



Science and Security Update: NIH Other Support and Biosketch

Jennifer Teixeira, Sr. Director of Research
Administration, OSR
Sherry Whitaker, Director of Sponsored
Programs Office

September 16, 2021

Agenda

- NIH Notice of Changes
- NIH Other Support Changes
- NIH Biosketch Changes
- NIH Useful Information Links



NIH Notice of Changes

In response to improper influence concerns and to clarify past National Institutes of Health (NIH) statements, the NIH has published Notice Number **NOT-OD-21-073** and Notice Number **NOT-OD-21-110**. These notices implement new requirements for NIH Other Support and Biosketch documents.

NOT-OD-21-073: Original Deadline of May 25, 2021

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html>

NOT-OD-21-110: Revised Deadline to January 25, 2022

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-110.html>

The new requirements become mandatory for applications with due dates on or after January 25, 2022, but NIH strongly encourages you to begin following them now. Failure to follow the new requirements after the January date may cause NIH to withdraw applications or delay funding.



NIH Other Support Changes

- What is Other Support?
 - Financial Resources
 - In-Kind Resources
- Key Considerations
- Significant Changes
- Additional Changes
- UNC NIH Other Support Resources
- Important NIH Other Support FAQ's



What is Other Support?

- Other Support includes **all resources** made available to researchers or senior key personnel in support of and/or related to **all their research** endeavors.
- Includes financial and in-kind resources.



Financial Resources

- **All** funded active and pending awards, regardless of funding entity, including active and pending:
 - Direct awards
 - Incoming subcontracts
 - Pilot project (Ex. Funding provided by NC TraCS Institute).

Be sure to include both domestic and foreign awards and use **TOTAL** budget.



Financial Resources (Cont.)

- Funded **Service Agreements** awarded to the University that involve the individual submitting the Other Support Document
 - The funding organization must report these to the federal government through Open Payment disclosures



Financial Resources (Cont.)

- **Funded external activities** (aka EPAP) that impact your research or are research-related.
 - An estimated amount you will be paid is required.
 - If payment is via **private equity financing** (e.g., shares in a company, etc), this **must be disclosed**.
 - Time and effort reflected in calendar months is **NOT** required.



Financial Resources (Cont.)

- **Financial Resources** provided to another party in support of the individuals research or research project, example includes:
 - a grant to another University who donates some of the funds for specific use in a project.



Financial Resources (Cont.)

- **Startup Funds** provided by an entity other than UNC-Chapel Hill.

PLEASE NOTE

Gift Funds:

- NIH no longer requires gifts to be reported but we strongly suggest you report them if they **subsidize your research** in some way.

Training Grants or Prizes:

- NIH also no longer requires you to report this type of financial resource



In-Kind Resources

- All Lab or office space that is in use **outside of UNC-Chapel Hill** to conduct research (e.g., a lab at a pharmaceutical company or other University.)
 - **Both** domestic and foreign locations.
- UNC-Chapel Hill resources should be placed in the:
 - Facilities and Other Resources section of your application **unless they are not broadly available to all researchers/faculty.**
 - If they are not broadly available, they should be disclosed as Other Support.



In-Kind Resources (Cont.)

- High value scientific materials that are not publicly available, used in research (e.g., drugs, mouse lines, assays, etc.)
 - **Must be given in the past 3 years and still in use.**
 - NIH has not defined “high value” so err on the side of caution.
 - This includes materials provided to another party in support of research or research project (e.g., free drugs provided to collaborators who then provide for our research).
 - Include the source, a description of the materials, and an estimated value.



In-Kind Resources (Cont.)

- Collaborators whose efforts support research in some way.
 - If individual has many collaborators, you may use a summary statement to describe them.
 - See the example in the NIH section on the OSR Science and Security webpage: <https://research.unc.edu/sponsored-research/resources/science-security/#sciUpdate>



Key Considerations

- When thinking about relationships, existing or potential, that **may** impact:
 - Research Integrity,
 - Financial Conflict of Interests, and/or
 - Overlap

You should keep the following three questions in mind.



Key Considerations

1. Does the relationship affect the integrity of the research by impacting established principles?
 - The “relationship” could be with a collaborator, an outside employer (aka EPAP), external appointment commitment, etc.
 - The “impact” could be real, apparent, or perceived.
 - The “compensation” could be any type or level, including financial or in-kind support.



Key Considerations

2. Is there a potential scientific, budgetary, and/or commitment overlap?
3. Is there a potential financial conflict of interest?

If the answer to any of these questions is **yes**, disclose it. When in doubt, err on the side of **full transparency**.



NIH Other Support – Significant Changes

- **Certification**

- Each PD/PI and Other Senior/Key Personnel must electronically sign their respective Other Support document prior to submission, certifying that the information is true, complete, and accurate.
- For UNC, that means a hand signature with document saved in a flat PDF format or an electronic signature via Adobe. **A typed name or “signature font” in Word will not be allowed.**
- You must maintain supporting documentation to “reasonable authenticate” that the appropriate individual signed – e.g., an e-mail from the faculty member to department administrator that includes the signed document.



NIH Other Support – Significant Changes (Cont.)

- **Supporting Documentation**

- Each PD/PI and Other Senior/Key Personnel are now required to provide copies of contracts, grants, agreements (in English) for any foreign appointments, affiliations, and/or employment with a foreign institution, including External Professional Activities for Pay (EPAP).
- Machine-read (aka software driven) translations are acceptable.
- **Applies to new applications AND all post award actions on or after January 25, 2022.**



NIH Other Support – Significant Changes (Cont.)

- **Immediate Notification of Undisclosed Information**
 - When UNC or its faculty/staff discovers that a PI/PD or Other Senior/Key Personnel failed to disclose previously known Other Support, the institution must immediately notify NIH.
 - Send updated documents to OSR/SPO if discovered during pre-award stage and OSR if discovered during post-award stage.
- **Completed (or Inactive) category**
 - NO LONGER needs to be included in the Other Support document.



NIH Other Support – Additional Changes

- NIH no longer wants to see multiple versions of the Other Support Document.
 - **Both the Active and Pending categories** are combined into a single document.
- **In-Kind Contributions**
 - In-Kind Contributions are now listed separately from funded projects and **must** include reasonable estimates for time commitment or dollar value.
- New Requirements Include
 - **Primary Place of Performance:** Primary location of project or activity
 - **Person Months:** For an active project, provide the level of actual effort in person months (even if unsalaried) for the current budget period and indicate the proposed level effort for each remaining budget period.



UNC NIH Other Support Resources

- The UNC template has been updated to include these new requirements.
- NIH Other Support blank and sample Templates are available on OSR Forms & Tools Website: <https://research.unc.edu/sponsored-research/forms/#>

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

**For New and Renewal Applications – DO NOT SUBMIT UNLESS REQUESTED
PHS 398 OTHER SUPPORT**

There is no "form page" for reporting Other Support. Information on Other Support should be provided in the format shown below.

*Name of Individual:
Commons ID:

Other Support – Project/Proposal

*Title:

Major Goals:

*Status of Support:

Project Number:

Name of PD/PI:

*Source of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date: (MM/YYYY) (if available):

* Total Award Amount (including Indirect Costs):

* Person Months (Calendar/Academic/Summer) per budget period.

Year (YYYY)	Person Months (###)
1. <u> </u> enter year 1	
2. <u> </u> enter year 2	
3. <u> </u> enter year 3	
4. <u> </u> enter year 4	
5. <u> </u> enter year 5	

OMB No. 0925-0001 and 0925-0002 (Rev. 12/2020 Approved Through 02/28/2023)

Name of Individual:
Commons ID:

IN-KIND

*Summary of In-Kind Contribution:

*Status of Support:

*Primary Place of Performance:

Project/Proposal Start and End Date (MM/YYYY) (if available):

*Person Months (Calendar/Academic/Summer) per budget period

Year (YYYY)	Person Months (###)
1. <u> </u> enter year 1	
2. <u> </u> enter year 2	
3. <u> </u> enter year 3	
4. <u> </u> enter year 4	
5. <u> </u> enter year 5	

*Estimated Dollar Value of In-Kind Information:

***Overlap** (summarized for each individual):

I, PD/PI or other senior/key personnel, certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

*Signature: _____

Date: _____



UNC Other Support Resources (cont.)

- Modifications to the NIH template, to add resource categories and resources, are allowed so long as the overall format stays the same.
- It is recommended that you complete all data fields in the template documents, not just required ones, to insure an accurate review.
- Enhancements to UNC's Other Support Tool will support the changes to the NIH requirements and should be implemented by the beginning of October. You may view a recording of today's session on the Updates to the Other Support Tool on the symposium website after it has been uploaded: <https://symposium.web.unc.edu/current-symposium/>



Important NIH Other Support FAQ's

NOTE: Questions and answers are pulled directly from the NIH FAQs for Other Support.

- **What if NIH determines that an institution is not complying with NIH policies for transparency and disclosure of all Other Support?**

NIH takes the issue of protecting the integrity of U.S. biomedical research seriously. When issues of noncompliance are identified, NIH will take action as outlined in the NIH Grants Policy Statement, Section 8.5. This may include withdrawing approval of the Program Director/Principal Investigator or other researchers contributing to the NIH award, imposing specific award conditions, disallowing costs, withholding future awards including the possibility of suspending or terminating the award.



Important NIH Other Support FAQ's (Cont.)

- **A researcher at my institution has a 9-month appointment. They spend two months at a University outside of the United States during the summer conducting research under a foreign award. Does this count as Other Support?**

Yes. Available resources in support of and/or related to an investigator's research endeavors should be disclosed even if they relate to work that is performed outside of a researcher's appointment period.



Important NIH Other Support FAQ's (Cont.)

- **Are the costs of translating foreign contracts allowable on NIH grants as a direct cost?**

The costs associated with translations of foreign contracts for inclusion in Other Support submissions are not typically allocable to a specific NIH grant project and are therefore not allowable as a direct cost. NIH recommends that institutions consider including such costs in their negotiations for indirect cost reimbursement.



Important NIH Other Support FAQ's (Cont.)

- **Contracts, grants or other agreements submitted as supporting documentation may contain confidential and/or sensitive information. Can recipients redact confidential/sensitive information prior to submitting?**

NIH needs access to all information necessary to make an informed judgement about possible scientific, budgetary, or commitment overlap and to make an informed judgment about management of possible significant financial conflicts of interest. NIH handles confidential and sensitive information in accordance with our cybersecurity requirements and requires submission of complete documentation.



Important NIH Other Support FAQ's (Cont.)

- If a researcher indicates that they do not have a “formal” agreement in place, is supporting documentation still required for that foreign appointment, affiliation, and/or employment with a foreign institution?

Yes. If the individual is performing activities under any active contract, grant or other agreement, it must be provided as supporting documentation. **UNC translation** – if a formal agreement is not in place, other supporting documentation should be provided, such as an email finalizing the appointment, etc.



NIH Biosketch Changes

- Form Instruction Update
- NIH Biosketch Significant Changes
- Biosketch Resources



NIH Biosketch – Form Instructions Update

- New Biosketch updates are required for all submissions on or after January 25, 2022.
- These instructions will be incorporated into the NIH Application Form Instructions with the next update.
 - NIH "FORMS-G": NOT-OD-21-169
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-169.html>



Biosketch – Significant Changes

- **Personal Statement**
 - May now include ongoing and completed research projects from the past three years that you want to draw attention to.
 - Previously known as research support.
 - All other requirements remain same.



Biosketch – Significant Changes

- **Positions, *Scientific Appointments*, and Honors**
 - This section is renamed
 - You must list all **current** positions and scientific appointments, both domestic and foreign, including affiliations with foreign entities or governments in ***reverse*** chronological order (most recent first).
 - **If the scientific appointment is paid and is with a foreign institution, it must also be listed on the Other Support documentation.**



Biosketch – Significant Changes

- **Section D. Scholastic Performance**
 - Section D is now only present on the fellowship version of the Biosketch.



Biosketch – Resources

- Biosketch Format Pages, Instructions and Samples available online at:

- <https://grants.nih.gov/grants/forms/biosketch.htm>

[m](https://grants.nih.gov/grants/forms/biosketch.htm)

OMB No. 0501-001 and 0501-002 (Rev. 10/2010) Approved Through 12/31/2022

BIOGRAPHICAL SKETCH
Provide the following information for the biographical sketch of the principal investigator.
Follow the format for each person. DO NOT EXCEED FIVE PAGES.

NAME: Hunt, Morgan Casey

OR A COMMONS USER NAME (optional, e.g., agency login): huntmc1

POSITION TITLE: Associate Professor of Psychology

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

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date (MM/YYYY)	FIELD OF STUDY
University of California, Berkeley	BS	05/2003	Psychology
University of Vermont	PHD	05/2009	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/2013	Public Health and Epidemiology

A. Personal Statement

I am an Associate Professor of Psychology, and my research is focused on neuropsychological changes associated with substance use disorders. 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 substance use disorders. 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 older people with substance use disorders, and by establishing strong ties with community providers that will make it possible to recruit and track participants over time as documented in the following publications. In addition, I successfully administered the projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2015-2016, my career was disrupted due to family obligations. However, upon returning to the field, I immediately resumed my research projects and collaborations and successfully completed for NIH support. In summary, I have the expertise, leadership, training, expertise, and motivation necessary to successfully carry out the proposed research project.

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

R01 DA042367
Hunt (PI)
08/01/16-08/31/21
Health trajectories and behavioral interventions among older people with substance use disorders

R01 MH022731
Meayla (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression, and substance use among older adults

R21 AA088075

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

Citation:

1. Meayla, R.J. & Hunt, M.C. (2015). Independent living, physical disability and substance use among older adults. *Psychology and Aging, 29*(4), 10-22.
2. Hunt, M.C., Jensen, J.L., & Crenshaw, W. (2018). Substance use and mental health among community-dwelling older adults. *International Journal of Geriatric Psychiatry, 24*(9), 1124-1135.
3. Hunt, M.C., Woodhull, S.A., & Meayla, R. (2018). Predicting the substance use treatment needs of an aging population. *American Journal of Public Health, 108*(2), 236-245. PMID: PMC6192292
4. Meayla, R. & Hunt, M.C. (2020). Randomized clinical trial of cotinine in older people with nicotine use disorder. *Age and Aging, 38*(2), 9-23. PMID: PMC6900294

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

- 2021 – Present Associate Professor, Department of Psychology, Washington University, St. Louis, MO
2020 – Present Adjunct Professor, McGill University Department of Psychology, Montreal, Quebec, Canada
- 2018 – Present NIH Risk, Adult Substance Use Disorder Study Section, member
2015 – 2017 Consultant, Coastal Psychological Services, San Francisco, CA
2014 – 2021 Assistant Professor, Department of Psychology, Washington University, St. Louis, MO
2014 – 2015 NIH Peer Review Committee, Psychology of Aging, ad hoc reviewer
2014 – Present Board of Advisors, Senior Services of Eastern Missouri
2013 – 2014 Lecturer, Department of Psychology, Middlebury College, Middlebury, VT
2011 – Present Associate Editor, *Psychology and Aging*
2009 – Present Member, American Geriatrics Society
2009 – Present Member, Gerontological Society of America
2009 – 2013 Fellow, Intramural Research Program, National Institute on Drug Abuse, Baltimore, MD
2006 – Present Member, American Psychological Association

Honors

- 2020 Award for Best in Interdisciplinary Ethnography, *International Ethnographic Society*
2019 Excellence in Teaching, Washington University, St. Louis, MO
2018 Outstanding Young Faculty Award, Washington University, St. Louis, MO

C. Contributions to Science

1. My early publications directly addressed the fact that substance use 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 concerns about a substance use disorder. These publications document the emerging concern and guide primary care providers and geriatric mental health providers to recognize symptoms, assess the nature of the behavior, and apply the necessary interventions. By providing evidence and simple clinical approaches, this body of work has changed the standards of care for older adults with substance use disorders and will continue to improve substance in relevant medical settings well into the future. I served as the primary investigator or co-investigator in all of these studies.
 - a. Gajewski, J., Shaft, B.M., Meayla, R., & Hunt, M.C. (2013). Community based participatory research with late-life substance use disorder. *American Journal of Alcohol and Drug Abuse, 15*(3), 222-238.

- b. Shaft, B.M., Hunt, M.C., Meayla, R., & Venturi, R. (2014). Policy implications of genetic transmission of alcohol and drug use in women who do not use drugs. *International Journal of Drug Policy, 30*(5), 46-58.
- c. Hunt, M.C., Marks, A.E., Shaft, B.M., Meayla, R., & Jensen, J.L. (2015). Early-life family and community characteristics and late-life substance use. *Journal of Applied Gerontology, 20*(2), 26-37.
- d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W., & Balesaga, A. (2018). Community-based intervention strategies for reducing alcohol and drug use in older adults. *Addiction, 104*(9), 1438-1495. PMID: PMC5000292

2. In addition to the contributions described above, with a team of collaborators, I directly documented the effectiveness of various intervention models for older people with substance use disorders and demonstrated the importance of social support networks. These studies emphasized contextual factors in the etiology and maintenance of substance use disorders and the disruptive potential of networks in substance use treatment. This body of work also discusses the prevalence of alcohol and amphetamine use in older adults and how networking approaches can be used to mitigate the effects of these disorders.
 - a. Hunt, M.C., Meayla, R., & Jensen, J.L. (2015). The effect of social support networks on mortality among older adults with substance use disorders. *Journal of the American Geriatrics Society, 57*(4), 15-23.
 - b. Hunt, M.C., Four, B., Marks, A.E., Meayla, R., & Jensen, J.L. (2018). Aging out of methadone treatment. *American Journal of Alcohol and Drug Abuse, 15*(5), 134-145.
 - c. Meayla, R. & Hunt, M.C. (2020). Randomized clinical trial of cotinine in older people with nicotine use disorders. *Age and Aging, 38*(2), 9-23. PMID: PMC6900294
3. Methadone maintenance has been used to treat people with substance use disorder 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. Older adults were shown, in carefully constructed ethnographic studies, to be especially responsive to balanced 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.

- a. Hunt, M.C. & Jensen, J.L. (2013). Morbidity and personal assets with substance use disorders. *Journal of the Geriatrics, 62*(4), 45-51.
- b. Hunt, M.C. & Pour, B. (2015). Methadone treatment and personal assessment. *Journal Drug Abuse, 42*(5), 15-28.
- c. Meayla, R. & Hunt, M.C. (2018). The use of various nicotine delivery systems by older people with nicotine use disorder. *Journal of Aging, 54*(1), 24-41. PMID: PMC6912994
- d. Hunt, M.C., Jensen, J.L., & Meayla, R. (2020). Aging and substance use disorder: ethnographic profiles of older people with substance use disorder. NY, NY: W. W. Norton & Company.

Complete List of Published Work in My Bibliography:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6900292/bibliography/public>



THE UNIVERSITY
of NORTH CAROLINA
at CHAPEL HILL

Biosketch – Resources Cont.)

NOTE: Question and answer are pulled directly from the NIH FAQs for Biosketch.

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

The Biosketch must include all current positions and scientific appointments.



NIH Useful Information Links

NIH Notice NOT-OD-21-073 Upcoming Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html>

NIH Notice NOT-OD-21-110 Implementation of Changes to the Biographical Sketch and Other Support Format Page

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-110.html>

NIH updated format pages and instructions for **Other Support**

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

NIH updated format pages and instructions for the **Biosketch**

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

NIH FAQs – Other Support

<https://grants.nih.gov/faqs#/other-support-and-foreign-components.htm>

NIH FAQs – Biosketch

https://grants.nih.gov/grants/policy/faq_biosketches.htm

