and Data Tables.

The attachments in this form, together with the rest of your application, should include sufficient information needed for evaluation of the training plan, independent of any other documents (e.g., previous application). Be specific and informative, and avoid redundancies.

Quick Links

Introduction

View larger image
<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>Project Summary/Abstract</td>
<td>For all Activity Codes</td>
<td>30 lines of text</td>
</tr>
<tr>
<td>Project Narrative</td>
<td>For all Activity Codes excluding C06, UC6 and G20.</td>
<td>three sentences</td>
</tr>
<tr>
<td>Introduction to Resubmission and Revision Applications</td>
<td>For all Activity Codes (including each applicable component of a multi-component application)</td>
<td>1</td>
</tr>
<tr>
<td>Specific Aims</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>Biographical Sketch</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>
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<tr>
<td>-------------------------</td>
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<tr>
<td>Research Strategy</td>
<td><strong>For Activity Code DP1</strong></td>
<td>5</td>
</tr>
<tr>
<td></td>
<td><strong>For Activity Codes R03, R13, U13, R13, U13, R21, R35, R36, R41, R43, SC2, SC3, X01, X02, R50, UT1</strong></td>
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<tr>
<td></td>
<td><strong>For Activity Code DP2</strong></td>
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<td></td>
<td><strong>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, S12, UB1, UC2, UH2,UH3, UG1, UC4, UF1, UG3/UH3, UH2/UH3, U01, U18, U24, U2C, U34, U42, U44,UT2, X01, X02</strong></td>
<td>12</td>
</tr>
<tr>
<td></td>
<td><strong>For all other Activity Codes</strong></td>
<td>Follow FOA instructions</td>
</tr>
</tbody>
</table>

* FOA instructions always supersede these instructions.*

Components of the NIH R01 Grant Application

SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE
### Application for Federal Assistance

#### SF 424 (R&R)

<table>
<thead>
<tr>
<th>1. TYPE OF SUBMISSION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-application</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. DATE SUBMITTED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicant Identifier</td>
</tr>
</tbody>
</table>

#### 5. APPLICANT INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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<tbody>
<tr>
<td>Legal Name</td>
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<tr>
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<td>Street2</td>
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<td>City</td>
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<tr>
<td>County / Parish</td>
<td></td>
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<td>State</td>
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<tr>
<td>Zip / Postal Code</td>
<td></td>
</tr>
</tbody>
</table>

Person to be contacted on matters involving this application:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prefix</td>
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<td>Fax Number</td>
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<td>Email</td>
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</tr>
</tbody>
</table>

#### 6. EMPLOYER IDENTIFICATION (E&I) or (T&U):

#### 7. TYPE OF APPLICANT:

Please select one of the following:

- Small Business Organization Type
- Women Owned
- Socially and Economically Disadvantaged
- Other (Specify):

#### 8. TYPE OF APPLICATION:

- New
- Resubmission
- Renewal
- Continuation
- Revision

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>If Revision</td>
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<tr>
<td>Number</td>
<td></td>
</tr>
<tr>
<td>Org. Number</td>
<td></td>
</tr>
</tbody>
</table>

Is this application being submitted to other agencies? **Yes** **No**

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>What other Agencies?</td>
<td></td>
</tr>
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</table>

#### 9. NAME OF FEDERAL AGENCY:

#### 10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER:

<table>
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<th>Value</th>
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<tbody>
<tr>
<td>Title</td>
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#### 11. DESCRIPTIVE TITLE OF APPLICANT’S PROJECT:

#### 12. PROPOSED PROJECT:

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
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</thead>
<tbody>
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<tr>
<td>Ending Date</td>
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#### 13. CONGRESSIONAL DISTRICT OF APPLICANT:

<table>
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<th>Value</th>
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14. PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR CONTACT INFORMATION

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

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

*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.

I agree
# Cover Letter Attachment

**SF 424 (R&R) APPLICATION FOR FEDERAL ASSISTANCE**

<table>
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<tr>
<th>21. Cover Letter Attachment</th>
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[https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.200-sf-424-(r&r)-form.htm](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.200-sf-424-(r&r)-form.htm)
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
  - Human fetal tissue (HFT) obtained from elective abortions
- Not review assignment requests

Components of the NIH R01 Grant Application

PHS Assignment Request Form
PHS Assignment Request Form

Funding Opportunity Number: Pre-populated from announcement information.

Funding Opportunity Title: Pre-populated from announcement information.

Awarding Component Assignment Suggestions (optional)

If you have a suggestion for an awarding component (e.g., NIH Institute/Center) assignment, use the link below to identify the appropriate short abbreviation (e.g., "NCI" for National Cancer Institute) and enter it below in the boxes for "Suggested Awarding Components". All suggestions will be considered; however, not all assignment suggestions can be honored.

Information about Awarding Component can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents

Suggested Awarding Components: 

Study Section Assignment Suggestions (optional)

If you have a suggestion for a study section assignment, use the link below to identify a study section(s). Enter the short abbreviation for that study section in the boxes for “Suggested Study Sections.” Remove all hyphens, parentheses, and spaces. All suggestions will be considered; however, not all assignment suggestions can be honored.

For example, enter "CAMP" if you wish to suggest assignment to the NIH Cancer Molecular Pathobiology study section, or "ZRG1HDMR" if you wish to suggest assignment to the NIH Healthcare Delivery and Methodologies SBIR/STTR panel for informatics.

Information about Study Sections can be found here: https://grants.nih.gov/grants/phs_assignment_information.htm#StudySection

Suggested Study Sections: 

Rationale for assignment suggestions (optional) Entry is limited to 1000 characters.

Up to 1000 characters.
Components of the NIH R01 Grant Application

PHS 398 Cover Page Supplement Form
I. 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

Answer required if euthanasia is NOT consistent with AVMA guidelines. Up to 1000 characters.
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):

Error if provided human embryonic stem cell lines are not listed at http://stemcells.nih.gov/research/registry/ at time of submission. Use NIH Registration Number (e.g., 0004, 0005). Provide up to 200 cell lines.
4. Human Fetal Tissue Section

*Does the proposed project involve human fetal tissue obtained from elective abortions?*

- **Yes** [ ]
- **No** [ ]

If "yes" then provide the HFT Compliance Assurance

**Required if Yes. Cannot be included if No.**

Add Attachment  |  Delete Attachment  |  View Attachment

If "yes" then provide the HFT Sample IRB Consent Form

**Required if Yes. Cannot be included if No.**

Add Attachment  |  Delete Attachment  |  View Attachment
Project/Performance Site(s)

Where the work described in the Research Plan will be conducted

- Applicant organization (e.g., Columbia University)
- 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 also responsible for compliance
  - e.g., lab animals, human subjects, financial management

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Components of the NIH R01 Grant Application

R&R Other Project Information Form

RESEARCH & RELATED Other Project Information
RESEARCH & RELATED Other Project Information

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: 

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.220-r&r-other-project-information-form.htm
1. Are Human Subjects Involved

"If activities involving human subjects are planned at any time during the proposed project at any performance site, check "Yes." Check "Yes" even if the proposed project is exempt from regulations for the Protection of Human Subjects, or if activities involving human subjects are anticipated within the period of award but plans are indefinite, or if the proposed activities include public health surveillance activities.

Whether you answer "Yes" or "No" to the "Are Human Subjects Involved?" question here, your answer will populate the relevant field in the G.500 - PHS Human Subjects and Clinical Trials Information form...

Note on the use of human specimens or data: Applications involving the use of human specimens or data may or may not be considered to be research involving human subjects, depending on the details of the materials to be used. If you check "No" to "Are Human Subjects Involved?" but your application proposes using human specimens or data, you will be required to provide a clear justification about why this use does not constitute human subjects research. Follow the G.500 - PHS Human Subjects and Clinical Trials Information form instructions."
Definition of Human Subjects Research

Decision Tool: Am I Doing Human Subjects Research?

The questionnaire is a tool to assist you with determining whether your project involves non-exempt human subjects research, meets the criteria for exempt human subjects research, or does not involve human subjects research.

Human Subjects Research Infographic

This resource summarizes the definition of human subjects research and provides examples of human subjects research projects. It also describes what you will need when you are preparing your NIH application and what is required if you are funded.

Exempt Human Subjects Research Infographic

This resource is a guide to simplify the understanding of the criteria for exempt human subjects research.

Research Involving Private Information or Biospecimens Flowchart

Studies involving the use of human specimens or data may or may not be considered to be research involving human subjects, depending on the details of the materials to be used. Use this flowchart to help determine if studies involving private information or biospecimens may meet the definition of human subjects research.


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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 reasons why the facilities or other aspects of the proposed project are more appropriate than a domestic setting.”
### RESEARCH & RELATED Other Project Information

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<td>7.</td>
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<td>9.</td>
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<td>Facilities &amp; Other Resources</td>
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https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.220-r&r-other-project-information-form.htm

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

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[https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.220-r&r-other-project-information-form.htm](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.220-r&r-other-project-information-form.htm)
R&R Other Project Information:

9. Bibliography/References Cited

- Full citations of all references cited in the Research Plan and the Human Subjects/Clinical Trials Information Form
- Relevant and current literature
- Citing interim research products is permitted (e.g., preprints, preregistered research protocols)
- 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)

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.220-r&r-other-project-information-form.htm

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## RESEARCH & RELATED Other Project Information

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<td>12</td>
<td>Other Attachments</td>
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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
R&R Other Project Information:

10. Facilities & Other Resources

- How will the scientific environment “contributes 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, collaborative arrangements)

- Facilities for research involving biohazards or other potentially dangerous substances
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.”
7. Project Summary/Abstract

8. Project Narrative

9. Bibliography & References Cited

10. Facilities & Other Resources

11. Equipment

12. Other Attachments
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.
Components of the NIH R01 Grant Application

PHS 398 Research Plan
**Introduction**

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

**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. Other Plan(s)

12. Authentication of Key Biological and/or Chemical Resources

**Appendix**

13. Appendix
Introduction

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

2. Specific Aims  →  1 page


4. Progress Report Publication List

Add Attachment
Add Attachment
Add Attachment
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

- If there is >1 Specific Aims, the Significance, Innovation, and Approach may be discussed for each Specific Aim separately, or all Specific Aims together.

- “Overall strategy, methodology and analyses”

- Human Subjects/Clinical Trial Form will contain detailed information on eligibility, demographics, protection, monitoring, etc. However, Form cannot be used as a way to avoid Research Strategy’s page limit.
3. Research Strategy

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

12 pages for an R01 application
6 pages for R03 and R21 applications
3. Research Strategy - (a) Significance

- **Importance** of the problem/ Impact on a **critical barrier to progress** in the field

- “**Strengths and weaknesses** in the **rigor of the prior research**” (e.g., preliminary data), published/unpublished, that supports the proposed research

- 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 or clinical practice paradigms”

- “Novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or 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”
- “Plans to address weaknesses in the rigor of the prior research” that support the proposed research
- How will experimental design and methods lead to “robust and unbiased results”
- How “data will be collected, analyzed, and interpreted”
- Potential problems (challenges/limitations), alternative strategies/approaches
- Benchmarks (milestones) for success, strategies to establish feasibility

https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g:400-phs-398-research-plan-form.htm
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## Timeline for Specific Aims and Benchmarks/Milestones of Research Progress

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<td>Summary of Specific Aim 3</td>
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## Timeline for Specific Aims and Benchmarks/Milestones of Research Progress

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<td>Summary of Specific Aim 3</td>
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Specific Aims: Milestones

Specific Aim 1a Milestone:

Specific Aim 1b Milestone #1:

Specific Aim 1b Milestone #2:

Specific Aim 2a Milestone #1:

Specific Aim 2a Milestone #2:

Specific Aim 2b Milestone #1:

Specific Aim 2b Milestone #2:

Specific Aim 3 Milestone:
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
Reviewer Guidance to Evaluate Sex as a Biological Variable (SABV)

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

Is strong justification provided for the single sex study?³

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

Are both sexes included in the study?

Is the study intended to test for sex differences?²

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

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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


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

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

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3. Research Strategy – changes

- For applications with deadlines on or after January 25, 2019

- “clarify the current application instructions and review criteria by replacing the term "scientific premise" with "the rigor of the prior research" and adding instruction and review language so that "the rigor of the prior research" is addressed under Significance and Approach.”

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
### 3. Research Strategy – changes

<table>
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<th>Revised language</th>
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<tbody>
<tr>
<td>Research Plan</td>
<td>Research Strategy</td>
<td>Significance</td>
<td>Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application. Describe the strengths and weaknesses in the rigor of the prior research (both published and unpublished) that serves as the key support for the proposed project.</td>
<td></td>
</tr>
<tr>
<td>Research Plan</td>
<td>Research Strategy</td>
<td>Approach</td>
<td>Not Applicable</td>
<td>Describe plans to address weaknesses in the rigor of the prior research that serves as the key support for the proposed project.</td>
</tr>
</tbody>
</table>

3. Research Strategy – Preliminary Studies

- Aids reviewers in assessing the likelihood of project’s feasibility and success
- Helps establishes the competence and experience of PI and research team
- Helps demonstrate the availability of required “research resources” (e.g., patient population, access to unique animal models, reagents, databases or specialized instrumentation, etc.)


- For competitive renewal applications
<table>
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<td>2. Specific Aims</td>
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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 PubMed Central (PMC) (PMCID#) or NIH Manuscript Submission reference number (NIHMS#) for publications that fall under NIH Public Access Policy
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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 analgesia, anesthesia, sedation, palliative care, and humane endpoints… to minimize discomfort, distress, pain and injury.”


https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.400-phs-398-research-plan-form.htm
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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
7. Multiple PD/PI Leadership Plan

- Can strengthen a **multi-disciplinary** application

- **Multiple PI’s do not** need to be at the **same institution**.
  
  - Award document (Notice of Grant Award) made to the institution of the Contact PI
  
  - If other MPI’s are at other institutions, then they are funded via a subcontract from the Contact PI’s institution (prime)

- **To meet the requirements for the **ESI** payline, all MPI’s must be ESI’s**
## Other Research Plan Section

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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 official administrative and budgetary documentation from the subcontracted organization, a Letter of Support/Collaboration from the lead subcontract investigator is included as well as their NIH Biosketch

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
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. Other Plan(s)

12. Authentication of Key Biological and/or Chemical Resources
9. Letters of Support

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

All letters in one **single PDF file**

Many of these individuals will also provide an **NIH Biosketch** (different section)
9. Letters of Support

Not “Letters of Reference” from those not involved in the project

Should not contain information that should instead be in the Research Plan Section (Specific Aims, Research Strategy); e.g., Background, Significance, preliminary data, graphs, tables, other figures
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10. Resource Sharing

■ 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
Model Organism Sharing Policy

Learn how NIH expects applicants to share novel model organisms and related resources generated with NIH funding or support.

ON THIS PAGE:

- Why Share Model Organisms?
- Policy Overview
- Applicability
- Definitions of Model Organisms and Related Resources
- Interaction with other NIH Data Sharing Policies
- Compliance
- Sharing Plans
- Sample Sharing Plans
- Costs of Sharing
- Intellectual Property

Frequently Asked Questions (FAQs)

A. Definitions, Policy, Applicability, and Rationale
B. Considerations for Developers/Providers of Model Organisms
C. Writing the Sharing Plan, Review, and Progress Reporting
D. Considerations for Requestors/Recipients of Model Organisms
10. Resource Sharing

- **Research Tools**
  - “sharing of unique research resources developed through NIH-sponsored research…”
  - “When resources have been developed with NIH funds, and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.”

Research Tools Policy

Explore how NIH expects funding recipients to appropriately disseminate and access research tools developed with NIH funding.

ON THIS PAGE:

- Definition of Research Tools
- Disseminating & Accessing Research Tools and Resources
- Principles of Disseminating Research Tools
- Dissemination Expectations
- Obligations to Other Funding Sources
- Limiting Exclusive Licenses to Appropriate Field of Use
- Prompt Publication Expectation
- Consistent Obligations to Share Materials
- Grantbacks
- Definitions of Materials in Agreements

https://sharing.nih.gov/other-sharing-policies/research-tools-policy
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https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.400-phs-398-research-plan-form.htm

11. Other Plans

- **Data Management and Sharing (DMS) Plan**
  - For NIH applications (e.g., R01) with deadlines on/after January 25, 2023.
  
  - For specific application activity codes

  - Proposed research that will generate scientific data

- **Genomic Data Sharing Policy**

- **Oversight of Data Management and Sharing:**
  
  - “Describe how compliance with the Plan will be monitored and managed, frequency of oversight, and by whom at the applicant institution (e.g., titles, roles).”

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Data Management and Sharing (DMS) Plan

- Proposed “research that will generate scientific data”

- **Scientific data**: “Recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications. Scientific data includes any data needed to validate and replicate research findings.”

- **Scientific data does not include**: “Laboratory notebooks, preliminary analyses, completed case report forms, drafts of scientific papers, plans for future research, peer reviews, communications with colleagues, or physical objects such as laboratory specimens.”

Data Management and Sharing (DMS) Plan

- Elements to Include

- Recommended to be no more than 2 pages

- NIH optional DMS Plan format page

- Sample Plans available

- NIH Institute and Center Data Sharing Policies

Jaime S. Rubin, Ph.D.; http://grantcourse.columbia.edu
Data Management and Sharing Policy

NIH has a longstanding commitment to making the results of NIH-funded funded research available. Responsible data management and sharing has many benefits, including accelerating the pace of biomedical research, enabling validation of research results, and providing accessibility to high-value datasets.

Planning & Budgeting for Data Management and Sharing

Find out what NIH expects in a Data Management & Sharing plan and what costs are allowed in a request.

Data Management

Proper data management is crucial for maintaining scientific rigor and research integrity. Learn about best practices for scientific data management.

Sharing Scientific Data

Under the NIH Data Management & Sharing Policy, investigators are empowered to choose the most appropriate methods for sharing scientific data. Learn more about methods for data sharing and selecting data repositories.
Writing a Data Management & Sharing Plan

- Writing a Data Management and Sharing Plan
- Submitting Data Management and Sharing Plans
- Data Management and Sharing Plan Format
- Elements to Include in a Data Management and Sharing Plan
- Sample Plans
- Assessment of Data Management and Sharing Plans
- Revising Data Management and Sharing Plans
- Additional Considerations

Frequently Asked Questions (FAQs)

- A. Policy Scope
- B. Managing and Sharing Scientific Data
- C. Considerations for Scientific Data Derived from Human Participants
- D. Compliance and Enforcement
- E. Contracts


Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
“Program staff... will assess DMS Plans to ensure the elements of a DMS Plan have been adequately addressed and to assess the reasonableness of those responses.

During peer review, reviewers will not be asked to comment on the DMS Plan nor will they factor the DMS Plan into the Overall Impact score, unless sharing data is integral to the project design and specified in the Funding Opportunity Announcement...

Although part of the official submission, when not considered during peer review the attachment is maintained as a separate “Data Management and Sharing (DMS) Plan” document... This document is viewable by authorized users and is not part of the assembled e-Application.”
11. Other Plans

- **Genomic Data Sharing (GDS)**

  - Research that generates large-scale human or non-human genomic data
  
  - Data derived from humans: “How the privacy, rights, and confidentiality of human research participants will be protected (e.g., through de-identification, Certificates of Confidentiality, and other protective measures)…”
  
  - Institutional certification required before award
Developing Genomic Data Sharing Plans

Genomic Data Sharing (GDS) plans describe how the research will meet the expectations of NIH's GDS policy. Learn how to write and submit a GDS plan.

Institutional Certifications

Investigators working with large-scale human genomic data are required to submit an Institutional Certification to NIH. Learn about this important document and how to prepare it.

Submitting Genomic Data

Learn more about the genomic data submission process, from choosing an appropriate repository to submitting datasets. Generating human genomic data? Follow our step-by-step instructions for registering a study in the Database of Genotypes and Phenotypes (dbGaP), which is required for human genomic datasets.
### Other Research Plan Section

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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.
12. 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
12. Authentication of Key Biological and/or Chemical Resources

- 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) Are 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”

Limited listing of allowed documents, includes:
- Blank informed consent/assent forms, Blank data collection instruments, survey forms, questionnaires, interview questions

Not permitted, includes:
- Page of acronyms, larger versions of figures, publications

Additional items may be specified in the Funding Announcement
Components of the NIH R01 Grant Application

PHS Human Subjects and Clinical Trials Information
Definition of Human Subjects Research

Decision Tool: Am I Doing Human Subjects Research?

The questionnaire is a tool to assist you with determining whether your project involves non-exempt human subjects research, meets the criteria for exempt human subjects research, or does not involve human subjects research.

Human Subjects Research Infographic

This resource summarizes the definition of human subjects research and provides examples of human subjects research projects. It also describes what you will need when you are preparing your NIH application and what is required if you are funded.

Exempt Human Subjects Research Infographic

This resource is a guide to simplify the understanding of the criteria for exempt human subjects research and how to navigate the process.

Research Involving Private Information or Biospecimens Flowchart

Studies involving the use of human specimens or data may or may not be considered to be research involving human subjects, depending on the details of the materials to be used. Use this flowchart to help determine if studies involving private information or biospecimens may meet the definition of human subjects research.

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

Meets the definition of human subjects research.

Exempt studies involve human subjects research: research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

Meets the criteria of one of the following exemptions:

**Exemption 1:** conducted in an educational setting using normal educational practices*

*Cannot include any other procedures, such as collection of clinical data or biospecimens

**Exemption 2:** uses educational tests, surveys, interviews, or observations of public behavior*

*Limited IRB review may be required.

**Exemption 3:** benign behavioral interventions in adults*

*Limited IRB review may be required.

**Exemption 4:** involves the collection/study of data or specimens if publicly available, or recorded such that subjects cannot be identified*

*May be identifiable in limited cases. See §46.104(d)(4)(i) and (iv)

**Exemption 5:** research or demonstration projects designed to study, evaluate, improve, or examine an NIH public benefit or service program*

*Applies to projects that NIH itself administers

**Exemption 6:** taste and food quality evaluations

**Exemption 7:** storage of identifiable information or biospecimens for secondary research use. Broad consent and limited IRB review are required

**Exemption 8:** secondary research use of identifiable information or biospecimens. Broad consent and limited IRB review are required

For more information see the [NIH OER Human Subjects Research website](https://grants.nih.gov/policy/humansubjects/research.htm).
Send questions/comments to [OER-HS@nih.gov](mailto:OER-HS@nih.gov).

**NIH Requirements:**
- HS education
- Inclusion tracking for all except 4.

**45 CFR 46 Requirements:**
- Limited IRB review for 7 & 8, and some study designs under 2 & 3.
- Broad consent for 7 & 8.

Cannot involve prisoners, unless includes a broader population that happens to include prisoners.

Cannot involve children in:
- Exemption 2 if investigators participate in the activity being observed or includes identifiable info, OR
- Exemption 3.
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.”
**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
“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 that will be 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
- Only one aim or sub-aim of your study meets the clinical trial definition

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.”
“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 G.220 - R&R Other Project Information Form.”
Research Involving Private Information or Biospecimens flowchart

“Does any of the proposed research in the application involve human specimens and/or data?...

Note: Applications involving the use of human specimens or data may not be considered to be research involving human subjects, depending on the details of the materials to be used.

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research....

If you answered "Yes" to the "Does any of the proposed research in the application involve human specimens and/or data?" question, you must provide an explanation for any use of human specimens and/or data not considered to be human subjects research....

This explanation should include:

- information on who is providing the data/biological specimens and their role in the proposed research;
- a description of the identifiers that will be associated with the human specimens and data;
- a list of who has access to subjects' identities; and
- information about the manner in which the privacy of research participants and confidentiality of data will be protected.”
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; Age limits; Inclusion of Women, Minorities, and Children; Recruitment; Inclusion Enrollment Report

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

- **Section 4** – Protocol Synopsis

- **Section 5** – Other Clinical Trial-related Attachments
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; Age limits; Inclusion of Women, Minorities, and Children; Recruitment; 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
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<th>If you answered &quot;no&quot; to any of the questions in the Clinical Trial Questionnaire</th>
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<tr>
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<td>Required if specified in the FOA</td>
<td>Do not complete</td>
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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: Disease/Condition, Eligibility; Age limits, Inclusion of Individuals Across the Lifespan, Women and Minorities, Recruitment and Retention Plan, Timeline, Inclusion Enrollment Report

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

- **Section 4 – Protocol Synopsis**

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

“NIH is revising its NIH Policy and Guidelines on the Inclusion of Children. Changes to the policy include (1) the applicability of the policy to individuals of all ages, including children and older adults; (2) clarification of potentially acceptable reasons for excluding participants based on age; and (3) a requirement to provide data on participant age at enrollment in progress reports…. This policy applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt"…. 
“It is the policy of NIH that individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research… unless there are scientific or ethical reasons not to include them… Applications or proposals for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. Applications/proposals must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the recipient/offeror must provide an acceptable justification for the exclusion.”
### PHS Human Subjects and Clinical Trials Information

#### Inclusion Enrollment Report

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[https://era.nih.gov/erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/Incl_Enroll_Rprt.htm](https://era.nih.gov/erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/Incl_Enroll_Rprt.htm)
# PHS Human Subjects and Clinical Trials Information

## Inclusion Enrollment Report

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</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

- **Section 2 – Study Population Characteristics**
  - Including: Eligibility; Age limits; 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**
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. Populations that are vulnerable to coercion or undue influence and pregnant women, fetuses and neonates, if relevant to your study

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

4. Importance of the Knowledge to be Gained
3.2 Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

3.3 Data and Safety Monitoring Plan

3.4 Data and Safety Monitoring Board

3.5 Structure of Study Team

- Organizational and administrative structure
  - Administrative site(s), Data coordinating site(s), Enrollment site(s), Lab or testing site(s)
- Roles, Governance, Decision-making
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; Age limits; Inclusion of Women, Minorities, and Children; Recruitment; Inclusion Enrollment Report

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

- **Section 4 – Protocol Synopsis**

- **Section 5 – Other Clinical Trial-related Attachments**
4.1 Study Design
4.2 Outcomes Measures
4.3 Statistical Design and Power
4.4 Subject Participation Duration
4.5 FDA-regulated intervention?
4.6 Clinical trial under FDA Amendments Act (FDAAAA)?
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; Age limits; Inclusion of Women, Minorities, and Children; Recruitment; Inclusion Enrollment Report

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

- **Section 4 – Protocol Synopsis**

- **Section 5 – Other Clinical Trial-related Attachments**
Include if Funding Opportunity Announcement permits or requires

- **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
For applications with deadlines on or after January 25, 2019

“NIH Policy and Guidelines on the Inclusion of Children. Changes to the policy include (1) the applicability of the policy to individuals of all ages, including children and older adults; (2) clarification of potentially acceptable reasons for excluding participants based on age; and (3) a requirement to provide data on participant age at enrollment in progress reports.

“NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects”

### Human Subjects/Clinical Trials Info - changes

| Human Subjects and Clinical Trials Information | Section 2 – Study Population Characteristics | 2.4 Inclusion of Women, Minorities, and Children | 2. Inclusion of Children
[References to the Inclusion of Children in Clinical Research policy] | 2. Inclusion Across the Lifespan
[References to Inclusion of Children replaced with Inclusion Across the Lifespan] |
|------------------------------------------------|-----------------------------------------------|-----------------------------------------------|-----------------------------------------------------------------|------------------------------------------------------------------|

Components of the NIH R01 Grant Application

R&R Senior/Key Person Profile (Expanded) Form

RESEARCH & RELATED Senior/Key Person Profile (Expanded)
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

#### PROFILE - Project Director/Principal Investigator

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#### Project Role

- **PD/PI**

#### Other Project Role Category

- Add Attachment
- Delete Attachment
- View Attachment

#### Attach Biographical Sketch

- Add Attachment
- Delete Attachment
- View Attachment

#### Attach Current & Pending Support

- Add Attachment
- Delete Attachment
- View Attachment

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Credential, agency login: NIH eRA Commons username - **required field**
Multiple Principal Investigators (MPI)

- The contact PI is listed first
- If there is more than one Principal Investigator, all are given the role of “PD/PI” (even if not at applicant organization)
- NIH does not use the term co-PD/PI
  [PD = Project Director]
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 the definition of senior/key regardless of what organization they work for.”

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

“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
# RESEARCH & RELATED Senior/Key Person Profile (Expanded)

**PROFILE - Senior/Key Person 1**

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**Attach Biographical Sketch**

**Attach Current & Pending Support**
*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)

**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]
Other Significant Contributors

- “contribute to the scientific development or execution of the project”
- No committed measureable effort - “zero person months” or “as needed”
- Listed after Senior/Key Personnel
- Can include NIH Biosketch
- e.g., Advisors
## RESEARCH & RELATED Senior/Key Person Profile (Expanded)

### Profile - Senior/Key Person 1

- **Prefix:**
- *** First Name:**
- **Middle Name:**
- *** Last Name:**
- **Suffix:**
- **Position/Title:**
- **Department:**
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- *** Project Role:**
- **Other Project Role Category:**
- **Degree Type:**
- **Degree Year:**

### Attachments
- **Biographical Sketch**
- **Current & Pending Support**

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Components of the NIH R01 Grant Application

R&R Senior/Key Person Profile (Expanded) Form

RESEARCH & RELATED Senior/Key Person Profile (Expanded)

Biosketch Format
Biographical Sketch

For Key Personnel (e.g., PI’s, Co-Investigators, Collaborators), Other Significant Contributors, Advisors, Consultants, etc.

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

No graphics, figures, pictures, tables, etc.

5 pages in length total

Jaime S. Rubin, Ph.D.; http://grantscourse.columbia.edu
Biosketch Format Pages, Instructions and Samples

- Biosketch topic page
- FAQs
- Learn whether a particular activity should be reported in the biosketch, other support, or annual progress reports: NIH Pre-award and Post-award Disclosures Relating to the Biographical Sketch and Other Support
- Format Attachments (fonts, margins, page limits, etc.)
- Related Topics:
  - Other Support topic page
  - Annual Progress Reports (RPPR)

Try SciENcv to help you develop your biosketch and automatically format it according to NIH requirements. Reflects removal of Section D per NOT-OD-21-073 first guide notice.

Updated Date
October 2021

https://grants.nih.gov/grants/forms/biosketch.htm
Biosketch Format Pages, Instructions and Samples

Frequently Asked Questions (FAQs)
Biosketches

- I. General
- II. SciENcv
- III. Citations
- IV. Contributions to Science
- V. Biosketch Compliance

Featured Questions

Q: The Biosketch instructions state that all positions and scientific appointments must be provided. Does this refer to active positions and appointments, or all positions a researcher has ever held?

The Biosketch must include all current positions and scientific appointments.
ADMINISTRATIVE NOTE:
During the review of this application, reviewers and/or NIH staff noted that one or more biosketches did not comply with the required format (NOT-OD-15-032). An electronic notification has been sent to the contact Program Director/Principal Investigator and Signing Official for this application, to ensure that future applications use the correct biosketch format. NIH has the authority to withdraw such applications from review or consideration for funding.
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 experience, technical expertise; collaborations, scientific environment, past relevant performance, etc.)

- Up to four relevant “research products” relevant to proposed project (e.g., publications, conference proceedings/abstracts/posters/presentations, databases, software). Citing interim research products is permitted (e.g., preprints, preregistered protocol)
Biographical Sketch

Education Block: Education and Training

A. Personal Statement (cont.)

- “Contributions to Science” not included in Section C.
- Ongoing and recently completed research projects (last 3 years)
  - Relevant to the proposed research
  - Other projects that you want to highlight for the reviewers (e.g., another large/complex project that you lead or had another significant role, high profile award)
- “Impediments” to past productivity (e.g., family responsibilities, illness, disability, military service) (optional)
B. Positions, Scientific Appointments and Honors

(most current listed first)

- Domestic and Foreign
  - "Including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary)"

- Professional experience
- Previous positions/employment
- Honors, awards, fellowships
- Professional achievements/recognition
- Advisory/Review committees
- Professional memberships
- Clinical licensures, specialty board certifications

https://grants.nih.gov/grants/forms/biosketch.htm
C. Contributions to Science

- Describe your most significant contributions to science (up to five), Not longer than \( \frac{1}{2} \) page (including citations)
  - Historical background of scientific problem
  - Main finding(s) – Impact on the field/progress of science and/or the application to health or technology
  - Describe your specific role in each “Contribution”
  - May mention not yet accepted publications (not cited “research product”)

https://grants.nih.gov/grants/forms/biosketch.htm
Biographical Sketch

C. Contributions to Science

- Reference up to 4 “research products” [e.g., publications, interim research product (with citation), abstracts, presentations, patents, databases, protocols, software,]
  - May describe your specific contribution/role in “Contribution”
- May include URL to a full list of publications (not required)
  - If included, must be a federal website
  - NIH recommends “My Bibliography”
### BIOGRAPHICAL SKETCH

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

<table>
<thead>
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**eRA COMMONS USER NAME** (credential, e.g., agency login):

**POSITION TITLE:**

**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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**A. Personal Statement**

**B. Positions, Scientific Appointments, and Honors**

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

BIOGRAPHICAL SKETCH

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

NAME: Hunt, Morgan Casey

ERA COMMONS USER NAME (credential, e.g., agency login): huntmc1

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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<td>University of California, Berkeley</td>
<td>Postdoctoral</td>
<td>08/2013</td>
<td>Public Health and Epidemiology</td>
</tr>
</tbody>
</table>
A. Personal Statement

I am an Associate Professor of Psychology, and my research is focused on neuropsychological changes associated with addiction. 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. 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 2015-2016, 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. In summary, I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project.

Ongoing and recently completed projects that I would like to highlight include:

R01 DA942367
Hunt (PI)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older substance abusers

R01 MH922731
Merryle (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression and substance abuse in the elderly

R21 AA998075
Hunt (PI)
01/01/19-12/31/21
Community-based intervention for alcohol abuse


## B. Positions, Scientific Appointments, and Honors

### Positions and Scientific Appointments

<table>
<thead>
<tr>
<th>Year</th>
<th>Position and Affiliation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021– Present</td>
<td>Associate Professor, Department of Psychology, Washington University, St. Louis, MO</td>
</tr>
<tr>
<td>2020 – Present</td>
<td>Adjunct Professor, McGill University Department of Psychology, Montreal, Quebec, Canada</td>
</tr>
<tr>
<td>2018 – Present</td>
<td>NIH Risk, Adult Addictions Study Section, members</td>
</tr>
<tr>
<td>2015 – 2017</td>
<td>Consultant, Coastal Psychological Services, San Francisco, CA</td>
</tr>
<tr>
<td>2014 – 2021</td>
<td>Assistant Professor, Department of Psychology, Washington University, St. Louis, MO</td>
</tr>
<tr>
<td>2014 – 2015</td>
<td>NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer</td>
</tr>
<tr>
<td>2014 – Present</td>
<td>Board of Advisors, Senior Services of Eastern Missouri</td>
</tr>
<tr>
<td>2013 – 2014</td>
<td>Lecturer, Department of Psychology, Middlebury College, Middlebury, VT</td>
</tr>
<tr>
<td>2011 – Present</td>
<td>Associate Editor, Psychology and Aging</td>
</tr>
<tr>
<td>2009 – Present</td>
<td>Member, American Geriatrics Society</td>
</tr>
<tr>
<td>2009 – Present</td>
<td>Member, Gerontological Society of America</td>
</tr>
<tr>
<td>2009 – 2013</td>
<td>Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD</td>
</tr>
<tr>
<td>2006 – Present</td>
<td>Member, American Psychological Association</td>
</tr>
</tbody>
</table>

### Honors

<table>
<thead>
<tr>
<th>Year</th>
<th>Honor</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>Award for Best in Interdisciplinary Ethnography, International Ethnographic Society</td>
</tr>
<tr>
<td>2019</td>
<td>Excellence in Teaching, Washington University, St. Louis, MO</td>
</tr>
<tr>
<td>2018</td>
<td>Outstanding Young Faculty Award, Washington University, St. Louis, MO</td>
</tr>
</tbody>
</table>
C. Contributions 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 and 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:
### RESEARCH & RELATED Senior/Key Person Profile (Expanded)

**PROFILE - Senior/Key Person 1**

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

**Attach Biographical Sketch**

**Attach Current & Pending Support**
Other Support

- Usually, not included with NIH research applications, 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 requested for Other Significant Contributors.

New Policies in Effect as of January 25, 2022

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

Jaime S. Rubin, Ph.D.; http://grantcourse.columbia.edu
Components of the NIH R01 Grant Application

R&R Budget Form

Research & Related Budget
Budget Justification

- Complete
- Comprehensive
- Concise
- Calculated correctly
NIH and other agencies usually require detailed budgets and budget 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

- Categories are sometimes increased 2%-3% per year
  - NIH may not award (fund) “cost-of-living” increases
- Equipment is usually purchased early in the research
- 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 (no committed effort), Collaborators at other institutions

Budget Justification: Role on Project

- Identify role, does not have to be official university title
- Justify and describe specific functions
- Describe background and expertise as they pertain to role in this project

RESEARCH & RELATED BUDGET - Budget Period 1

ORGANIZATIONAL DUNS: 
Enter name of Organization: 

Budget Type:  
- Project  
- Subaward/Consortium

Budget Period: 1  
Start Date: 
End Date: 

A. Senior/Key Person

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

Project Role: PD/PI

Additional Senior Key Persons: 

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>
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</tr>
<tr>
<td></td>
<td>Graduate Students</td>
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</tr>
<tr>
<td></td>
<td>Undergraduate Students</td>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>Secretarial/Clerical</td>
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</tr>
</tbody>
</table>

Total Number 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 (and “sister” DHHS agencies) uses a salary cap of $212,100/year (as of 1/1/2023)

- “Special” rules for some categories of personnel
  - e.g., Graduate Research Assistants (GRA’s), administrative/clerical staff


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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>
</table>

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

Total funds requested for all equipment listed in the attached file

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

## D. Travel

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

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

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

## E. Participant/Trainee Support Costs

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

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

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

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

- Itemize in budget justification
- Justify purpose, destination of each trip, no. of individuals traveling, length of trip
- Special consideration for foreign travel

E. Participant/Trainee Support Costs

- Usually not used for NIH applications
- Tuition for Graduate Research Assistants (GRA’s) is listed in “F. Other Direct Costs”


[https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.300-r&r-budget-form.htm](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.300-r&r-budget-form.htm)
### F. Other Direct Costs

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
<th>Funds Requested ($)</th>
</tr>
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<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>
<td></td>
<td></td>
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<td>9</td>
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<td>16</td>
<td></td>
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<tr>
<td>17</td>
<td></td>
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</tr>
</tbody>
</table>

**Total Other Direct Costs**
Budget - categories

F. Other Direct Costs

Material and Supplies

Glassware, chemicals and reagents, radioisotopes, tissue culture/molecular biology supplies (Categories ≥ $1,000)

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
- Data Management and Sharing Costs
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, monitoring board, 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)


https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/general/g.300-r&r-budget-form.htm
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.

1) Please attach Attachment 1
2) Please attach Attachment 2
3) Please attach Attachment 3
4) Please attach Attachment 4
5) Please attach Attachment 5
6) Please attach Attachment 6
7) Please attach Attachment 7
8) Please attach Attachment 8
9) Please attach Attachment 9
10) Please attach Attachment 10
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, costs per test/treatment, 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

Data Management and Sharing (DMS) Costs

- Single line item: Data Management and Sharing Costs
- e.g., Personnel costs for those curating data, Data storage
- Costs described in the Budget Justification
- Information available to peer reviewers
<table>
<thead>
<tr>
<th>G. Direct Costs</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Direct Costs (A thru F)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>H. Indirect Costs</th>
<th>Funds Requested ($)</th>
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</thead>
<tbody>
<tr>
<td>Indirect Cost Type</td>
<td>Indirect Cost Rate (%)</td>
</tr>
<tr>
<td>Cognizant Federal Agency</td>
<td>Total Indirect Costs</td>
</tr>
<tr>
<td>(Agency Name, POC Name, and POC Phone Number)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>I. Total Direct and Indirect Costs</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Direct and Indirect Institutional Costs (G + H)</td>
<td></td>
</tr>
</tbody>
</table>
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 institutions’ rates are 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

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Budget - Future Years

- In addition to NIH, other agencies may also require composite, not detailed, budgets for future years
- Sometimes categories may be increased 2%-3% per year
- Equipment is usually purchased early in the project
- Plan for unusual changes in future years (e.g., additional personnel, use of core facility, reduction in 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 A, Senior/Key Person</th>
<th></th>
</tr>
</thead>
<tbody>
<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>
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</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>
<tr>
<td>3. Travel</td>
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<tr>
<td>4. Subsistence</td>
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<tr>
<td>5. Other</td>
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<tr>
<td>6. Number of Participants/Trainees</td>
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</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>5. Subawards/Consortium/Contractual Costs</td>
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<tr>
<td>6. Equipment or Facility Rental/User Fees</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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<td>10. Other 3</td>
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<tr>
<td>Section G, Direct Costs (A thru F)</td>
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<tr>
<td>Section H, Indirect Costs</td>
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</tr>
<tr>
<td>Section I, Total Direct and Indirect Costs (G + H)</td>
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</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>

**Totals ($)**
Budget Justification

- Must be included
- Detailed information on personnel and their expertise and role in proposed project
- Budget calculations for other categorical items
- Separate budget justification for subcontract/consortium
- Discuss significant increases or decreases
- Discuss and explain budget categories that use more than the standard yearly increase (NIH may not fund standard yearly increases)
- Can include price quotes (e.g., for equipment)

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Components of the NIH R01 Grant Application

PHS 398 Modular Budget Form
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

Modular Budgets

- Applies to all new/competing R01, R03, and R21 proposals with up to $250,000 requested direct costs in every 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.

- Cannot be used for projects involving human fetal tissue obtained from elective abortions (HFT).

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 may 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’s 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>Direct Cost less Consortium Indirect (F&amp;A)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.00</td>
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</table>

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

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

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

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

### Total Indirect (F&A) Costs

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

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
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<tbody>
<tr>
<td>0.00</td>
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</table>
### 1. Total Costs, Entire Project Period

<table>
<thead>
<tr>
<th>Item</th>
<th>Amount</th>
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<tbody>
<tr>
<td>Section A, Total Direct Cost less Consortium Indirect (F&amp;A)</td>
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<tr>
<td>for Entire Project Period</td>
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</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>
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</tr>
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</table>

### 2. Budget Justifications

<table>
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<tr>
<th>Justification</th>
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</thead>
<tbody>
<tr>
<td>Personnel Justification</td>
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</tr>
<tr>
<td>Consortium Justification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Narrative Justification</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>
# PHS 398 Modular Budget

**Budget Period:** 1  
**Start Date:** 10/01/2014  
**End Date:** 09/30/2015

### A. Direct Costs

<table>
<thead>
<tr>
<th>Funds Requested ($)</th>
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<tbody>
<tr>
<td>Direct Cost less Consortium F&amp;A</td>
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<tr>
<td>Consortium F&amp;A</td>
</tr>
<tr>
<td>Total Direct Costs</td>
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</tbody>
</table>

### B. Indirect Costs

<table>
<thead>
<tr>
<th>Indirect Cost Type</th>
<th>Indirect Cost Rate (%)</th>
<th>Indirect Cost Base ($)</th>
<th>Funds Requested ($)</th>
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</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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</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
Modular Budgets: Budget Justification

- Information, in narrative form:
  - All Personnel
  - Subaward/Consortium arrangements
  - Additional Narrative
    - Data Management and Sharing (DMS) Plan
    - Significant budget items that result in a yearly change in the number of $25,000 modules
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 Narrative:** e.g., (i) Required if Data Management and Sharing (DMS) Plan is required in the application, (ii) Justification for any yearly variation in the number of modules requested, (iii) Price quotes

NIH Grant Forms and Instructions

- **How to Apply - Application Guide**

- **Annotated Application Forms**

- **Submitting an Application**
  https://grants.nih.gov/grants/forms/format-pages.htm

- **Page Limits**

- **Format Attachments (e.g., fonts, margins)**

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

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