BROWN BAG LUNCHEON

Pre-Award Planning

NIH proposal submission changes
Office of Sponsored Programs foreign travel approval
Intent to submit proposal notification to HHD Research Office
Proposal Internal Approval Form (PIAF) signatures
Questions

Wednesday, January 13, 2010
110 Henderson Building (The Bennett-Pierce Living Center)
12 noon to 1:00 p.m.

Presented by
Boe Itinger, Director, Grants and Contracts
The College of Health and Human Development

For planning purposes, please reply to Amy Mitchell (alb1@psu.edu) and let her know of your plans to attend.

For more information, please contact:
Amy L. Mitchell
The College of Health and Human Development
The Pennsylvania State University
201 Henderson Building
University Park PA 16802
Phone: (814) 863-7519
Email: alb1@psu.edu
Parent Announcements (For Unsolicited or Investigator-Initiated Applications)

NIH and other agencies serviced by eRA Commons want your investigator-initiated applications. Electronic grant applications must be submitted in response to a Funding Opportunity Announcement (FOA)*. We have developed Parent announcements for use by applicants who wish to submit what were formerly termed investigator-initiated or ‘unsolicited’ applications. Apply using the electronic application package for your chosen mechanism, listed in the table below. Read More About Parent Announcements. Not all Institutes and Centers participate in all FOAs. Please read announcements carefully to determine participation.

The following Parent Announcements are available (sorted by Activity Code):

**Alert:** NIH is in the process of reissuing all parent announcements. If you intend to apply for a due date of January 25 or beyond, please be sure to use the parent announcement that has a release date of December 2009 or beyond, as marked with a red asterisk. If you don’t see a new announcement for the type of grant application you’re considering – check back, it may be posted soon. See Notice NOT-OD-10-031 for more information.

### Research (R) Announcements

<table>
<thead>
<tr>
<th>Activity Code(s)</th>
<th>Title</th>
<th>Announcement Number</th>
<th>Issuing Organization</th>
<th>Release Date</th>
<th>Opening Date (SF424 Only)</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>R01</strong> *</td>
<td>Research Project Grant (Parent R01)</td>
<td>PA-10-067</td>
<td>NIH</td>
<td>12/17/2009</td>
<td>01/05/2010</td>
<td>01/08/2013</td>
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<tr>
<td><strong>R03</strong> *</td>
<td>NIH Small Research Grant Program (Parent R03)</td>
<td>PA-10-064</td>
<td>NIH</td>
<td>12/17/2009</td>
<td>01/16/2010</td>
<td>01/08/2013</td>
</tr>
<tr>
<td><strong>R13,U13</strong> *</td>
<td>NIH Support for Conferences and Scientific Meetings (Parent R13/U13)</td>
<td>PA-10-071</td>
<td>NIH</td>
<td>01/04/2010</td>
<td>03/12/2010</td>
<td>01/08/2013</td>
</tr>
<tr>
<td><strong>R15</strong> *</td>
<td>Academic Research Enhancement Award (Parent R15)</td>
<td>PA-10-070</td>
<td>NIH</td>
<td>12/24/2009</td>
<td>01/25/2010</td>
<td>01/08/2013</td>
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<tr>
<td><strong>R21</strong> *</td>
<td>NIH Exploratory Developmental Research Grant Program (Parent R21)</td>
<td>PA-10-069</td>
<td>NIH</td>
<td>12/24/2009</td>
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### Research Training (T) Announcements

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<th>Issuing Organization</th>
<th>Release Date</th>
<th>Opening Date (SF424 Only)</th>
<th>Expiration Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>T32</strong> *</td>
<td>Ruth L. Kirschstein National Research</td>
<td>PA-10-036</td>
<td>NIH</td>
<td>11/25/2009</td>
<td>01/05/2010</td>
<td>01/08/2013</td>
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<tr>
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<td>Issuing Organization</td>
<td>Release Date</td>
<td>Opening Date (SF424 Only)</td>
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<tr>
<td><strong>T35</strong></td>
<td>Ruth L. Kirschstein National Research Service Award Short-Term Institutional Research Training Grants (T35)</td>
<td>T35</td>
<td>NIH</td>
<td>11/25/2009</td>
<td>01/05/2010</td>
<td>01/08/2013</td>
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<td><strong>K01</strong></td>
<td>Mentored Research Scientist Development Award (Parent K01)</td>
<td>PA-10-056</td>
<td>NIH</td>
<td>12/16/2009</td>
<td>01/12/2010</td>
<td>05/08/2012</td>
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<tr>
<td><strong>K02</strong></td>
<td>Independent Scientist Award (Parent K02)</td>
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<td>12/16/2009</td>
<td>01/12/2010</td>
<td>01/08/2013</td>
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<tr>
<td><strong>K07</strong></td>
<td>Academic Career Award (Parent K07)</td>
<td>PA-10-058</td>
<td>NIH</td>
<td>12/16/2009</td>
<td>01/12/2010</td>
<td>01/08/2013</td>
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<tr>
<td><strong>K08</strong></td>
<td>Mentored Clinical Scientist Research Career Development Award (Parent K08)</td>
<td>PA-10-059</td>
<td>NIH</td>
<td>12/16/2009</td>
<td>01/12/2010</td>
<td>01/08/2013</td>
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<tr>
<td><strong>K23</strong></td>
<td>Mentored Patient-Oriented Research Career Development Award (Parent K23)</td>
<td>PA-10-060</td>
<td>NIH</td>
<td>12/17/2009</td>
<td>01/12/2010</td>
<td>01/08/2013</td>
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<tr>
<td><strong>K24</strong></td>
<td>Midcareer Investigator Award in Patient-Oriented Research (Parent K24)</td>
<td>PA-10-061</td>
<td>NIH</td>
<td>12/16/2009</td>
<td>01/12/2010</td>
<td>01/08/2013</td>
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<tr>
<td><strong>K25</strong></td>
<td>Mentored Quantitative Research Development Award (Parent K25)</td>
<td>PA-10-062</td>
<td>NIH</td>
<td>12/17/2009</td>
<td>01/12/2010</td>
<td>01/08/2012</td>
</tr>
</tbody>
</table>
Fellowship (F) Announcements

Additional Tips for Identifying Opportunities

- Applicants may also want to search RePORTER to find out if projects in their area have been funded by NIH and what NIH Institutes and Centers have shown an interest in their area in the past. This may help narrow their search for a suitable opportunity. RePORTER is part of the Research Portfolio Online Reporting Tool (RePORT), which provides access to reports, data, and analyses of NIH research activities, including information on NIH expenditures and the results of NIH-supported research.

- Don’t be afraid to contact staff at NIH Institutes/Centers (PDF - 4.5 MB) to discuss your application.

Helpful Links

- For information on grants and grants policy: http://grants.nih.gov/grants/oer.htm

- For information on types of grant programs and NIH ActivityCodes: http://grants.nih.gov/grants/funding/funding_program.htm

More about Parent Announcements

An important procedural change with electronic submission of grant applications is that all applications must be submitted in response to a Funding Opportunity Announcement (FOA)*. NIH and other HHS Agencies have developed omnibus Parent announcements for use by applicants who wish to submit what were formerly

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termed “unsolicited” applications. Responding to such an omnibus or umbrella Parent FOA ensures that the correct application package is used and enables NIH to receive the application from Grants.gov. This process in no way diminishes the interest of NIH Institutes and Centers in investigator-initiated, unsolicited research grant applications. Parent announcements are NIH-wide, but some NIH institutes may limit their participation, so check the announcement’s statement of interest. For institute-specific opportunities in your area of science, search the NIH Guide for Grants and Contracts.

While Parent announcements mark a big change in the way R01s have traditionally been received at NIH and other HHS agencies, Parent announcements are not new to NIH. NIH has required a Parent announcement for small research grants (R03) and exploratory/developmental grants (R21) for many years. Parent announcements are now also used for conference grants (R13), AREA grants (R15), SBIR grants (R43, R44), STTR grants (R41, R42), Career Development awards (K01, K08, K23, K24, K25 and K99/R00) and Individual Fellowships (F31, F32 and F33), and will be issued for and Institutional Research Training Grants (T32 and T35) in the future. Most NIH Institutes and Centers (ICs) participate in these Parent announcements. Parent announcements are not generally available for other highly specialized grant mechanisms (e.g. resource programs, construction grants, or education projects) and thus individual ICs will be issuing specific FOAs.

**Note:** FOA is Grants.gov’s terminology for what NIH refers to as Program Announcement (PA), Request for Application (RFA), Program Announcement with special receipt, referral and/or review consideration (PAR) and Program Announcement with a set aside (PAS).
Reissuing Parent Announcements

Reissued Parent Funding Opportunity Announcements with new Enhancing Peer Review language and links to the new, restructured application forms are available according to the following schedule.

All other NIH funding opportunity announcements are in the process of being revised to reflect the enhancing peer review language. These announcements will be available 1-2 months before the application due date. If you do not see an updated version of the funding opportunity announcement, please check back soon.

<table>
<thead>
<tr>
<th>Parent</th>
<th>Announcement Number (Reissued)</th>
<th>Release Date of New Announcement</th>
<th>Announcement Number (Former)</th>
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<td>T32</td>
<td>PA-10-036</td>
<td>November 25, 2009</td>
<td>PA-08-226</td>
</tr>
<tr>
<td>T35</td>
<td>PA-10-037</td>
<td>November 25, 2009</td>
<td>PA-08-227</td>
</tr>
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<td>R01</td>
<td>PA-10-067</td>
<td>December 17, 2009</td>
<td>PA-07-070</td>
</tr>
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<td>R03</td>
<td>PA-10-064</td>
<td>December 17, 2009</td>
<td>PA-09-163</td>
</tr>
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<td>R13/U13</td>
<td>PA-10-071</td>
<td>Mid December 2009</td>
<td>PA-08-149</td>
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<td>R15</td>
<td>PA-10-070</td>
<td>December 24, 2009</td>
<td>PA-06-042</td>
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<td>R21</td>
<td>PA-10-069</td>
<td>December 24, 2009</td>
<td>PA-09-164</td>
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<td>K01</td>
<td>PA-10-056</td>
<td>December 16, 2009</td>
<td>PA-09-040</td>
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<td>K02</td>
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<td>December 16, 2009</td>
<td>PA-09-038</td>
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<td>K07</td>
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<td>December 16, 2009</td>
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<td>PA-10-062</td>
<td>December 17, 2009</td>
<td>PA-09-039</td>
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<td>K99/R00</td>
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<td>PA-09-036</td>
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<td>F30</td>
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<td>January 2010</td>
<td>PA-09-207</td>
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<td>Diversity F31</td>
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<td>January 2010</td>
<td>PA-09-209</td>
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<td>January 2010</td>
<td>PA-09-208</td>
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<td>F32</td>
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<td>January 2010</td>
<td>PA-09-210</td>
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<td>F33</td>
<td></td>
<td>January 2010</td>
<td>PA-09-211</td>
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<tr>
<td>R41, R42 (STTR Omnibus)</td>
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<td>January 2010</td>
<td>PA-09-081</td>
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<tr>
<td>R43, R44 (SBIR Omnibus)</td>
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<td>January 2010</td>
<td>PA-09-080</td>
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<tr>
<td>Section of Application</td>
<td>Activity Codes</td>
<td>Page Limits</td>
<td></td>
</tr>
<tr>
<td>----------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>-------------</td>
<td></td>
</tr>
<tr>
<td>Introduction to Revision Application</td>
<td>For all Activity Codes</td>
<td>1 page</td>
<td></td>
</tr>
<tr>
<td>Introduction to Resubmission Application</td>
<td>For all Activity Codes, EXCEPT Training T, D43, D71, K12, and R25 applications</td>
<td>1 page</td>
<td></td>
</tr>
<tr>
<td>Introduction to Resubmission Applications</td>
<td>For institutional Training (T), International Training (D43, D71), Institutional Career Awards (K12), and Research Education Applications (R25)</td>
<td>3 pages</td>
<td></td>
</tr>
<tr>
<td>Specific Aims</td>
<td>For all Activity Codes that use an application form with the Specific Aims section</td>
<td>1 page</td>
<td></td>
</tr>
<tr>
<td>Research Strategy</td>
<td>For Activity Codes R03, R13/U13, R21, R36, R41, R43, Fellowships (F), SC2, SC3, X01</td>
<td>6 pages</td>
<td></td>
</tr>
<tr>
<td>Research Education Program Plan</td>
<td>For Activity Codes R01, single project U01, R10, R15, R18, U18, R21/R33, R24, R33, R34, U34, R42, R44, DP3, G08, G11, G13, UH2, UH3, SC1, X01</td>
<td>12 pages</td>
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<tr>
<td>Research Education Program Plan (uploaded via the Research Strategy)</td>
<td>For Research Education Grant Applications (R25)</td>
<td>25 pages</td>
<td></td>
</tr>
<tr>
<td>Combined: First four items of Candidate Information (Candidate’s Background, Career Goals and Objectives, Career Development/Training Activities During Award Period, and Training in the Responsible Conduct of Research) and Research Strategy</td>
<td>For Individual Career Development Award (K) Applications</td>
<td>12 pages</td>
<td></td>
</tr>
</tbody>
</table>
**FOA instructions always supersede these instructions.**

Each project or core will follow the page limit of the equivalent activity code. For example, if a project is equivalent to an R01, the project will be allowed 12 pages. Review the FOA and IC website for details.

<table>
<thead>
<tr>
<th>Combined: Items 2-5 of Research Training Program Plan</th>
<th>For Institutional Career Development and Research Training Applications, including K12, T, D43, and D71</th>
<th>25 pages</th>
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<tbody>
<tr>
<td>Commercialization Plan</td>
<td>For R42 and R44</td>
<td>12 pages</td>
</tr>
<tr>
<td>Biographical Sketch</td>
<td>For all Activity Codes except DP1 and DP2</td>
<td>4 pages</td>
</tr>
<tr>
<td></td>
<td>For DP1 and DP2</td>
<td>2 pages</td>
</tr>
</tbody>
</table>
1. **Foreword**

Adobe B Application Guide — Released November 13, 2009

This application includes changes to SF424 Research & Related (R&R) form instructions necessitated by the June, 2008 OMB renewal of the forms, which includes changes to assist agencies implementing the Federal Funding Accountability and Transparency Act. Changes have also been made to various PHS398 forms as part of the NIH initiative to enhance peer review. Changes to the PHS398 forms were approved by OMB in June, 2009.

Modifications related to changes in the SF424 (R&R) forms include:

- A new Agency Routing Identifier field has been added to the Cover Component.
- A document upload field has been added to the Cover Component for attaching the SFLLL or other explanatory documents.
- A new field has been added to the Project/Performance Site Location(s) form for the Congressional District of the project. The Areas affected by Project and Congressional Districts of Project fields on the Cover component have been deleted.
- Fields requesting the type and year of degree have been added to the Senior/Key Personnel forms.
- Questions on Human Subjects Research on the Other Project Information form have been re-ordered and a new question, whether the project is exempt from Federal regulations, has been added.

The PHS398 application components have been modified by realigning the structure and content of applications with new review criteria. Additionally, page limits for many applications have been shortened to help reduce the administrative burden placed upon applicants, reviewers, and staff. Specific modifications related to changes in the PHS398 components include:

- Three sections of the previous Research Plan (Background and Significance, Preliminary Studies/Progress Report, and Research Design and Methods) have been consolidated into a new single section within the Research Plan entitled Research Strategy. The new Research Strategy section will be sub-divided into three parts: Significance, Innovation, and Approach, although this will now be a single upload.
- The Facilities and Other Resources section has been changed to require a description of how the scientific environment will contribute to the probability of success of the project, unique features of the environment, and for Early Stage Investigators, the institutional investment in the success of the investigator (e.g., resources, classes, etc.).
- A new Personal Statement requirement has been incorporated into the Biographical Sketch.

Additional details on all the form changes noted above can be found at:


A description of how these application changes relate to the enhancement of peer review can be found at http://enhancing-peer-review.nih.gov/docs/application_changes.pdf. Additional information on NIH’s efforts to enhance peer review can also be found at http://enhancing-peer-review.nih.gov.

This version of the Application Guide now also includes a separate instruction section for Institutional Training Grants to accommodate their transition to electronic submission effective with submissions on/after January 25, 2010.
A separate Research Plan component is required for NIH and other PHS agencies applications. Refer to Section 5.5, Research Plan Component, for separate file uploads and instructions.

9. Bibliography & References Cited

Provide a bibliography of any references cited in the Project Narrative. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application. To attach a document for Bibliography and References Cited, click Add Attachment.

Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section (formerly “Literature Cited”) should include any references cited in the PHS 398 Research Plan component (see Section 5.5 for details on completing that component). When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the Pubmed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate “PMC Journal – In Process.” A list of these journals is posted at: http://publicaccess.nih.gov/submit_process_journals.htm.

Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PMCID numbers along with the full reference (note that copies of publicly available publications are not accepted as appendix material). The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

10. Facilities & Other Resources

This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project. Please click the Add Attachment button to the right of this field to complete this entry.

No special form is required but this section must be completed and attached for submissions to NIH and other PHS agencies unless otherwise noted in an FOA. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

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

If there are multiple performance sites, describe the resources available at each site.
Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Plan, Section 11 (Select Agent Research).

11. Equipment
List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities. Please click the Add Attachment button to the right of this field to complete this entry.

12. Other Attachments
Attach a file to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction.

Once all data have been entered use the scroll bar to scroll up. You will be returned to the Grant Application Package screen. To remove a document from the Submission box, click the document name to select it and then click the Move Form to Delete button. This will return the document to the Mandatory Documents Submission List or Optional Documents Submission List.
BIOGRAPHICAL SKETCH

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

<table>
<thead>
<tr>
<th>NAME</th>
<th>POSITION TITLE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hunt, Virginia Lively</td>
<td>Associate Professor of Psychology</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>eRA COMMONS USER NAME (credential, e.g., agency login)</th>
</tr>
</thead>
<tbody>
<tr>
<td>huntvl</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
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<td>University of California, Berkeley</td>
<td>B.S.</td>
<td>05/90</td>
<td>Psychology</td>
</tr>
<tr>
<td>University of Vermont</td>
<td>Ph.D.</td>
<td>05/96</td>
<td>Experimental Psychology</td>
</tr>
<tr>
<td>University of California, Berkeley</td>
<td>Postdoctoral</td>
<td>08/98</td>
<td>Public Health and Epidemiology</td>
</tr>
</tbody>
</table>

A. Personal Statement

The goal of the proposed research is to investigate the interaction between drug abuse and normal aging processes. Specifically, we plan to measure changes in cognitive ability and mental and physical health across a five-year period in a group of older drug users and matched controls. I have the expertise, leadership and motivation necessary to successfully carry out the proposed work. I have a broad background in psychology, with specific training and expertise in key research areas for this application. As a postdoctoral fellow at Berkeley, I carried out ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. At the Division of Intramural Research at the National Institute on Drug Abuse (NIDA), I expanded my research to include neuropsychological changes associated with addiction. As PI or co-Investigator on several previous 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. 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, and I have chosen co-investigators (Drs. Gryczynski and Newlin) who provide additional expertise in cognition, gerontology and geriatrics. In summary, I have a demonstrated record of successful and productive research projects in an area of high relevance for our aging population, and my expertise and experience have prepared me to lead the proposed project.

B. Positions and Honors

Positions and Employment

1998-2000 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
2002-2005 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2005- Associate Professor, Department of Psychology, Washington University, St. Louis, MO
**Other Experience and Professional Memberships**

1995- Member, American Psychological Association
1998- Member, Gerontological Society of America
1998- Member, American Geriatrics Society
2000- Associate Editor, Psychology and Aging
2003- Board of Advisors, Senior Services of Eastern Missouri
2003-04 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2005-09 NIH Risk, Adult Addictions Study Section, member

**Honors**

2003 Outstanding Young Faculty Award, Washington University, St. Louis, MO
2005 Excellence in Teaching, Washington University, St. Louis, MO
2008 Award for Best in Interdisciplinary Ethnography, International Ethnographic Society

**C. Selected Peer-reviewed Publications** (Selected from 42 peer-reviewed publications)

**Most relevant to the current application**


**Additional recent publications of importance to the field (in chronological order)**

D. Research Support

**Ongoing Research Support**

R01 DA942367-03  Hunt (PI)  09/01/07-08/31/12
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 MH922731-05  Merryle (PI)  07/15/05-06/30/10
Physical disability, depression and substance abuse in the elderly
The goal of this study is to identify disability and depression trajectories and demographic factors associated with substance abuse in an independently-living elderly population.
Role: Co-Investigator

Faculty Resources Grant, Washington University  08/15/09-08/14/11
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.

**Completed Research Support**

K02 AG442898  Hunt (PI)  09/01/06-08/31/09
Drug Abuse in the Elderly
Independent Scientist Award: to develop a drug addiction research program with a focus on substance abuse among the elderly.
Role: PI

R21 AA998075  Hunt (PI)  01/01/04-12/31/06
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
Please be aware of the following when traveling abroad and forward to any other personnel on the project who may also be traveling for this project.

1. You should be aware that hardware, software, and various materials, chemicals, microorganisms, and toxins taken with you abroad could constitute an export. Technology should be checked against the Munitions List (http://www.sipri.org/contents/expcon.us_munitionslist.pdf) and the Commerce Control List (http://www.access.gpo.gov/bis/ear/ear_data.html (Part 774).

2. Most laptops and GPS (excluding software or technology that contains source code for 64-bit encryption software or mass market encryption products), as well as I Phones and cell phones, are considered “tools of the trade” and are frequently carried abroad, but the investigator carrying these devices abroad must keep it on his or her person at all times. Software and proprietary data may also be controlled.

3. If project personnel will be providing training to foreign persons (non-students) in the use of ITAR-controlled technology, please inform OSP, because such training could be considered a “defense service.”

4. Presentations at international conferences are generally acceptable. It is important to note, however, that sidebar conversations with conference attendees should be limited to information already in the public domain. If you have any export control, you should contact OSP for further review.

5. Please note that Penn State’s policies on export control can be found here: http://guru.psu.edu/policies/RA18.html and here: http://guru.psu.edu/policies/RAG11.html (See specifically “PRESENTATION OF PREVIOUSLY UNPUBLISHED RESEARCH DATA AT CONFERENCES”).

6. Current travel warnings can be found here: http://travel.state.gov/travel/cis_pa_tw/tw/tw_1764.html. Register your trip outside the United States with the U.S. Department of State at https://travelregistrations.state.gov/ibrs/us/. Registration allows you to record information about your trip so that the Department of State can assist you in case of an emergency.

Feel free to contact me if you have questions. Thanks!
Projects with a “foreign component”

An OSP export specialist must review projects subject to the following conditions:

When the project involves any interaction with an embargoed country . . . YES
It is illegal to perform any service for an embargoed country (or certain individuals associated with such countries), including Belarus, Burma, Congo, Cuba, Iran, Iraq, Ivory Coast, Liberia, North Korea, Sudan, Syria, Zimbabwe, and the Balkans. A complete list of embargoed countries and applicable sanctions can be found here: [http://www.treas.gov/offices/enforcement/ofac/programs/index.shtml](http://www.treas.gov/offices/enforcement/ofac/programs/index.shtml)

When the sponsor is foreign . . . YES
Submission of deliverables to a foreign sponsor could be considered an export of U.S. technology.

When using a foreign subcontractor or consultant . . . YES
Sharing of research materials with a collaborating institution could be considered an export of U.S. technology.

When shipping anything abroad . . . YES
Even some very basic U.S. software (pre-installed on most computers purchased in the U.S.) is restricted for export.

When traveling abroad to conduct research . . . YES
Some common research equipment, including GPS equipment, is controlled for export.

When traveling abroad to conduct training . . . YES
Training of foreign nationals can be considered a “defense service,” controlled for export.

When traveling abroad to attend a conference . . . NO
There may be controls on an investigator’s personal belongings, such as a laptop, but presenting a paper at a foreign conference is not considered an export, unless the project is classified or subject to access or dissemination restrictions.

When hosting visiting scientists . . . YES
Training of foreign nationals (not enrolled or employed by Penn State) can be considered a “defense service,” controlled for export.

When employing foreign graduate students, research associates, and postdocs . . . NO
Foreign PSU students and foreign PSU employees are permitted to work on research projects, unless the project is classified or subject to access or dissemination restrictions.
**INVESTIGATOR DATA**

1. Principal Investigator/Project Correspondent
2. PI Notification e-mail

3. College/Unit
4. College/Unit Notification e-mail

5. Department/Subunit (Consortium/Institute/Center, etc.)
6. Project Location/Building Name:

**PROPOSAL DATA**

7. Type of Project
   - [ ] RESEARCH
   - [ ] INSTRUCTION
   - [ ] OUTREACH
   - [ ] SERVICE (Hershey Only)

8. Project Title

9. Type of Submission (Check Applicable)
   - [ ] New Proposal
   - [ ] Continuation
   - [ ] Supplement
   - [ ] Grant Transfer
   - [ ] Renewal
   - [ ] Resubmission to College Proposal ID No:

10. If Not New, List Current Grant, Contract or PSU Account Info.

**SPONSOR TRANSMITTAL DATA**

11. Prime Sponsor:
    (Sponsor's Source of Funding)

12. Sponsor Name and Address
    Contact:
    Sponsor Protocol No.:

13. CFDA No.:

14. Submitted by:
    - [ ] College/Unit
    - [ ] OSP
    OSP Instructions

15. Number of copies sent or to be sent:

16. Deadline (Check Box)
    Mailing Date:
    YES
    Date Due in Hands of Sponsor:

**BUDGET DATA**

17. **Initial** Start Date: 
    End Date: 
18. **Total** Start Date: 
    End Date: 

19. Applicable F&A Rate(s) or Management Fee:
    - MTDC
    - Other
    - N/A
    - TDC
    - Total Amount

20. **Initial**
    - Requested Direct: $
    - Requested F&A: $
    - Requested Fee: $
    - Total Requested: $

21. **Total**
    - Requested Direct: $
    - Requested F&A: $
    - Requested Fee: $
    - Total Requested: $

22. University Cost Sharing: (Check all that apply)
    - [ ] Includes Committed* Cost Sharing
    - [ ] College/Unit Is Providing Cost Sharing
      (Responsibility of College/Units)
    - [ ] Central Is Providing Cost Sharing
      (Documentation of Commitment Attached)

   *Committed Cost Sharing includes both mandatory (sponsor-required) cost sharing and voluntary cost sharing committed in the proposal (see RAG10).
**Proposal Internal Approval Form -- Page 2**

**SPECIAL REVIEW CHECKLIST**

The proposal submitted herewith involves the following:

<table>
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<th>Yes</th>
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*Checking this box yes invokes the requirement for the PI to submit the material to appropriate offices or committees for review in accordance with each applicable University Policy or Guideline.

**PRINCIPAL INVESTIGATOR/PROJECT CORRESPONDENT DISCLOSURES AND ASSURANCES**

By signing below (or on the Additional Approvals Page - Page 3), I certify that I have read the following statements and those contained on the Proposal Internal Approval Form -- Assurances Page (Pages 5, 6, 7), and I further certify that the statements contained herein are accurate and truthful to the best of my knowledge and belief:

Yes | No
---|---
- All applicable items contained in the Special Review Checklist have been identified. Investigators agree to abide by any obligations that university policies or legal requirements governing these items may evoke (e.g., obtaining approval for protocols, abiding by export laws, maintaining confidentiality, etc.).
- All investigators have read and understood Penn State's conflict of interest and Investigator Significant Financial or Business Interests Disclosure Policies (HR91, RA12, RA20, and RA21), have made all disclosures required by them, and, prior to the expenditure of any award funds, shall have reached an agreement with the University which provides for conditions or restrictions necessary to manage, reduce, or eliminate conflicts of interest under University policy.
- The proposal submitted herewith is (i) complete in its technical content (ii) adheres to the rules of proper scholarship, including specifically the proper attribution and citation for all text and graphics, (iii) complies with federal standards for the integrity of research (e.g., NSF Misconduct in Science Policy, see Penn State Policy RA10 and IAF-P08 Instructions), and (iv) is in accordance with specifications established by the sponsoring agency.
- The facilities/space and other University resources necessary to complete the proposed project are available to the project, or provisions have been arranged with Department/College/Unit to make such space or other University resources available in the event an award is made.
- If the proposal submitted herewith is funded and accepted by the University, I will conduct the project in accordance with the terms and conditions of the sponsoring agency and the policies of the University, and I will be fully responsible for meeting the requirements of the award, including, but not limited to, providing the proper stewardship of sponsored funds, submitting all required technical reports and deliverables on a timely basis, properly disclosing all inventions to the University's Intellectual Property Office, and adhering to all federal compliance requirements, (e.g., Export Control, HIPAA, Human Research Participants, etc.).

**APPROVALS**

<table>
<thead>
<tr>
<th>Principal Investigator/Project Correspondent Assurance (Initial one): Project does does not require SFBID</th>
<th>Approval Authority (Initial one): Department Head(s) or Subunit Director(s) or Director(s) of Academic Affairs</th>
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IAF-P08
Investigators Assurance: "By signing below, I certify that I have read the assurance statements contained on the Proposal Internal Approval Form (Page 2) and on the Proposal Internal Approval Form -- Assurances Page (Pages 5,6,7), and I further certify that the statements contained therein and below are accurate and truthful to the best of my knowledge and belief."

### ADDITIONAL INVESTIGATOR APPROVALS

<table>
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<tr>
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One objective of this form is to assign credit to the home colleges/departments of the PIs and principal contributors on a grant. Shared credit will be assigned to investigators, co-investigators, project directors, and other participants identified in the left hand column of the table below. Credit will be attributed to the home college and department of those individuals in proportion to the percentages appearing in the far right column. These percentages reflect "credit" for intellectual and technical responsibility for the project. They need not represent salary or time distributions for all project participants. No Research Incentive Funds (RIFs) go to the strategic initiative areas, and columnar summations for strategic initiatives do not take credit away from the colleges/departments.

The second objective is to identify connections with a strategic initiative area. The fractions provided in the bottom row associate the project with the University’s Strategic Interdisciplinary Research Initiatives (SIRI) areas. The work need not be specifically within or supported by one of the Consortia or Institutes in order to be associated with an SIRI area. If the work is at all related to one or more of the SIRI areas, then the work should be specifically identified as falling within that field. The information collected is, in part, aimed at communicating with those outside of Penn State where we wish to project the full extent of the University’s research programs in these key areas. If a project is in the area of Life Sciences, then the individual’s percent credit is entered in the Life Sciences column. If this project supports more than one area, the individual’s percent credit can be divided between different SIRI. For instance, if this project is partially Materials and partially Computational Sciences, the individual’s percentage can be divided between these two areas. Please note that in the annual report, CYF will be rolled up under Social Sciences.

Please take a minute to accurately complete the form -- use whole percentages for all table entries. Data collected provides a global assessment of the size and vitality of the University’s research activities in each SIRI area. In addition to providing a gauge on size and growth, the information provided identifies college/departmental contributions to each area, thereby allowing deans and department heads to assess the extent to which their faculty benefit from participation in each of the Strategic & Interdisciplinary Research Initiatives. Summaries of data collected using this form allow the University to capture the full breadth and strength of its programs in each of the SIRI areas and to subsequently communicate those strengths to potential students, sponsors and faculty recruits.
Certification of Procurement Integrity

(Applicable only if proposal is part of a Federal Procurement and amount proposed or awarded is equal to or in excess of $100,000)

1) By signing the Proposal Internal Approval Form, I certify, to the best of my knowledge and belief, that I am the employee responsible for the preparation of the proposal submitted herewith and that I have no information concerning a violation or possible violation of subsection 27 (a), (b), (d) or (f) of the Office of Federal Procurement Policy Act, as amended (41 U.S.C. 423), hereinafter referred to as "the Act") as implemented in the FAR, occurring during the conduct of this procurement.

2) As required by subsection 27 (e) (1) (B) of the Act, I further certify that, to the best of my knowledge and belief, each employee and consultant who has participated personally and substantially in the preparation or submission of this offer has certified that he or she is familiar with, and will comply with, the requirements of subsection 27 (a) of the Act, as implemented in the FAR, and will report immediately to me any information concerning a violation or possible violation of the Act, as implemented in the FAR, pertaining to this procurement.

THIS CERTIFICATION CONCERNS A MATTER WITHIN THE JURISDICTION OF AN AGENCY OF THE UNITED STATES AND THE MAKING OF A FALSE, FICTITIOUS, OR FRAUDULENT CERTIFICATION MAY RENDER THE MAKER SUBJECT TO PROSECUTION UNDER TITLE 18, UNITED STATES CODE, SECTION 1001.

Certification Regarding Lobbying

By signing the Proposal Internal Approval Form, I certify, to the best of my knowledge and belief, that:

1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the [Investigator], to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the [Investigator] shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," [to the University].

3) The [University] shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U. S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less that $10,000 and not more that $100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters

(Applicable only if proposal is submitted to the Federal Government)

By signing the Proposal Internal Approval Form, I certify to the best of my knowledge and belief, that:

(a) I am not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any Federal Department or agency;

(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against me for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Have not within a three-year period preceding this application/proposal has one or more public transactions (Federal, State or local) terminated for cause or default.

Required Education in the Protection of Human Research Participation

(Applicable to all projects involving the use of human subjects)

By signing the Proposal Internal Approval Form, I certify to the best of my knowledge and belief, that:

All individuals responsible for the design and conduct of the proposed research involving human subjects have completed (or shall have completed by the time of award) the University’s required web-based educational program on the protection of human subjects.
Investigator Financial or Business Interest Disclosure Policy
(Summary of Penn State Policy RA20-- Applicable to all Sponsored Project Proposals)

What is required?
Federal regulations require institutions to have policies and procedures in place that ensure that Investigators disclose any significant financial or business interest that may present an actual or potential conflict of interest in relationship to externally sponsored projects. Such disclosures must be made prior to the submission of a proposal,* and institutions must develop specific mechanisms by which conflicts of interest will be satisfactorily managed, reduced, or eliminated prior to the expenditure of any funds on an award.

* If a new reportable significant conflict of interest arises at any time during the period after the submission of the proposal through the period of the award, the filing of a disclosure is also required.

Who is covered?
"Investigator" means the principal investigator/project director, co-principal investigators, and any other person at the University who is responsible for the design, conduct, or reporting of research, educational, or service activities funded, or proposed for funding, by an external sponsor. In this context, the term "Investigator" includes the Investigator's spouse and dependent children.

What must be disclosed?
Each Investigator shall disclose all significant financial or business interests:
(i) that would reasonably appear to be affected by the research, educational, or service activities funded, or proposed for funding, by an external sponsor; or
(ii) in entities whose financial interests would reasonably appear to be affected by such activities.

What is covered?
"Significant financial or business interests" means anything of monetary value/interest, including, but not limited to, compensation or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); intellectual property rights (e.g., patents, copyrights, and separately, royalties from such rights); and/or holding a management position or playing an advisory or consultative role (whether compensated or not) with a company or on the board of a company. The term does not include:
(1) Salary or other remuneration from the University;
(2) Income from seminars, lectures, or teaching engagements sponsored by public entities;
(3) Income from service on advisory committees or review panels for public or non-profit entities;
(4) Income from service on advisory committees or review panels for non-profit entities that are not affiliated with "for profit" companies;
(5) An equity interest that, when aggregated for the Individual and the Individual's spouse and dependent children, meets any of the following tests: does not exceed $10,000 (considered as a De minimis amount) in value as determined through reference to public prices or other reasonable measures of fair market value, does not represent more than a five percent ownership interest in any single entity, does not involve research with human participants, and will not be affected by the outcome of the study;
(6) Broad based mutual funds;
(7) Other compensation, royalties or other payments that, when aggregated for the Individual and the Individual's spouse and dependent children over the next twelve months, are not expected to exceed $10,000 (considered as a De minimis amount), does not involve human participants and will not be affected by the outcome of the study.

Financial and business interests in human participants research must be the focus of intense scrutiny. When human participants are involved, no De minimis will apply.

Disclosure Procedures:
(1) All Investigators must disclose their significant financial or business interests to their college/academic unit utilizing this form and attaching all required supporting documentation. The completed form and packet must be signed by the investigator and appropriate college/unit officials and submitted with the proposal and University Proposal Internal Approval Form to the Office of Sponsored Programs or the Office of Research Affairs at Hershey Medical Center. Supporting documentation should be submitted to the appropriate office in a sealed envelope marked confidential.
(2) In accordance with Federal regulations, a complete disclosure must be made by Investigator(s) prior to submission of the proposal.
(3) Resolutions to conflicts of interest will be incorporated into a Memorandum of Understanding (MOU) between the Investigator(s) and the University [signed by Investigator(s), the Department Chair/ Unit Head, and the Dean/Director] prior to expenditure of any award funds.
Significant Financial or Business Interest Disclosure
(Applicable to all Sponsored Project Proposals)

Faculty/Staff Name ____________________________________________
Department/Unit _____________________________________________
College/Unit _________________________________________________
Proposal Title ________________________________________________
Proposal Submitted to __________________________________________

I am disclosing the following significant financial or business interests (check one) and attaching supporting documentation (in an envelope marked confidential) that identifies the business enterprise or entity involved and the nature and amount of the interest:

("Significant financial or business interests" are defined as interests or projected annual income valued at greater than $10,000 or an equity or ownership interest of more than five percent held by an Investigator and the Investigator's spouse or dependent children. Please note that when human participants are involved, any financial or business interest must be disclosed, even if it is less than the $10,000/5% De minims amount. See page 1 for exempt interests.)

☐ Compensation or other payment for services (e.g., consulting fees or honoraria).
☐ Equity interests (e.g., stocks, stock options, or other ownership interests).
☐ Intellectual property rights (e.g., patents, copyrights, and separately, royalties from such rights).
☐ Holding a management position or playing an advisory or consultative role (whether compensated or not) with a company or on the board of a company.
☐ Other significant financial interest of the Investigator that possibly could affect or be perceived to affect the results of the research, educational, or service activities funded or proposed for funding.

Further I agree:

• To update this disclosure during the period of the award as new reportable significant financial interests are obtained.
• To cooperate in the development of a Memorandum of Understanding (MOU) that constitutes a conflict of interest "resolution plan."
• To comply with any conditions or restrictions imposed by the University to manage, reduce, or eliminate actual or potential conflicts of interest or forfeit the award.
• To have a fully-executed MOU in place prior to making any expenditures of sponsored project funds.

Signed: __________________________ Date: ____________

(Original signature only -- a "per" signature is not acceptable.)

Endorsements:

I have reviewed the significant financial or business interest disclosure and believe that it will be possible to develop and execute, prior to expenditure of award funds, an MOU to manage, reduce, or eliminate any actual or potential conflict of interest; and, therefore, I recommend that that proposal be submitted to the agency at this time.

Department/Unit Head: __________________________ Date: ____________

Signed

College Dean/Director: __________________________ Date: ____________

Signed

OSP# __________________________