Update: New NIH Requirements for 2016 Grant Proposals

What are they and how do I get it right?

21 March 2016

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SCHOOL OF MEDICINE
UNIVERSITY OF COLORADO
ANSCHUTZ MEDICAL CAMPUS

Outline

- Overview of upcoming NIH changes for 2016
- Rigor and Transparency
- Vertebrate Animals
- Biosketch clarifications
- Summary of other changes

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Overview:
Timeline of recent and upcoming changes

New Biosketch Format
5 pages
Scientific accomplishments
Link to publication list

Phase 1
Rigor and Transparency
Vertebrate Animals
Definition of Child (under 18 yrs)
Research Training
Others

Phase 2
Switch to application FORMS-D
Phase 1 changes extended to T and F series
(Rigor, Vertebrate Animals)
Inclusion forms
Research training (additional changes)
Appendix policy
New font guidelines
Biosketch clarifications
Others

May 25, 2015

January 25, 2016

May 25, 2016

See NOT-OD-15-032, December 5, 2015 (new biosketch)
and NOT-OD-16-004, October 13, 2015 (summary of 2016 changes)

Outline

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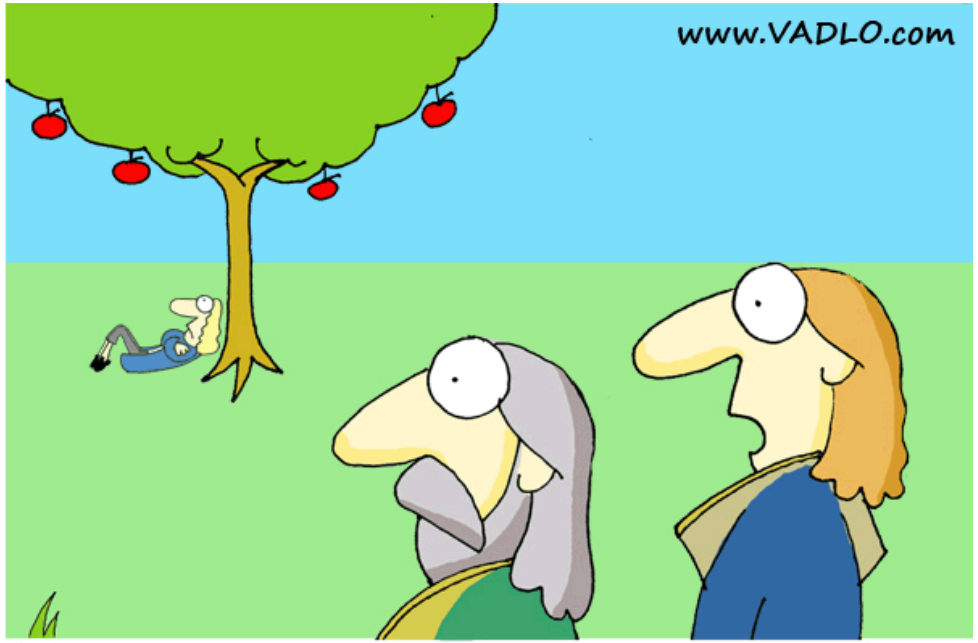


"Reviewers have asked him to reproduce the experiment."

Newton cartoon source: http://vadlo.com/cartoons.php?id=2

The Research Community's Call for Better Reporting and Reproducibility

Many publications have noted trouble with lack of reproducibility, transparency when reporting research findings…

The Research Community's Call for Better Reporting and Reproducibility

How to Make More Published Research True

John P. A. Ioannidis[1,2,3,4]*

PLOS Medicine | www.plosmedicine.org

October 2014 | Volume 11 | Issue 10 | e1001747

Believe it or not: how much can we rely on published data on potential drug targets?

NATURE REVIEWS | DRUG DISCOVERY

Florian Prinz, Thomas Schlange and Khusru Asadullah

Review Article Biomolecular Detection and Quantification 2 (2014) 35–42

The reproducibility of biomedical research: Sleepers awake!

Stephen A. Bustin*

Faculty of Medical Science, Postgraduate Medical Institute, Anglia Ruskin University, Chelmsford CM1 1SQ, UK

The Scientist » The Nutshell

Nature Announces Reproducibility Initiative

The journal is sharpening its review of life science papers and giving authors additional space to document more detailed methods.

By Kate Yandell | April 25, 2013

The Economist World politics Business & finance Economics Science & technology Culture

Unreliable research

Trouble at the lab

Scientists like to think of science as self-correcting. To an alarming degree, it is not

Oct 19th 2013 | From the print edition Timekeeper

NIH plans to enhance reproducibility

Francis S. Collins and **Lawrence A. Tabak** discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

A growing chorus of concern, from scientists and laypeople, contends that the complex system for ensuring the reproducibility of biomedical research is failing and is in need of restructuring[1,2]. As leaders of the US National Institutes of Health (NIH), we share this concern and here explore some of the significant interventions that we are planning.

Science has long been regarded as 'self-correcting', given that it is founded on the replication of earlier work. Over the long term, that principle remains true. In the shorter term, however, the checks and balances that once ensured scientific fidelity have been hobbled. This has compromised the ability of today's researchers to reproduce others' findings.

Let's be clear: with rare exceptions, we have no evidence to suggest that irreproducibility is caused by scientific misconduct. In 2011, the Office of Research Integrity of the US Department of Health and Human Services pursued only 12 such cases[3]. Even if this represents only a fraction of the actual problem, fraudulent papers are vastly

Rigor and Transparency: new requirements

- 4 new areas of focus
- New instructions for Research Strategy
- New attachment: “Authentication of Key Biological and/or Chemical Resources”
- New review criteria

See NOT-OD-16-011 and NOT-OD-16-012

Rigor and Transparency: 4 areas of focus

1) **Scientific Premise** for the proposed research
2) **Rigorous Experimental Design** for robust and unbiased results
3) Consideration of **Relevant Biological Variables**
4) **Authentication** of key biological and/or chemical resources

This applies to the full spectrum of research, from basic to clinical.

**activity code exceptions can be found in the notice*

See NOT-OD-16-011 and http://grants.nih.gov/reproducibility/index.htm

Rigor and Transparency: New Instructions for Research Strategy

- **Significance**: "Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application."
- **Approach**: "Describe the experimental design and methods proposed and how they will achieve robust and unbiased results."
- **Approach**: "Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans…."

See NOT-OD-16-011, NOT-OD-15-102

What is Scientific Premise?

- “Scientific Premise = Research that is used to form the basis for the proposed research questions”
- “Describe general strengths and weaknesses of prior research that is crucial to support the application”
- “Could include attention to rigor of previous experimental designs…”

http://grants.nih.gov/reproducibility/index.htm

Premise versus Significance

- Significance:
  - Importance of problem
  - Barriers to progress
  - How project will improve knowledge
  - How field will change after project
- Premise:
  - Retrospective consideration of the foundation for the application

http://grants.nih.gov/reproducibility/faqs.htm#4825

Suggested structure to address Premise

Within Significance subsection of Research Plan:

Include subheading: "**Scientific Premise**"

- 1-2 paragraphs describing foundation of application
- Discuss current state of knowledge in the area
- Include brief description of your preliminary data (strengths)
- Describe knowledge gap that your proposal will address

What is Scientific Rigor?

- “Strict application of scientific method to ensure robust and unbiased experimental design, methodology, analysis, etc…”
- “Includes full transparency in reporting experimental details…”

http://grants.nih.gov/reproducibility/index.htm

Elements of Rigorous Experimental Design

- Appropriate controls
- Replication of experiments
- Randomization
- Blinding
- Sample size/study power
- Statistical methods
- Missing data (plan to address)
- Others as appropriate

Rigor Example 1

- Aim 3: Male and female mice will be randomly allocated to experimental groups at age 3 months. At this age the accumulation of CUG repeat RNA, sequestration of MBNL1, splicing defects, and myotonia are fully developed. The compound will be administered at 3 doses (25%, 50%, and 100% of the MTD) for 4 weeks, compared to vehicle-treated controls. IP administration will be used unless biodistribution studies indicate a clear preference for the IV route. A group size of n = 10 (5 males, 5 females) will provide 90% power to detect a 22% reduction of the CUG repeat RNA in quadriceps muscle by qRT-PCR (ANOVA, α set at 0.05). The treatment assignment will be blinded to investigators who participate in drug administration and endpoint analyses. This laboratory has previous experience with randomized allocation and blinded analysis using this mouse model [refs]. Their results showed good reproducibility when replicated by investigators in the pharmaceutical industry [ref].

http://grants.nih.gov/reproducibility/index.htm

Rigor Example 2a

- Aim 1: Primary screen: In this high throughput screening assay, we combined the SMN promoter with exons 1-6 and an exon 7 splicing cassette in a single construct that should respond to compounds that increase SMN transcription, exon 7 inclusion, or potentially stabilize the SMN RNA or protein [refs]. The details of the assay and the SMN2-luciferase reporter HEK393 cell line have been extensively validated [refs]. Each point is run in triplicate, the compounds are tested on three separate occasions, and the results are averaged to give an EC50 with standard deviation. Secondary screen: …We analyze SMN protein levels by dose response in quantitative immunoblots with statistical analysis by one-way ANOVA with post-hoc analysis using Dunnett or Bonferroni, as appropriate.

http://grants.nih.gov/reproducibility/index.htm

Rigor Example 2b

- Aim 2: Each set of compounds will include a blinded negative control compound that has been determined to be inactive and that is solubilized in the same manner as test compounds. Mice will be randomly assigned within a litter, and data will be collected and submitted to the PI. For compounds that demonstrate extended survival, the PI will be sure to have these tested in {the collaborators'} labs, and data will be merged and evaluated. To calculate the number of the experimental mice, we will perform an SSD sample size power analysis to ensure that the appropriately minimal number of mice is used in each experimental context. Typically for each compound in life span studies, we will need ~20 SMA animals in the treated group; ~20 SMA animals in the vehicle treated group; ~20 SMA animals in the untreated group. If we can administer the compound in aqueous solution without expedient, the vehicle and untreated groups might be combined, as these should have identical survival. Therefore, no more than 80 SMA animals will be needed per compound.

http://grants.nih.gov/reproducibility/index.htm

Suggested structure to address Rigor

Within Approach subsection of Research Plan:

- Include subheading(s): “**Rigorous Experimental Design**”
- Highlight key elements of rigor (which may be woven through your aims)
- Make it easy for reviewers to find and evaluate

What are Relevant Biological Variables?

- Sex (studies on only one sex must be well justified)
- Age
- Weight
- Underlying health conditions

- How to address? Again, make it easy for reviewers…
- Subsection in Research Plan: “Consideration of Relevant Biological Varibles”

What is Authentication of Key Biological and/or Chemical Resources?

- Cell lines
- Specialty chemicals
- Antibodies
- Other biologics

- May differ from lab to lab or over time
- Qualities that could influence research data
- Integral to proposed research

http://grants.nih.gov/reproducibility/index.htm

New Attachment: Authentication

"Authentication of Key Biological and/or Chemical Resources"

Describe methods to ensure the identity and validity of key biological and/or chemical resources (may include cell lines, specialty chemicals, antibodies, other biologics).

Do not put preliminary data and other methods in this section

See NOT-OD-16-011

Authentication Attachment Guidance

AUTHENTICATION OF KEY BIOLOGICAL AND CHEMICAL RESOURCES (1 page)

All key resources for this proposal will be authenticated to enhance the reproducibility of our results, as appropriate and according to NIH policy.

Key Biological Resources that will be utilized in this proposal include:

Cell lines: xxxxx

Transgenic mouse strains: xxxxxx

Antibodies: xxxxx

Cell lines will be validated via…<describe methods, including short tandem repeat (STR) analysis if appropriate>

Transgenic mouse strains are validated by...<describe techniques for genotyping, etc>

Antibodies will be confirmed by…<describe methods>

All other antibodies and reagents we anticipate using for the proposed work are commercially available and validated by the companies that provide them. Other resources used in this proposal will be standard laboratory reagents. Should we need to generate or obtain additional unique resources in the course of this proposal, they will be authenticated using methods similar to those described above, as appropriate.

NOTE: NO additional text or preliminary data; do NOT circumvent page limits of your 12 page research plan.

CELL BIOLOGY

Fixing problems with cell lines

Technologies and policies can improve authentication

By **Jon R. Lorsch[1]*, Francis S. Collins[2], Jennifer Lippincott-Schwartz[3,4]**

Despite the important role of cell culture in the study of biology and medicine, evidence has accumulated that cell lines are frequently misidentified or contaminated by other cells or microorganisms. This can be a substantial problem in many fields, such as cancer research, where drugs are initially tested using a cell line derived from the targeted type of tumor (*1*). If a drug is tested on the wrong cell line, research can lead to unreliable results, and discovery of effective treatments can be delayed. Even in basic research, use of mistaken cell lines can hinder progress because of variations in cell behavior among different cell types. Given these concerns, developing corrective measures for cell line misidentification and contamination warrants renewed attention.

POLICY

Since the 1960s, more than 400 widely used cell lines worldwide have been shown to have been misidentified (*2*, *3*). Cells originally thought to have been derived from one tissue type have later been found to be from a different tissue. In some cases, even the species of the cells has been misidentified. A 2011 study of 122 different head and neck cancer cell lines revealed that 37 (30%) were misidentified (*4*). Analyses of a variety of tissue culture collections and cells sent to repositories for curation and storage from labs in the United States, Europe, and Asia suggest that at least 15% of cell lines are misidentified or contaminated (*4*, *5*).

Misidentified cell lines can create problems at many levels of biomedical research. For example, studies using just two misidentified cell lines were included in three grants funded by the U.S. National Institutes of Health (NIH), two clinical trials, 11 patents, and >100 papers (*6*). Nonetheless, the need for validation and accurate reporting of cell line identity does not appear to be widely recognized by researchers; a 2013 study found that fewer than half of cell lines were unambiguously identified in published studies (*7*).

A number of factors contribute to the problems of cell line misidentification and contamination. For example, inadvertently using a pipette more than once when working with different cell lines in culture can lead to cross contamination. If the contaminating cell line divides more rapidly than the original cells, it can quickly dominate the population, changing the identity of the culture. This event often goes undetected because cells from dif-

ILLUSTRATION: PETER ANDMARIA HOEY/WWW.PETERHOEY.COM

Corrected 19 December, 2014; see full text.

Cell line validation

- One method uses short tandem repeat analysis (STR)
- Rapid, inexpensive, can use online databases to compare STR fingerprints to verify cell line identity for common human cell lines

- Barbara Davis Center core facility provides cell line authentication services using Promega kit with 16 STR loci
- Investigator provides DNA or cells, receives results in ~1 week.
- Cost is $65 per sample, or $120 with match analysis
- Contact Randy Wong (Randall.wong@ucdenver.edu) for information

Barbara Davis Center
Molecular Biology Service Center

OMG!

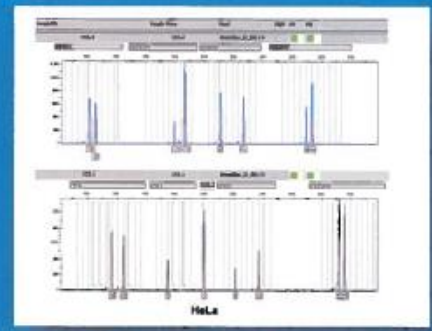
They're HeLa Cells!

...between 18 and 36% of cell lines might be misidentified or cross contaminated, most commonly by HeLa cells...
Hughes, P., et al. (2007) BioTechniques 43, 575-86.

Make sure you are working with the right human cell line.

Authenticate!

How do I know?



The BDC BioResources Core Facility did the STR profile and told me so!

- NIH is expecting authentication for 2016 applications.
  For grant applications due on January 25, 2016 and beyond, grantees will be required to authenticate key biological resources, including cell lines.
- More and more journals are requiring cell line authentication prior to publication
  e.g. AACR strongly encourages the authentication of cell lines used in the research reported in its journals.
  -AACR Journals, Instructions to Authors

Learn More About the BDC BioResources Core Facility's **Cell Line Authentication Service,** Contact:

Randy Wong
303.724.6825
randall.wong@ucdenver.edu

Rigor and Transparency: New Scored Review Criteria

- **Significance**: “Is there a strong scientific premise for the project?”

- **Approach**: “Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?”

- **Approach**: “Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?”

See NOT-OD-16-011

Additional Review Considerations

- **Authentication of Key Biological and/or Chemical Resources**: “For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.”

See NOT-OD-16-011

Summary of Rigor Requirements

	Scientific Premise	**Rigorous Experimental Design**	**Relevant Biological Variables**	**Authentication of Key Resources**
Where to address?	Significance	Approach	Approach	New Attachment
Scored?	Yes	Yes	Yes	No, but…

http://grants.nih.gov/reproducibility/index.htm

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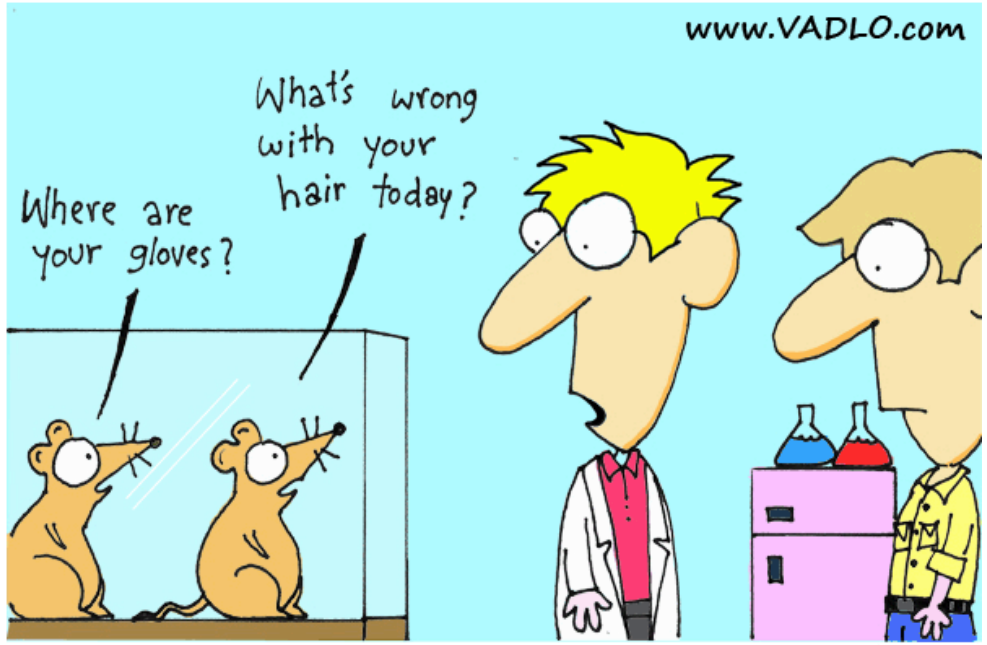

"At first I was happy I made smart transgenic mice.."

Smart mice cartoon source: http://vadlo.com/cartoons.php?id=42

Simplification of Vertebrate Animals Section

Changes remove redundancy with IACUC review

Things you DO still need:

- **Description of procedures** (species, strains, ages, sex, total numbers)
- **Justifications** (appropriateness of species for proposed research
- **Minimization of pain and distress** (describe interventions to minimize)
- **Euthanasia** (state whether consistent with AVMA guidelines)

Things you NO LONGER need:

- Description of **veterinary care**
- Justification for the **number of animals**
- A description and justification of the **method of euthanasia** is required only if the method is not consistent with AVMA Guidelines

See NOT-OD-16-006

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New Biosketch Format (May 25, 2015)

- 5 page limit (increased from 4)
- Scientific accomplishments (describe up to 5)
- Link to publications

OMB No. 0925-0001 and 0925-0002 (Rev. 10/15 Approved Through 10/31/2018)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key 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): huntmc

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.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of California, Berkeley	B.S	05/1990	Psychology
University of Vermont	Ph.D.	05/1996	Experimental Psychology
University of California, Berkeley	Postdoctoral	08/1998	Public Health and Epidemiology

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 projects (e.g. staffing, research protections, budget), collaborated with other researchers, and produced several peer-reviewed publications from each project. As a result of these previous experiences, I am aware of the importance of frequent communication among project members and of constructing a realistic research plan, timeline, and budget. The current application builds logically on my prior work. During 2005-2006 my career was disrupted due to family obligations. However, upon returning to the field I immediately resumed my research projects and collaborations and successfully competed for NIH support.

1. Merryle, R.J. & Hunt, M.C. (2004). Independent living, physical disability and substance abuse among the elderly. Psychology and Aging, 23(4), 10-22.
2. Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among community-dwelling elderly. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
3. Hunt, M.C., Wiechelt, S.A. & Merryle, R. (2008). Predicting the substance-abuse treatment needs of an aging population. American Journal of Public Health, 45(2), 236-245. PMCID: PMC9162292 Hunt, M.C., Newlin, D.B. & Fishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.

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
2007- 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
2003-05 NIH Peer Review Committee: Psychobiology of Aging, ad hoc reviewer
2007-11 NIH Risk, Adult Addictions Study Section, members

Honors

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

C. Contribution to Science

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.
   a. Gryczynski, J., Shaft, B.M., Merryle, R., & Hunt, M.C. (2002). Community based participatory research with late-life addicts. American Journal of Alcohol and Drug Abuse, 15(3), 222-238.
   b. Shaft, B.M., Hunt, M.C., Merryle, R., & Venturi, R. (2003). Policy implications of genetic transmission of alcohol and drug abuse in female nonusers. International Journal of Drug Policy, 30(5), 46-58.
   c. Hunt, M.C., Marks, A.E., Shaft, B.M., Merryle, R., & Jensen, J.L. (2004). Early-life family and community characteristics and late-life substance abuse. Journal of Applied Gerontology, 28(2),26-37.
   d. Hunt, M.C., Marks, A.E., Venturi, R., Crenshaw, W. & Ratonian, A. (2007). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. Addiction, 104(9), 1436-1606. PMCID: PMC9000292

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.
   a. Hunt, M.C., Merryle, R. & Jensen, J.L. (2005). The effect of social support networks on morbidity among elderly substance abusers. Journal of the American Geriatrics Society, 57(4), 15-23.
   b. Hunt, M.C., Pour, B., Marks, A.E., Merryle, R. & Jensen, J.L. (2005). Aging out of methadone treatment. American Journal of Alcohol and Drug Abuse, 15(6), 134-149.
   c. Merryle, R. & Hunt, M.C. (2007). Randomized clinical trial of cotinine in older nicotine addicts. Age and Ageing, 38(2), 9-23. PMCID: PMC9002364

3. Methadone maintenance has been used to treat narcotics addicts for many years but I led research that has shown that over the long-term, those in methadone treatment view themselves negatively and they gradually begin to view treatment as an intrusion into normal life. Elderly narcotics users were shown in carefully constructed ethnographic studies to be especially responsive to tailored social support networks that allow them to eventually reduce their maintenance doses and move into other forms of therapy. These studies also demonstrate the policy and commercial implications associated with these findings.
   a. Hunt, M.C. & Jensen, J.L. (2003). Morbidity among elderly substance abusers. Journal of the Geriatrics, 60(4), 45-61.
   b. Hunt, M.C. & Pour, B. (2004). Methadone treatment and personal assessment. Journal Drug Abuse, 45(5), 15-26.
   c. Merryle, R. & Hunt, M.C. (2005). The use of various nicotine delivery systems by older nicotine addicts. Journal of Ageing, 54(1), 24-41. PMCID: PMC9112304
   d. Hunt, M.C., Jensen, J.L. & Merryle, R. (2008). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/collections/public/1PgT7IEFIAJBtGMRDdWFmjWAO/?sort=date&direction=ascending

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 AA998075 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

See NOT-OD-15-032

Biosketch Clarifications

- A URL for a publication list is optional and must be to a government website (.gov) like My Bibliography
- Allowing publications and research products to be cited in both the personal statement and the contributions to science sections
- Graphics, figures and tables are **not allowed**

See NOT-OD-16-004

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Summary of Other Changes (1)

Effective for January 25, 2016 due dates:

- **Definition of Child** = under 18 years old (previously under 21)
- **Research Training**: updated instructions

See NOT-OD-16-004

Summary of Other Changes (2)

Effective for May 25, 2016 due dates:

- **Use new FORMS-D application forms**
- **Rigor and Transparency, Vertebrate Animals Changes extended** to institutional training and individual fellowship applications
- **Research Training**: new table format
- **Inclusion Forms**: new Inclusion Enrollment Report form replaces old Planned and Cumulative Inclusion Enrollment Reports
- **New PHS Assignment Request Form**: Specify NIH institute preference, study section, reviewers in conflict, expertise needed to review.
- **New Fonts**: additional fonts allowed
- **Appendix Policy**: changes to be announced spring 2016

See NOT-OD-16-004

Thank you!

Please provide feedback and
share your experiences during upcoming peer review

Jennifer.T.Kemp@ucdenver.edu

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RESEARCH OFFICE

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Resources Available

Grant Writing Assistance
Proposal development, writing, and editing support

DOM Research Funding Programs
Grants from the DOM supporting innovative research

Divisional Grant Support
Pre- and post-award support augmenting divisional grant management

Clinical Research Support
Key resources and access to DOM-specific regulatory assistance

Research Development
Identification and targeting of funding sources beyond the NIH

Application Tools & Resources
Tools and templates to streamline grant application processes

Management of Research Space
Requests for additional research, storage or office space

Department of Medicine
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