Contacts Meeting - May 3, 2016

NIH Updates & Changes

w/ Rachel Cook & Ella Trubman
Agenda

- NIH Updates
  - Parent Announcements
  - Restructured & Streamlined Application Guides & Supplemental Instructions
  - NIH Website Overhaul

- NIH Changes
  - SF424 Forms D
  - PHS 398 & 2590 Forms
NIH Updates: Parent Announcements

• Research (R) & Research Training (T) Announcements

  • Parent T32 → PA-16-152 (4/25/2016)
  • Parent T35 → PA-16-151 (4/25/2016)
  • Parent R01 → PA-16-160 (5/5/2016)
  • Parent R21 → PA-16-161 (5/16/2016)
  • Parent R03 → PA-16-162 (5/16/2016)
  • Parent R15 → PA-16-200 (5/25/2016)

NIH Updates: Parent Announcements

- Career Development (K) Announcements
  - Parent K01 → PA-16-190 (5/12/2016)
  - Parent K08 → PA-16-191 (5/12/2016)
  - Parent K02 → PA-16-192 (5/12/2016)
  - Parent K99/R00 → PA-16-193 (5/12/2016)
  - Parent K23 → PA-16-198 (5/12/2016)
  - Parent K24 → PA-16-206 (5/12/2016)

Note: Fellowship (F) & Administrative Supplements Announcements have not been revised.
NIH Updates: Restructured & Streamlined Application Guides & Supplemental Instructions

Use for due date before 5/25/2016

Form C:
1 General,
1 SBIR/STTR, and
1 Fellowship Application Guides

Use for due dates on or after 5/25/2016

Form D:
1 SF424 Application Guide

Forms D Change & Late & Continuous Submissions

• If you are eligible for submission under the NIH late, continuous submission, and system issue policies, you will need to pay special attention to the cutover dates to the new forms.
  • Use the forms and instructions for the intended due date (not actual submission date). The intended due date is the date listed in the Application Due Date or AIDS Application Due Date row of the Key Dates table in the funding opportunity announcement (FOA).

Forms D Change & Late & Continuous Submissions

- Continuous submission policy applies only to R01s, R21s and R34s with Standard Submission Due Dates. FOAs that close early will be configured to allow submissions for 14 days after the close date to accommodate late, continuous submission and system issue policies.

- If your intended due date is the May 7, 2016, AIDS due date, you must complete your submission using a Forms C application package by 5/23/2016.
  - Note, this is an earlier cutoff date for continuous submission applications than is typical – plan accordingly!

- Be sure to use an FOA with a Forms D application package if submitting to an intended due date on or after 5/25/2016.

*Note: As Is Submissions could experience errors at time of submission if the wrong form package is used.*
NIH Updates: NIH Website Overhaul

https://grants.nih.gov/grants/oer.htm
NIH Updates: NIH Website Overhaul

• “How to Apply - Application Guide” serves as the new central resource for application information

• Choice of Interactive HTML or PDF version of the General Application for Adobe Forms D
  ✓ Customize your view with the filter option for the application instructions by mechanism type
  ✓ Time burden searching the site will be reduced due to filters and customizations

• Automatic redirects from old to new URLs to minimize impact of overhaul
NIH Updates: Restructured & Streamlined Application Guides & Supplemental Instructions

• General (G) Instruction Guide (HTML):
  • http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/general/g.200-sf-424-%28r&r%29-form.htm

• General (G) Instruction Guide (PDF):

• Filtered Views (PDF):
  • http://grants.nih.gov/grants/how-to-apply-application-guide.htm

• Supplemental Instructions (PDF)
How to Select the Correct Application Instructions

- NIH has created a chart to assist with selecting the correct Application Guide:
NIH Changes: SF 424 Changes
NIH Changes: SF 424

- ASSIST
- Adobe Forms D

✓ Application guides are now applicable to not just NIH, but also all PHS agencies

✓ Forms have been reordered to match the order of appearance in the application package of the PHS agency
NIH Changes: SF 424 Changes

• Rigor & Transparency (NOT-OD-16-011/012)
  • Must use the new "Authentication of Key Biological and/or Chemical Resources" attachment to briefly describe methods used to ensure the identity and validity of key biological and/or chemical resources

• Vertebrate Animals (NOT-OD-16-006)
  • Must answer new euthanasia questions on the PHS 398 Cover Page Supplement and PHS Fellowship Supplemental forms when vertebrate animals are involved, instead of addressing the method of euthanasia in the Vertebrate Animals attachment.

• Inclusion
  • Must provide inclusion data on a new, consolidated PHS Inclusion Enrollment Report form
NIH Changes: SF 424 Changes

- Data Safety Monitoring Plans
  - Must provide a new "Data Safety Monitoring Plan" attachment when their project includes a clinical trial.

- Research Training (NOT-OD-16-007)

- PHS Awarding Component & Peer Review Requests (NOT-OD-16-008)
  - Must use a new PHS Assignment Request Form to communicate requests pertinent to the assignment and initial peer review of applications.

- New Font Guidelines (NOT-OD-16-009)
- Biosketch Clarifications (NOT-OS-16-080)
- *Appendix policy changes on hold*
New Font Guidelines (NOT-OD-16-009)

Text in PDF attachments must follow these minimum requirements:

• **Font size:** must be 11 points or larger (smaller text in figures, graphs, diagrams and charts is acceptable as long as it is legible when the page is viewed at 100%); **Type density:** must be no more than 15 characters per linear inch (including characters and spaces); **Line spacing:** must be no more than six lines per vertical inch; and **Text Color:** must be black (color text in figures, graphs, diagrams, charts, tables, footnotes and headings is acceptable as long as it is legible).

• Since some PDF converters may reduce font size, it is important to confirm that the final PDF document complies with the font requirements.

• The following fonts are recommended, although other fonts are acceptable if they meet the above requirements.

  Arial  Helvetica  **Verdana**
  Garamond  Palatino Linotype
  Georgia  **Times New Roman**

UC San Diego
Health Sciences
What is the 15 CPI type density requirement?

<table>
<thead>
<tr>
<th>Font</th>
<th>Compliant</th>
<th>Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arial*</td>
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<td>The quick brown fox jumps over the lazy dog.</td>
</tr>
<tr>
<td>Arial Narrow</td>
<td>✓</td>
<td>The quick brown fox jumps over the lazy dog. (Arial Narrow)</td>
</tr>
<tr>
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</tr>
<tr>
<td>Cambria</td>
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</tr>
<tr>
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<td>✗</td>
<td>The quick brown fox jumps over the lazy dog. (Cordia New)</td>
</tr>
<tr>
<td>Courier New</td>
<td>✓</td>
<td>The quick brown fox jumps over the lazy dog.</td>
</tr>
<tr>
<td>Franklin Gothic Book</td>
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<td>Garamond*</td>
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<td>The quick brown fox jumps over the lazy dog.</td>
</tr>
<tr>
<td>Georgia*</td>
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<td>The quick brown fox jumps over the lazy dog.</td>
</tr>
<tr>
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</tr>
<tr>
<td>Tahoma</td>
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</tr>
<tr>
<td>Times New Roman*</td>
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<tr>
<td>Tunga</td>
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<td>The quick brown fox jumps over the lazy dog.</td>
</tr>
<tr>
<td>Utsaah</td>
<td>✗</td>
<td>The quick brown fox jumps over the lazy dog.</td>
</tr>
<tr>
<td>Verdana*</td>
<td>✓</td>
<td>The quick brown fox jumps over the lazy dog. (Verdana)</td>
</tr>
</tbody>
</table>

* Recommended font.
What is the line spacing requirement?

- In most cases, fonts that meet the “no more than 15 characters per linear inch” requirement will also meet the line spacing requirement when “Line Spacing” is set to “Single”. When in doubt, print off a sample and use a ruler to verify you do not have more than 6 lines within an inch.
- Compliant example: Arial 11 pt font single-spaced

![Example Text](image)
NIH Changes:
SF424 Research and Related (R&R) Form Changes

• **R&R Other Project Information Form**
  - A list of referees is no longer required as an Other Attachment on the R&R Other Project Information Form. This information is only required in the cover letter attachment. Reference letters will continue to be submitted through eRA Commons.

• **R&R Senior/Key Person Profile (Expanded) Form**
NIH Changes: Biosketch Clarification

• Clarified instructions:
  • Indicate that a URL for a publication list is optional and, if provided, must be to a government website (.gov) like My Bibliography.
  • Allow publications (peer-reviewed and non-peer-reviewed) and research products to be cited in both the personal statement (up to four) and the contributions to science (up to five contributions) sections (up to four publications for each contribution)
  • Graphics, figures and tables are not allowed.
  • Removed the requirement that the past 3 years of research support are listed in order of relevance.
  • Option to add other names used to author research products in section A.
  • Research products can include conference proceedings such as meeting abstracts, posters, or other presentations.
  • Research products that are under development, such as manuscripts that have not yet been accepted for publication, can be mentioned in the narrative sections. However, they cannot be cited as one of their citations.

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


B. Positions and Honors

Positions and Employment
1988-2000 Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, MD
2000-2002 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2001- Consultant, Coastal Psychological Services, San Francisco, CA
2003-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2007- Associate Professor, Department of Psychology, Washington University, St. Louis, MO

Other Experience and Professional Memberships
1965- Member, American Psychological Association
1968- Member, Gerontological Society of America
1968- Member, American Geriatrics Society
2003- Board of Advisors, Senior Services of Eastern Missouri
2003-05 NIH Peer Review Committee: Psychology of Aging, ad hoc reviewer
2007-11 NIH Risk, Adult Addictions Study Section, members

Honors
2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO
2004 Excellence in Teaching, Washington University, St. Louis, MO
2009 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

C. Contribution to Science
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 various care settings or seek mental health providers to deal with emerging addiction problems. These publications documented this emerging problem not only 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 continues 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.


2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older substance abusers and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of addictive disorders and the disruptive potential of networks in substance abuse treatment. This body of work also discusses the prevalence of alcohol, amphetamine, and opioid abuse in older adults and how networking approaches can be used to mitigate the effects of these disorders.


3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.


Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PqT7jEFIAjYbtGMRdWFmJiWAO?sort=date&direction=descending

D. Research Support

Ongoing Research Support
R01 DA042537 Hunt (PI) 09/01/08-08/30/16
Health trajectories and behavioral interventions among older substance abusers
The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.
Role: PI

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

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

Completed Research Support
R21 AA989075 Hunt (PI) 01/01/11-12/31/13
Community-based intervention for alcohol abuse
The goal of this project was to assess a community-based strategy for reducing alcohol abuse among older individuals.
Role: PI

Biosketch Form Grants:
http://grants.nih.gov/grants/forms/biosketch-blankformat-Forms-D.docx

Biosketch Form for Fellowship Applicants:
http://grants.nih.gov/grants/forms/biosketch-blankformat-Forms-D.docx

- Samples:
  - Pre Doc:
    http://grants.nih.gov/grants/forms/predocfellowshipbiosample-Forms-D.docx
  - Post Doc:
    http://grants.nih.gov/grants/forms/predocfellowshipbiosample-Forms-D.docx

UC San Diego
Health Sciences
NIH Changes: Forms-D Change

PHS 398 Career Development Award Supplemental Form

• New "Candidate Information and Goals for Career Development" attachment
  • Combines "Candidate's Background", "Career Goals and Objectives", and "Candidate's Plan for Career Development/Training Activities during Award Period" attachments into a single attachment

• New "Data Safety Monitoring Plan" attachment

• New "Authentication of Key Biological and/or Chemical Resources" attachment

• Updated Citizenship selections

• Reorganization of attachments

• Field order and label changes

• Added/updated burden statement and form expiration date

• Updated form instructions
NIH Changes: Forms-D Change

PHS 398 Cover Page Supplement

• New Vertebrate Animals section added:
  • Are animals euthanized? Yes/No
  • If Yes, is method consistent with AVMA guidelines? Yes/No
  • If No to AVMA guidelines, describe method/provide scientific justification

• "Disclosure Permission Statement" question removed

• Ability to add Program Income information for 10 budget periods (previously 5)

• Field order and label changes

• Added/updated burden statement and form expiration date

• Updated form instructions
NIH Changes: Forms-D Change

PHS 398 Modular Budget

- Indirect (F&A) Costs section changed to dynamically add indirect costs rather than providing static fields for four entries
- Minor label changes
- Added/updated burden statement and form expiration date
- Updated form instructions
NIH Changes: Forms-D Change

PHS 398 Research Plan

- New "Data Safety Monitoring Plan" attachment
- New "Authentication of Key Biological and/or Chemical Resources" attachment
- Minor format and label changes
- Added/updated burden statement and form expiration date
- Updated form instructions
NIH Changes: Forms-D Change

PHS 398 Research Training Program Plan

• Removed "Background' and "Recruitment Plan to Enhance Diversity" attachments (information previously included in these attachments moved to existing "Program Plan" attachment)

• New "Plan for the Instruction in Methods for Enhancing Reproducibility" attachment

• New Data Safety Monitoring Plan attachment

• Format and label changes, including categorizing attachments into sections

• Added/updated burden statement and form expiration date

• Updated form instructions
NIH Changes: Forms-D Change

PHS 398 Training Budget
- Minor label changes
- Added/updated burden statement and form expiration date
- Updated form instructions

PHS 398 Training Subaward Budget Attachment(s) Form
- Streamlined instruction text
- Added/updated burden statement and form expiration date
- Updated form instructions
NIH Changes: Forms-D Change

PHS Assignment Request Form

• New, optional form
• Provides structured information to NIH referral staff regarding: funding component assignment preference, study section preference, individuals who should not review your application due to conflicts, and scientific areas of expertise needed to review your application
• Complements existing "Cover Letter Attachment" on SF424 (R&R) form
• Added/updated burden statement and form expiration date
• Updated form instructions
NIH Changes: Forms-D Change

PHS Fellowship Supplemental Form

- New "Applicant's Background and Goals for Fellowship Training" attachment
  - Combines "Doctoral Dissertation and Other Research Experience", "Goals for Training and Career", and "Activities Planned Under Award" attachments into a single attachment
- New "Letters of Support from Collaborators, Contributors, and Consultants" attachment
- New "Description of Institutional Environment and Commitment to Training" attachment
- New "Data Safety Monitoring Plan" attachment
- New "Authentication of Key Biological and/or Chemical Resources" attachment
NIH Changes: Forms-D Change

PHS Fellowship Supplemental Form (continued)

• New Vertebrate Animals questions added:
  • Are animals euthanized? Yes/No
  • If Yes, is method consistent with AVMA guidelines? Yes/No
  • If No to AVMA guidelines, describe method/provide scientific justification
• Updated list of values for the "Field of Training for Current Proposal" field; changed from 4-digit codes to 3-digit codes
• Updated Citizenship selections
• Reorganization of attachments
• Format and label changes
• Added/updated burden statement and form expiration date
• Updated form instructions
NIH Changes: Forms-D Change

PHS Inclusion Enrollment Report

• Combines Planned Enrollment Report & Cumulative Inclusion Enrollment Report forms into a single form
  • Questions used to identify type of report:
    • Delayed onset study? Yes/No
    • Enrollment Type? Planned/Cumulative (Actual)
    • Using an Existing Dataset or Resource? Yes/No
    • Enrollment Location? Domestic/Foreign
    • Clinical Trial? Yes/No
      • NIH-Defined Phase II Clinical Trial? Yes/No
  • Added/updated burden statement and form expiration date
  • Updated form instructions
Forms D Change

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

**Optional**
- [x] Research & Related Budget
- [x] R & R Subaward Budget Attachment(s) Form 5 YR 30 ATT
- [x] PHS 398 Modular Budget
- [x] PHS 398 Inclusion Enrollment Report
- [x] PHS Assignment Request Form

Combined Planned Enrollment Report & Cumulative Inclusion Enrollment Report forms into a single form.
# PHS 398 Research Plan

## Introduction
1. Introduction to Application (Resubmission and Revision)

## Research Plan Section
2. Specific Aims
3. *Research Strategy
4. Progress Report Publication List

## 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**

## Appendix
16. Appendix

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**Forms D**

**NEW!**

**NEW!**

**NEW!**

**PHS 398 Research Plan → Change**
PHS 398 Career Development Award Supplemental Form

<table>
<thead>
<tr>
<th>Form Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction</td>
<td>1. Introduction to Application (RESUBMISSION)</td>
</tr>
<tr>
<td>Candidate Section</td>
<td>2. Candidate Information and Goals for Career Development</td>
</tr>
<tr>
<td>Research Plan Section</td>
<td>3. Specific Aims</td>
</tr>
<tr>
<td></td>
<td>4. * Research Strategy</td>
</tr>
<tr>
<td></td>
<td>5. Progress Report Publication List (for RENEWAL applications only)</td>
</tr>
<tr>
<td></td>
<td>6. Training in the Responsible Conduct of Research</td>
</tr>
<tr>
<td>Other Candidate Information Section</td>
<td>7. Candidate's Plan to Provide Mentoring</td>
</tr>
<tr>
<td>Mentor, Co-Mentor, Consultant, Collaborators Section</td>
<td>8. Plans and Statements of Mentor and Co-Mentor(s)</td>
</tr>
<tr>
<td></td>
<td>9. Letters of Support from Collaborators, Contributors, and Consultants</td>
</tr>
<tr>
<td>Environment and Institutional Commitment to Candidate Section</td>
<td>10. Description of Institutional Environment</td>
</tr>
<tr>
<td></td>
<td>11. Institutional Commitment to Candidate's Research Career Development</td>
</tr>
<tr>
<td>Human Subject Sections</td>
<td>12. Protection of Human Subjects</td>
</tr>
<tr>
<td></td>
<td>13. Data Safety Monitoring Plan</td>
</tr>
<tr>
<td></td>
<td>14. Inclusion of Women and Minorities</td>
</tr>
<tr>
<td></td>
<td>15. Inclusion of Children</td>
</tr>
</tbody>
</table>
NEW!

PHS 398 CDA Supplemental Form →

* Citizenship

* U.S. Citizen or Non-Citizen National?
  - [ ] Yes
  - [ ] No

If no, select most appropriate Non-U.S. Citizen option
  - [ ] With a Permanent U.S. Resident Visa
  - [ ] With a Temporary U.S. Visa
  - [ ] Not Residing in the U.S.

If with a temporary U.S. visa who has applied for permanent resident status and expect to hold a permanent resident visa by the earliest possible start date of the award, also check here: [ ]
# PHS Fellowship Supplemental Form

**Form D**

## Fellowship Applicant Section
1. Introduction (for Resubmission)
2. Applicant's Background and Goals for Fellowship Training

## Research Training Plan Section
3. Specific Aims
4. Research Strategy
5. Respective Contributions
6. Selection of Sponsor and Institution
7. Progress Report Publication List (for RENEWAL applications only)
8. Training in the Responsible Conduct of Research

## Sponsor(s), Collaborator(s), and Consultant(s) Section
9. Sponsor and Co-Sponsor Statements
10. Letters of Support from Collaborators, Contributors, and Consultants

## Institutional Environment and Commitment to Training Section
11. Description of Institutional Environment and Commitment to Training
### Other Research Training Plan Section

**Human Subjects**

The following item is taken from the Research & Related Other Project Information form and repeated here for your reference. Any change to this item must be made on the Research & Related Other Project Information form.

<table>
<thead>
<tr>
<th>Human Subjects Involved Indefinitely?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trial?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Agency-Defined Phase III Clinical Trial?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

**Protection of Human Subjects**

16. Data Safety Monitoring Plan

**Vertebrate Animals**

The following item is taken from the Research & Related Other Project Information form and repeated here for your reference. Any change to this item must be made on the Research & Related Other Project Information form.

<table>
<thead>
<tr>
<th>Vertebrate Animals Used?</th>
<th>Yes</th>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>Indefinitely?</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

20. Are animals euthanized?  
   - 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 a scientific justification

24. Authentication of Key Biological and/or Chemical Resources

### PHS Fellowship Supplemental Form

- **NEW!**
- Change
PHS 398 Modular Budget

### A. Direct Costs
- Direct Cost less Consortium Indirect (F&A): 0.00
- Consortium Indirect (F&A):
- Total Direct Costs: 0.00

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

<table>
<thead>
<tr>
<th>Indirect (F&amp;A) Type</th>
<th>Indirect (F&amp;A) Rate (%)</th>
<th>Indirect (F&amp;A) Base ($)</th>
<th>Funds Requested ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
</tr>
</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)
- Funds Requested ($) 0.00

### Cumulative Budget Information

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

2. Budget Justifications
   - Personnel Justification
   - Consortium Justification
   - Additional Narrative Justification
Forms D

**PHS Inclusion Enrollment Report → Change**

- **Delayed Onset Study?**
  - Yes
  - No

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

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

- **Enrollment Location**
  - Domestic
  - Foreign

- **Clinical Trial**
  - Yes
  - No

- **NIH-Defined Phase III Clinical Trial**
  - Yes
  - No

**Ethnic Categories**

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

**Total**

0 0 0 0 0 0 0 0 0

Report 1 of 1

To ensure proper performance, please save frequently.
PHS Assignment Request Form → NEW
Forms D - PHS Assignment Request Form

- Awarding Component Assignment Request
  - Use the Short Abbreviation for the IC/C (i.e., NCI, NIMH)
  - Can state where NOT to be assigned as well

- Study Section Assignment Request
  - [https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents](https://grants.nih.gov/grants/phs_assignment_information.htm#AwardingComponents)
  - 20 Character Limit per text box

- List of Individuals Who Should NOT Review Your Application
  - 1,000 Character Limit for the text box

- Identify Scientific Areas Needed to Review Your Applications
  - 40 Character Limit per text box
Forms D – SF424 (R&R) Forms – § 21 Cover Letter

• Address to the Division of Receipt and Referral
• Include the following items
  • Application Title
  • FOA # and Title
  • Specific information about the timing and nature of the cause of the delay for Late Applications
  • Explanation of any subaward budget components that are not active for all periods of the proposed grant
  • For applications over $500,000/year DC, include a statement you have attached required agency approval documentation; it is recommended you include the official communication from an NIH Official as well in the Cover Letter
• Other items formerly listed in the Cover Letter only can now be included in both the PHS Assignment Request Form & the Cover Letter
PHS 398 & 2590 Form Pages

• Use the Revised 3/2016 Form Pages; approved till 10/31/2018
  • Health Sciences Pre-populated Face Pages: [link]
  • [http://healthsciences.ucsd.edu/vchs/research-services/hssppo/resources/Pages/Templates--Boilerplates.aspx](http://healthsciences.ucsd.edu/vchs/research-services/hssppo/resources/Pages/Templates--Boilerplates.aspx)

• Major Form Changes:
  • Combined Planned Enrollment Report and Cumulative Inclusion Enrollment Report forms into a single form
# PHS Inclusion Enrollment Report

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

## Study Title
(must be unique):

## Delayed Onset Study?
- Yes
- No

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

<table>
<thead>
<tr>
<th>Enrollment Type</th>
<th>Planned</th>
<th>Cumulative (Actual)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using an Existing Dataset or Resource</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Enrollment Location</td>
<td>Domestic</td>
<td>Foreign</td>
</tr>
<tr>
<td>Clinical Trial</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

| NIH-Defined Phase III Clinical Trial | Yes | No |

## Comments:

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### Ethnic Categories

#### Racial Categories

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<th>Male</th>
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- American Indian/Alaska Native
- Asian
- Native Hawaiian or Other Pacific Islander
- Black or African American
- White
- More than One Race
- Unknown or Not Reported

### Total

0 0 0 0 0 0 0

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