National Institutes of Health Policies and Procedures Update

UT Office of Sponsored Programs

Betsy Saylor, Contract Coordinator
Amber Hardie, Proposal Coordinator

April 15th, 2015
Changes in Proposal and Post-Award Phases

- New Biosketch Format
- SciENcv: Science Experts Network Curriculum Vitae
- Resubmissions: Elimination of Mark-up
- Relaxed “Two-Strikes” Policy
- eRA Commons Accounts for Students, Postdocs
- Individual Development Plans for Graduate Assistants, Postdocs
- 2015 Stipends and Salary Cap; Funding Levels
- Uniform Guidance and revised NIH Grants Policy Statement
- ASSIST resource
New Biosketch Format

- NIH *encourages* use of the new biosketch format for all applications submitted for due dates on or after Jan. 25, 2015.

- NIH will *require* the new format for applications due on or after *May 25, 2015*.

See NIH Notice [NOT-OD-15-085](#)
New Biosketch Format: What’s New

- Extends biosketch page limit from four to **five pages**
- Allows researchers to describe **five most significant contributions to science**, along with background that framed their research.
- Investigators can outline **central findings of prior work**, influence on the field.
- Those involved in **Team Science** can list their **specific role(s)** as well as up to four relevant peer-reviewed publications or other non-publication **research products**.
- Additionally, researchers can **include links** to a list of their published work as found in databases such as MyBibliography or SciENcv.
New Biosketch Format:

Instructions

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Completion Date M/Y/YYYY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
</table>

NOTE: The Biographical Sketch may not exceed five pages. Follow the formats and instructions below.

A. Personal Statement

Briefly describe why you are well-suited for your role in the project described in this application. The relevant factors may include aspects of your training, your previous experimental work on this specific topic or related topics; your technical expertise; your collaborators or scientific environment; and your past performance in this or related fields (you may mention specific contributions to science that are not included in Section C). Also, you may identify up to four peer-reviewed publications that specifically highlight your experience and qualifications for this project. If you wish to explain impediments to your past productivity, you may include a description of factors such as family care responsibilities, illness, disability, and active duty military service.

B. Positions and Honors

List in chronological order previous positions, concluding with the present position. List any honors. Include present membership on any Federal Government public advisory committee.

C. Contribution to Science

Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of these findings to health or technology; and your specific role in the described work. For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products, patents, data and research materials, databases, educational aids or curricula, instruments or equipment, models, protocols, and software or networks) that are relevant to the described contribution. The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciTrov or My Bibliography, which are maintained by the US National Library of Medicine.
New Biosketch Format:

Instructions

C. Contribution to Science

“Briefly describe up to five of your most significant contributions to science. For each contribution, indicate the historical background that frames the scientific problem; the central finding(s); the influence of the finding(s) on the progress of science or the application of those finding(s) to health or technology; and your specific role in the described work.

For each of these contributions, reference up to four peer-reviewed publications or other non-publication research products (can include audio or video products; patents; data and research materials; databases; educational aids or curricula; instruments or equipment; models; protocols; and software or netware) that are relevant to the described contribution.

The description of each contribution should be no longer than one half page including figures and citations. Also provide a URL to a full list of your published work as found in a publicly available digital database such as SciENcv or My Bibliography, which are maintained by the US National Library of Medicine.”
New Biosketch Format: Sample

**BIOGRAPHICAL SKETCH**

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

**NAME:** Hunt, Morgan Casey

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

**POSITION TITLE:** Associate Professor of Psychology

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

<table>
<thead>
<tr>
<th>INSTITUTION AND LOCATION</th>
<th>DEGREE (if applicable)</th>
<th>Completion Date MM/YYYY</th>
<th>FIELD OF STUDY</th>
</tr>
</thead>
<tbody>
<tr>
<td>University of California, Berkeley</td>
<td>B.S.</td>
<td>05/1990</td>
<td>Psychology</td>
</tr>
<tr>
<td>University of Vermont</td>
<td>Ph.D.</td>
<td>05/1999</td>
<td>Experimental Psychology</td>
</tr>
<tr>
<td>University of California, Berkeley</td>
<td>Postdoctoral</td>
<td>08/1998</td>
<td>Public Health and Epidemiology</td>
</tr>
</tbody>
</table>

**A. Personal Statement**

I have the expertise, leadership, training, expertise and motivation necessary to successfully carry out the proposed research project. I have a broad background in psychology, with specific training and expertise in ethnographic and survey research and secondary data analysis on psychological aspects of drug addiction. My research includes neuropsychological changes associated with addiction. As PI or co-investigator on several university- and NIH-funded grants, I laid the groundwork for the proposed research by developing effective measures of disability, depression, and other psychosocial factors relevant to the aging substance abuser, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the proposed project, defining the specific 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

**C. Contribution to Science**

1. My early publications directly addressed the fact that substance abuse is often overlooked in older adults. However, because many older adults were raised during an era of increased drug and alcohol use, there are reasons to believe that this will become an increasing issue as the population ages. These publications found that older adults appear in a variety of primary care settings or seek mental health providers to deal with emerging addiction problems. These publications document this emerging problem but guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the problem and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for addicted older adults and will continue to provide assistance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.

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
New Biosketch Format:
Sample cont.

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:

D. Research Support

Ongoing Research Support

R01 DA942367 Hunt (PI) 09/01/08-08/31/16
Health trajectories and behavioral interventions among older substance abusers
The goal of this study is to compare the effects of two substance abuse interventions on health outcomes in an urban population of older opiate addicts.
Role: PI

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

Faculty Resources Grant, Washington University 08/15/09-08/14/15
Opiate Addiction Database
The goal of this project is to create an integrated database of demographic, social and biomedical information for homeless opiate abusers in two urban Missouri locations, using a number of state and local data sources.
Role: PI

Completed Research Support

R21 AA998675 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
New Biosketch Format: Benefits

- Helps reviewers evaluate **beyond quantity** and placement of publications to other accomplishments.

- **Expands focus** of reviewers and scientific community beyond metrics (e.g., number of published papers, citations received, or one of several statistical approaches used to normalize citations).

The revised forms and instructions are now available on the [SF424 applications page](https://sf424applications.com), and can also be built from [SciEENcv](https://www.sciencenow.org/sciencenews).
SciENcv

- “Science Experts Network Curriculum Vitae”

- Free profile service from the National Center for Biotechnology Information (NCBI).
- SciENcv is My NCBI’s biosketch tool
- Federal Demonstration Partnership catalyzed
- One-stop repository for biosketch info
- SciENcv relates to NIH, NSF, other agencies soon
SciENcv

Grant applications

Biosketch generation

Grant compliance/reporting

My NCBI

eRA

PubMed

NIHMS

PMC

Manuscripts

Progress reports (RPPR, etc)

Published articles
SciENcv

- Begin at main SciENcv website:

- SciENcv links to My NCBI.
- Log-in with your eRA Commons account.
- Create a new profile in SciENcv: from scratch, an external source (e.g., eRA Commons), or an existing profile.
SciENcv

- The default “biosketch type” is NIH Biosketch.
- Review auto-filled info, add info, link publications, etc.
BIографическая отлихь

Имя: EVERs, BERNARD MARK
Занимаемая должность: Директор, заместитель декана исследования на Кентукки университета

Высшее образование и профессиональное обучение:

- University of Texas Medical Branch, OTHER — MMS 1/1/1991, Science
- University of Tennessee, Knoxville, BACHELOR OF ARTS (AB) 1/1/1979, VET MEDICINE/MICROBIOLOGY, Microbiology
- University of Tennessee, Memphis, DOCTOR OF MEDICINE (MD) 1/1/1983, OTHER AREAS, Medicine
- UNIVERSITY OF KENTUCKY, NIH training grant
- UNIVERSITY OF KENTUCKY, NIH training grant

A. PERSONAL STATEMENT

B. POSITIONS AND HONORS

- 2013 - 2019, Директор, заместитель декана исследования, 2769601 UNIVERSITY OF KENTUCKY
- 1988 - 2009, Член-основатель и профессор, 578406 UNIVERSITY OF TEXAS MEDICAL BR GALVESTON

Other experience and professional memberships:

HONORS

C. SELECTED PEER-REVIEWED PUBLICATIONS


D. RESEARCH SUPPORT

Ongoing Research Support
SciENcv

- Leverages data from existing systems
- Available to any researcher
- Researcher owns data
- Researcher controls what data is public
- Researcher edits and maintains information
- Researcher provides own data to describe research outcomes
- Researcher has ultimate control of data in biosketch

Resubmissions: Elimination of Mark-up

- Mark-up of specific, substantial changes in the Specific Aims, Research Strategy or other application attachments is no longer required.

- Outlining the changes made to the resubmission application in the Introduction attachment is sufficient.

- The Introduction must include a summary of substantial additions, deletions, and changes to the application.

- Introduction page limits (1 page for most programs) have not changed.
Resubmissions: Elimination of Mark-up

Why the Change?

- NIH response to confusion on how changes should be identified in resubmissions.
- Also addresses concerns raised that inline mark-ups provide too much emphasis on changes made and remove focus from the application as a whole.

Please see NIH Notice number NOT-OD-15-030 for more info.
Relaxed “Two-Strikes” Policy

- Effective April 2014, NIH allows unlimited resubmission of an **identical proposal** as a **new** submission.

- One chance to resubmit a proposal and respond to reviewers’ comments. But *now*, if that A1 application fails, PIs can resubmit the application as an A0 and NIH reviewers will consider it a **fresh** proposal.

- The subsequent new application does not need to show changes in scientific direction compared to previous submissions, and **should not** contain response to the critiques from the previous review.
Relaxed “Two- Strikes” Policy

- **The FOA prevails:** FOA requirements take precedence.
- NIH will not simultaneously review duplicate or highly overlapping applications.
- **Due Dates:** After an unsuccessful resubmission (A1), a PI may submit the same idea as a new (A0) application for any appropriate future due date.
- **No time limit** between an unsuccessful resubmission (A1) application and subsequent new (A0) application (nor between an unsuccessful new A0 and a subsequent new A0).
- Time limit of 37 months between an unsuccessful (A0) application and the subsequent resubmission (A1) application **does** remain in effect.
- Submission cycles are unlimited, but **updates** to proposals are expected over the interim period.

For additional details, please see Notice Number **NOT-OD-15-059**.
**eRA Commons Accounts:**

**Students and Postdocs – Proposal Stage**

- **Best practice:** Create accounts for all students/postdocs at time of proposal.

- **When applying for fellowships,** eRA Commons IDs are required for PI, Undergraduate, Graduate Student, Postdoctoral roles.
eRA Commons Accounts: Students and Postdocs – Reporting

- Effective Oct. 2014, NIH progress reports (RPPRs, etc.) require eRA Commons IDs not only for postdocs, but for graduate and undergrad students.

- Applies to all students/postdocs listed at 1 person month or more.

- Individual account owners will be required to answer demographic and educational questions.

- No one but the account owner can complete his/her profile information (plan ahead!).
eRA Commons Accounts: Students and Postdocs – Reporting

- Eventually grantees might be required to create eRA Commons accounts for all personnel listed in the Participant Section.

- Good news: Info collected in eRA Commons will be available to pre-populate SciENcv to more easily generate biosketches and progress reports.

- For more information, please see NOT-OD-13-097.
Individual Development Plans

- **Effective** Oct. 1, 2014, NIH progress reports must describe if individual development plans (IDPs) are used to support goals of grad students and postdocs working on the grant.

- NIH does not yet require, but **strongly encourages** use of IDPs for grad students and postdocs supported by NIH awards, regardless of their position title.
Individual Development Plans

- The Office of Research & Engagement and the Office of Graduate Training and Mentorship in the Graduate School are collaborating to provide resources and assistance:

  http://research.utk.edu/training-workshops/individual-development-plan-idp-program/
2015 Stipends for Fellows, Trainees

- Increased stipend levels for Federal fiscal year 2015 Kirschstein-NRSA awards (undergraduate, predoctoral, and postdoctoral trainees and fellows).

<table>
<thead>
<tr>
<th>Fellowships:</th>
<th>F30, F31, F32, F33</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training Grants:</td>
<td>T32, T34, T35, T90</td>
</tr>
</tbody>
</table>

- Tuition and Fees, Training Related Expenses, and Institutional Allowance amounts remain unchanged from 2014.
The following annual stipend levels are effective with all Kirschstein-NRSA awards made on or after October 1, 2014:

<table>
<thead>
<tr>
<th>Career Level</th>
<th>Years Experience</th>
<th>Stipend for FY 2015</th>
<th>Monthly Stipend</th>
</tr>
</thead>
<tbody>
<tr>
<td>Predoctoral</td>
<td>All</td>
<td>$22,920</td>
<td>$1,910</td>
</tr>
<tr>
<td>Postdoctoral</td>
<td>0</td>
<td>$42,840</td>
<td>$3,570</td>
</tr>
<tr>
<td></td>
<td>1</td>
<td>$44,556</td>
<td>$3,713</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>$46,344</td>
<td>$3,862</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>$48,192</td>
<td>$4,016</td>
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<td></td>
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<td>$50,112</td>
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<td>$52,116</td>
<td>$4,343</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>$54,216</td>
<td>$4,518</td>
</tr>
<tr>
<td></td>
<td>7+</td>
<td>$56,376</td>
<td>$4,698</td>
</tr>
</tbody>
</table>

See all details NIH Notice Number: NOT-OD-15-048
NIH Salary Cap

- This salary limitation is mandated by Congress.
- The “Executive Level II” salary increased to $183,300 effective January 11, 2015.
- 9-month salary correspondingly is $137,475.
- Always include accurate base salary in proposal.
- Rebudgeting to the current level is allowed if supported by base salary listed in proposal.
- FI0208 – Sponsored Projects – Federal Salary Rate Limitation
- Unsure how to budget with the cap? OSP can help!
FY 2015 Funding Levels

- NIH will be **fully or partially restoring** some non-competing continuation awards issued in federal FY 2015 that were funded at lower levels than anticipated.

- The Institute or Center can play a part, but, non-competing continuation grants including those that remain to be issued in FY 2015 likely will be made within the range between the commitment level indicated on the most recent NoA and 3% below that level.

- Commitments for continuation awards in FY 2016 and beyond will remain unchanged.
OMB Uniform Guidance

- Released December 26, 2013 by Office of Management and Budget: *2 CFR 200*
- Applicable to awards made on or after *December 26, 2014*.
- Dept. of Health and Human Services’ regulations implementing Uniform Guidance = *45 CFR Part 75*
Uniform Guidance

- OMB’s consolidation of several circulars into one, **Uniform Guidance**, resulted in HHS’s administrative regulations changing from 45 CFR Parts 74 and 92 to **45 CFR Part 75** (*this is the CFR to watch for in your Notice of Award!*).

- For awards made on or after December 26, 2014 the 3/31/2015 revised NIH Grants Policy Statement **supersedes** the 2013 NIH Grants Policy Statement (and the NIH Interim General Grant Conditions released last February).
Uniform Guidance

Please note (unless specified otherwise in the Notice of Award):

- All NIH awards providing **new** or **supplemental** funding on or after December 26, 2014 fall under the new NIH Grants Policy Statement implementing the UG per 45 CFR part 75.

- The new guidance will apply to **carryover** of NIH funds originally awarded prior to December 26, 2014 if a new Notice of Award is received citing the new guidance.
Uniform Guidance

The new NIH Grants Policy Statement contains important changes including:

- New recipient **authorities** (e.g., conditions for allowability of costs for computing devices, administrative clerical staff);

- New **prior approval** requirements (e.g., rebudgeting of cost share); and

- Stricter protocol for **sub-awarding** funds to grantees.
Uniform Guidance

Well thought-out proposals are more important than ever!

- For example, direct cost of essential admin personnel and computing devices meeting the requirements and included at the proposal stage are allowable if awarded (no more DCJs!)

- Note the effective date of the UG was more than three months ago. UT has federal awards in-hand falling under the new rules.

Uniform Guidance

Direct Charging of Admin and Clerical Personnel

- The salaries of administrative and clerical personnel should normally be treated as F&A costs. Inclusion of such costs may be appropriate only if all of the following conditions are met:

  1. Administrative or clerical services are integral to a project or activity;
  2. Individuals involved can be specifically identified with the project or activity;
  3. Such costs are explicitly included in the budget or have prior written approval of the Federal awarding agency; and
  4. The costs are not also recovered as indirect costs.

- Requests for direct charging or Secretarial/Clerical Personnel (i.e., administrative and clerical staff) must be appropriately justified in the Budget Justification.
ASSIST

What is ASSIST?

ASSIST is NIH's on-line system for the preparation and submission of grant applications through Grants.gov to NIH. ASSIST provides:

- Secure web-based data entry
- Collaboration of multiple users
- Pre-submission validation of NIH and key Grants.gov business rules
- Pre-population of data from eRA Commons profiles
- Pre-submission print/preview of application in NIH format
- Submission status tracking for both Grants.gov and eRA Commons within a single system
- And more (see NOT-OD-15-044)

*Note: Use of ASSIST is optional; Grants.gov downloadable forms and system-to-system solutions remain viable submission options.
References


- OSP website: [http://research.utk.edu/osp/](http://research.utk.edu/osp/)

- ORE Training website: [http://research.utk.edu/training-workshops/](http://research.utk.edu/training-workshops/)
Questions?

NIH Proposals:
Amber Hardie
Proposal Coordinator
A8C1 Blount Hall
1534 White Avenue
ahardie@utk.edu
974-2402

NIH Post-Award:
Betsy Saylor
Contract Coordinator
A8D Blount Hall
1534 White Avenue
bsaylor@utk.edu
974-3863

Thank you!