Office of Sponsored Projects

Federal Updates/Reminders

ROUNDTABLE
MAY 25, 2016
CAMPUS
NIH Updates & Reminders

- FORMS D Checklist for Departments
- RAPPORT FORMS D Instructions
- Rigor & Transparency
  - Fellowship Application Requirements
  - Resources & Reminders
- Individual Mentored CDA – Mentor Credentials Required
- Revised NRSA Notice
- New NIH Application Guide
Thank you to Renee & Vanderbilt!

List for R01/R21 Applications

Not a Substitute for Reading FOA

References NIH General Guide

Lists RAPPORT SF424 Manual Entry

Includes Important Links
Look how pretty it is!
PHS 398 Research Plan Changes

- New Data Safety Monitoring Plan attachment
  - Applicable to Human Subjects Research

- New Authentication of Key Biological and/or Chemical Resources attachment
**PHS 398 Research Plan**

**Manual Upload in RAPPORT**

**Human Subjects Section**

- 5. Protection of Human Subjects
- 6. Data Safety Monitoring Plan
- 7. Inclusion of Women and Minorities
- 8. Inclusion of Children

**Other Research Plan Section**

- 9. Vertebrate Animals
- 10. Select Agent Research
- 11. Multiple PD/PI Leadership Plan
- 12. Consortium/Contractual Arrangements
- 13. Letters of Support
- 14. Resource Sharing Plan(s)
- 15. Authentication of Key Biological and/or Chemical Resources

**New Data Safety Monitoring Plan**

Applicable to Human Subjects Research

Upload in SF424 (not in RAPPORT FP)

**New Authentication document**

Upload in SF424 (not in RAPPORT FP)
New Assignment Request Form

- Optional Form
- Provides Information to NIH Referral Staff
  - Funding component assignment preference
  - Study section preference
  - Individuals who should not review application due to conflicts
  - Scientific areas of expertise for review
- Compliments existing Cover Letter
Assignment Request Form Form (optional)

- Located on First Page of SF424 in Optional Forms Section
- Check the box to add the Form to your SF424 Application
- Will NOT be overwritten when Create/Update SF424 is run

<table>
<thead>
<tr>
<th>Form Name</th>
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<tbody>
<tr>
<td>Research &amp; Related Budget V1.3</td>
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<tr>
<td>Research &amp; Related Subaward Budget Attachment(s) Form 5 YR 30 ATT V1.3</td>
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<td>PHS 398 Modular Budget V1.2</td>
</tr>
<tr>
<td><strong>PHS Assignment Request (V1.0)</strong></td>
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<tr>
<td>PHS 398 Inclusion Enrollment Report (V1.0)</td>
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Application Filing Name:
Test PL Keyword NIH

Following forms are required:

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<tr>
<td>Research &amp; Related Project/Performance Site Location(s) V2.0</td>
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<tr>
<td>PHS 398 Cover Page Supplement (V3.0)</td>
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<tr>
<td>Research &amp; Related Other Project Information V1.3</td>
</tr>
<tr>
<td>PHS 398 Research Plan (V3.0)</td>
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<tr>
<td>SF424 (R&amp;R) V2.0</td>
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New Vertebrate Animals section added

New questions:

- Are animals euthanized? Yes/No
  - If Yes, is method consistent with AVMA guidelines
    - Yes/No
  - If No to AVMA guidelines, describe method

Program Income for 10 budget periods
Vertebrate Animals Section

Data Entry in RAPPORT

1. Human Subjects Section
   Clinical Trial?
   ○ Yes ○ No
   Agency-Defined Phase III Clinical Trial?
   ○ Yes ○ No

2. Vertebrate Animals Section
   Are vertebrate animal 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

Applicable to projects with Vertebrate Animal research

All manual data entry in the SF424 on Page 1 of PHS 398 Cover Page Supplement

3. * Program Income
   * Is program income anticipated during the periods for which the grant support is requested?
   ○ Yes ○ No

If you checked "yes" above (indicating that program income is anticipated), then use the format below to reflect the amount and source(s). Otherwise, leave this section blank.
Program Income Over 5yrs
Data Entry in RAPPORT

Applicable to projects with Program Income

Manual Data Entry for budget periods over 5 years up to 10 maximum

FP Data Entry Does not have limit; but no mapping over 5 years

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<th>Budget Period</th>
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4. Human Embryonic Stem Cells Section

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

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/ stem cell line cannot be referenced at this time, please check the box indicating that one from the registry will be used:
PHS Inclusion Enrollment Report Changes

- Planned Enrollment Report & Cumulative Inclusion Enrollment Report into One Form
- Questions to identify report type:
  - Delayed onset study? Yes/No
  - Enrollment Type? Planned/Cumulative (Actual)
  - Using Existing Dataset or Resource? Yes/No
  - Enrollment Location? Domestic/Foreign
  - Clinical Trial? Yes/No
    - Phase II Clinical Trial? Yes/No
PHS 398 Inclusion Enrollment Report Form

- Applicable to Human Subjects Research
- Located on First Page of SF424 in Optional Forms Section
- Check the box to add the Form to your SF424 Application
- Will NOT be overwritten when Create/Update SF424 is run
### PHS Inclusion Enrollment Report

**Studies**

There are no items to display.

**Note:** Studies will be listed in the order they are added. The display order field can be used to adjust the ordering of items.

#### PHS Inclusion Enrollment Report

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

**Display Order:**

- **Study Title (must be unique):**

- **Delayed Onset Study?**
  - [ ] Yes
  - [x] No

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

- **Enrollment Type**

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

- **Participants Location**

- **Clinical Trial**
  - [ ] Yes
  - [ ] No

**Comments:**

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</tr>
</tbody>
</table>
Includes Data Safety Plan, Authentication document, and Vertebrate Animals questions

New Background & Goals, Letters of Support, Description of Environment

Updated Citizenship selections

Reorganization of attachments
PHS 398 Career Development Form Changes in Short

- Includes Data Safety Plan, Authentication document, and Vertebrate Animals questions
- New Candidate Information and Goals
- Updated Citizenship selections
- Reorganization of attachments
PHS 398 Research Training Form Changes in Short

- Includes New Data Safety Monitoring Plan
- Removed Background and Recruitment Plan to Enhance Diversity
- New Plan for Reproducibility
- Format changes including categorizing attachments
Policies, Instructions, & Form Changes


- Rigor and Transparency
- Vertebrate Animals
- Inclusion Forms
- Data Safety Monitoring Plans
- Research Training
- Appendix Policy
- New Assignment Request Form
- New Font Guidelines
- Biosketch Clarifications
NIH Rigor & Transparency Reminders

- Required for Fellowships effective May 25, 2016
- Not Applicable for Construction & Equipment Projects
- Applies to RPPR Submissions
Rigor and Reproducibility

Scientific rigor and transparency in conducting biomedical research is key to the successful application of knowledge toward improving health outcomes. The information provided on this website is designed to assist the extramural community in addressing rigor and transparency in NIH grant applications and progress reports.

On This Page:

- Goals
- Guidance: Rigor and Reproducibility in Grant Applications
- Resources
- News
- References

Organized in Five Sections
Guidance: Rigor and Reproducibility in Grant Applications

Research Grants and Mentored Career Development Awards

The updates to NIH research grant and career development award application instructions and review language focus on four key areas:

1. The scientific premise of the proposed research
   - The **scientific premise** for an application is the research that is used to form the basis for the proposed research question(s). NIH expects applicants to describe the identification of key resources.
   - See related FAQs, blog post

2. Rigorous experimental design for robust and unbiased results
   - **Scientific rigor** is the strict application of the scientific method to ensure robust and unbiased results. 
     - Thought may be a key element in design and the planning of experiments, analysis, interpretation, and reporting of data.
   - See related FAQs, blog post

3. Consideration of relevant biological variables
   - **Biological variables**, such as sex, age, weight, and underlying health conditions, are often critical factors affecting health or disease. In particular, sex is a biological consideration that must be provided for applications proposing to study only one sex.
   - See related FAQs, blog posts, Article

4. Authentication of key biological and/or chemical resources
   - **Key biological and/or chemical resources** include, but are not limited to, cell lines, specialty chemicals, antibodies and other biologics. Key biological and/or chemical resources may or may not be generated with NIH funds and:
     1. may differ from laboratory to laboratory or over time;
     2. may have qualities and/or qualifications that could influence the research data;
Resources

- Staff Training Module: General Policy Overview (compiled by NIH OER, 10/30/2015)
- Reviewer Guidance on Rigor and Transparency (compiled by NIH OER, 03/21/2016)
- Frequently Asked Questions
- Examples of Rigor in Applications

These brief excerpts are taken from awarded applications reviewed under a pilot FOA for rigorous experimental design, which is only one part of the

Frequently Asked Questions

Rigor and Transparency

Last Revised: February 1, 2016

On This Page:

I. General FAQs
II. Scientific Premise
III. Scientific Rigor
IV. Consideration of Relevant Biological Variables, Such as Sex
V. Authentication of Key Biological and/or Chemical Resources
Individual Mentored Career Development Awards Update


- eRA Commons Usernames Required for Primary Mentors
- Begins for Applications Submitted for the June 12, 2016 Deadline
- “Other” or “Other Professional” as Project Role and enter “Mentor” in Text Box
- Add eRA Commons Credentials in Person Profile and it will Map to SF424
NRSA Update


- Increase in Training Related Expenses & Institutional Allowance for Postdoctoral Trainees and Fellows
- No Change for Predoctoral Trainees and Fellows
- No Change in Tuition and Fees
New NIH Application Guide

- Completely Revised Format
- Organized by Application Type
  - General (G)
  - Research (R)
  - Career Development (K)
  - Training (T)
  - Fellowship (F)
  - Multi-Project (M)
  - SBIR/STTR (B)
# New NIH Application Guide

## Forms Version D

Instructions for due dates on or after May 25, 2016

<table>
<thead>
<tr>
<th>Application Instructions</th>
<th>Description</th>
<th>View/Download</th>
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<tbody>
<tr>
<td>General (G) Instructions</td>
<td>Comprehensive guidance for research, training, fellowship, career development, multi-project, and small business applications</td>
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**Filtered views for your convenience:**

<table>
<thead>
<tr>
<th>Instruction Type</th>
<th>Description</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research (R) Instructions</td>
<td>Guidance for research only</td>
<td>PDF</td>
</tr>
<tr>
<td>Career Development (K)</td>
<td>Guidance for career development only</td>
<td>PDF</td>
</tr>
<tr>
<td>Training (T) Instructions</td>
<td>Guidance for training only</td>
<td>PDF</td>
</tr>
<tr>
<td>Fellowship (F) Instructions</td>
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<td>Multi-Project (M)</td>
<td>Guidance for multi-project only</td>
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</tr>
<tr>
<td>SBIR/STTR (B) Instructions</td>
<td>Guidance for small business only</td>
<td>PDF</td>
</tr>
</tbody>
</table>
How to Apply - Application Guide

Use the application forms and guidance found with the funding opportunity announcement together with the instructions for the SF424 (R&R) and Public Health Service (PHS) forms below to submit grant applications to NIH and other PHS agencies, such as the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Agency for Healthcare Research and Quality.

Prepare to Apply and Register
- Understand Key Systems and Roles
- Get Registered!
- Find and Understand Funding Opportunities
- Identify the Type of Application Submission
- Choose a Submission Option
- Obtain Software

Format and Write
- Write Your Application
- Develop Your Budget
- Format Attachments
- Refer to Table of Page Limits
- Utilize Biosketch, Data Tables and Other Format Pages

Submission Process
- Submit, Track and View Your Application
- Learn How We Check Your Application for Completeness
- Submit a Changed/Corrected Application
- Submit a Reference Letter

Due Dates and Submission Policies
- Due Dates
- Submission Policies
- Guidelines for Applicants Experiencing System Issues
~The End~

Thank you for your time.

We will post the presentation slides on the OSP web site