Welcome

Spartan RAN

Research Administrators Network

Biannual Meeting

April 23rd, 2015

Before we get started, please follow the instructions on your table! ©

We're "Going Green in 2015", so paper handouts will not be provided.

Presentation materials are available on the SPROUT Website:

https://sprout.vprgs.msu.edu/spartan-ran/

Spartan RAN

Research Administrators Network

April 23rd, 2015

Agenda

- Updates from November 2014 Meeting
- Guest Speakers Kristen Burt & Sally Light (Office of Regulatory Affairs)
- Networking Activity
- New Business/Hot Topics
- Upcoming Training & Events

Planning Committee: Barb Miller (Chair), Dania Diaz, Adriana Feldpausch, Jessica Hauptman, Jennifer Lafferty & Sue Sipkovsky

Presentation Materials Available on the SPROUT Website:

https://sprout.vprgs.msu.edu/spartan-ran/

Updates

From November 2014 Meeting

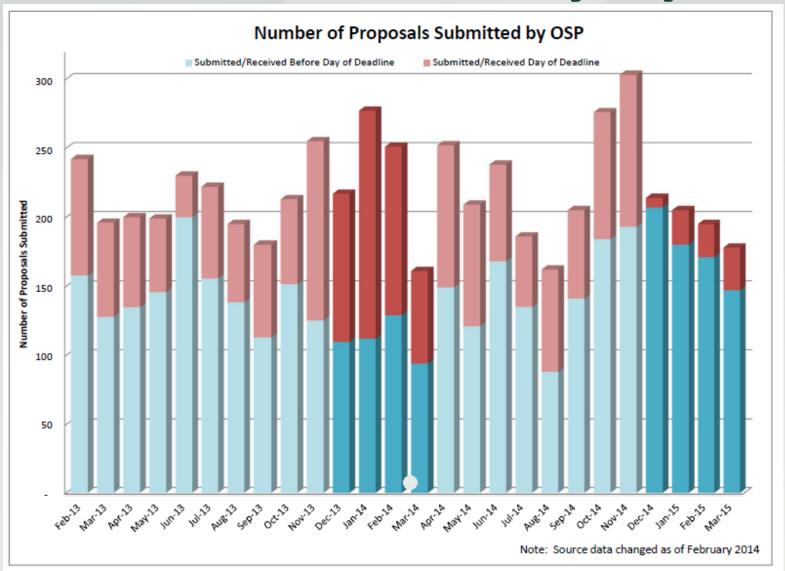
- MSU Proposal Deadline Policy
- Activity Log
- Conflict of Interest (COI)
- Uniform Guidance (UG)

Katie Cook, Director, Office of Sponsored Programs (OSP) Evonne Pedawi, Asst. Director, Contract and Grant Admin. (CGA)

MSU Deadline Policy Update

- Three Month Review:
 - At-Risk: 35 proposals (5%)
 - Late: 132 proposals (20%)
 - On Time: 369 proposals (55%)
 - After the Fact: 37 proposals (5%)
- Current known Results:
 - Reduced Deadline Day submissions
 - Larger percentage of proposals submitted to OSP/Sponsor with more time prior to deadline
- Still working towards:
 - Continued reduction of Late/At-Risk/After the Fact proposals

MSU Deadline Policy Update



Activity Log Update

Viewer Guide:



Conflict of Interest Update

- 62% of those required to complete COI Disclosures in 2015 are in compliance.
- Annual disclosures of significant financial interests were due for faculty and academic staff on February 28th and must be completed as soon as possible.
- Please be aware that even if your faculty and academic staff do not have any sponsored research or external financial interests to disclose, they still must certify through the disclosure system that they do not have personal interests related to their institutional responsibilities.
- Non-compliance Notifications were sent to Deans earlier this week.
- For more info on COI: http://coi.msu.edu
- Questions: fcoiio@msu.edu or 517.884.7000

Uniform Guidance Update

 Active and effective for new awards and modifications with new money.

Procurement portion of UG is still in process.

Future Guidance:

For the most current information:

http://www.ecfr.gov/cgi-bin/text-idx?SID=f8f3337301806d4f6aae306c170f2d6e&node=pt2.1.200&rgn=div5

Guest Speakers

Office of Regulatory Affairs

Kristen Burt – Human Research Protection

Sally Light – Animal Care and Use

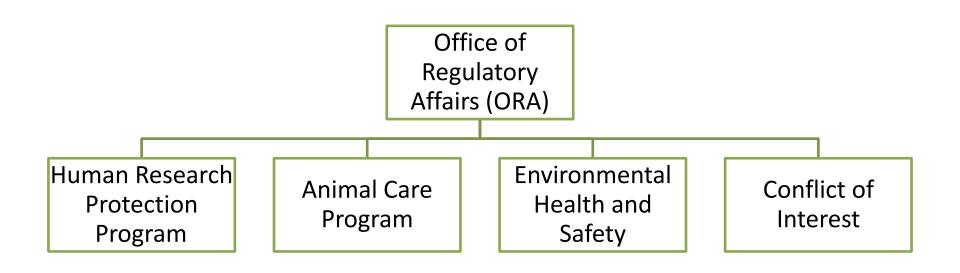


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Kristen Burt Office of Regulatory Affairs April 23, 2015

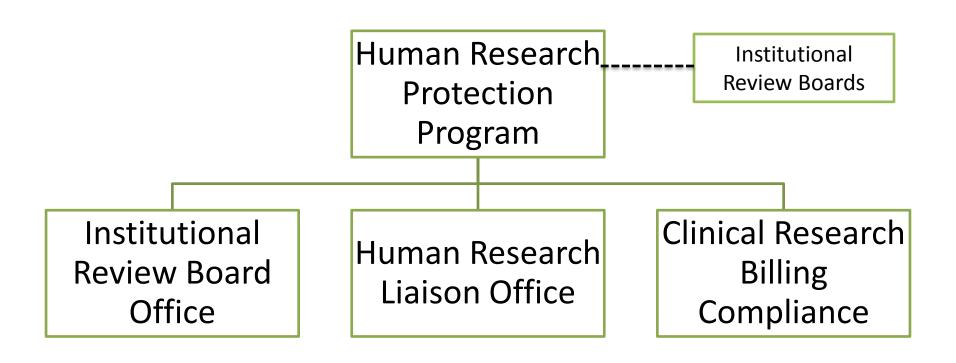


Office of Regulatory Affairs





Human Research Protection Program



Submit

• Researcher Submits Application

Pre-Review • IRB staff reviews submission for completeness.

Review

- · Exempt: IRB staff, chair, or reviewer
- Expedited: IRB chair or experienced reviewer(s)
- Full Board: Primary IRB reviewers, convened IRB

Q&A

- Questions are provided to researcher(s) to respond and if needed, submit modified documents (e.g. informed consent)
- Process repeats as needed

Decision

- Dependent on review type
 - Exempt: Determined exempt, not exempt
- Expedited: Approved
- Full Board: Approved, Denied, Tabled, Conditional Approval



Exempt

- If involvement of human subjects will only be in one or more of the exempt categories, research activities are exempt from the regulations
- Reviewed and determination made by IRB staff and/or IRB chair

Expedited

- If research study meets one or more of the *expedited categories* and is *no more than minimal risk*, the project can undergo expedited review
- ** Regulations for the protection of human subjects apply
- Project does not need to be reviewed and approved by a convened IRB
- Reviewed and approved by IRB chair or by one or more experienced reviewers designated by the IRB chair

Full Board

- More than minimal risk or research that does not fit into an expedited category
- ** Regulations for the protection of human subjects apply
- Reviewed and approved by convened IRB



Exempt Life Cycle (Overview)

 Review and determination before human research activities begin

Initial Review

Report changes that may impact exempt status

 When there are proposed modifications that change exempt category or review level or more than minimal risk E.g., unanticipated problems that may involve risks, subject complaints

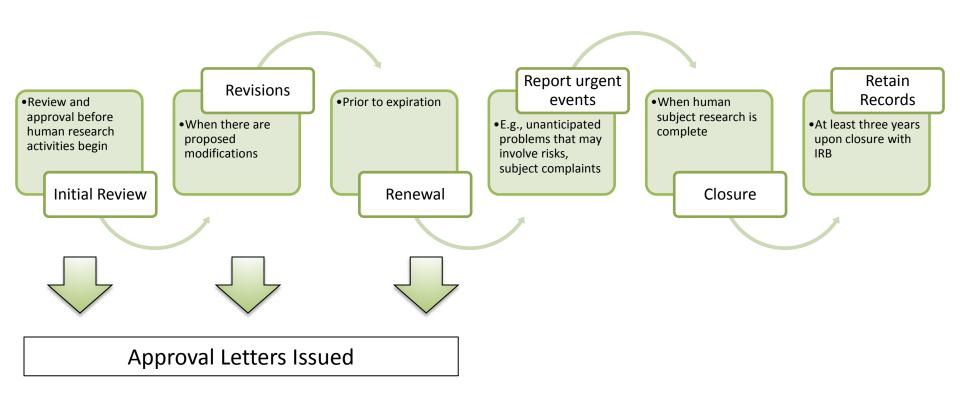
Report urgent events

Retain Records

 At least three years upon completion of human research

Determination Letter Issued

Expedited or Full Board Life Cycle (Overview)





New Investigator Resources

- Contact the IRB early
- Transfer of IRB projects
- Access to HRPP online system
- HRPP training
- HRPP website resources
 - "Getting Started"
 - Informed consent templates
 - Contacts



Research Participant Payments

- Disbursement Vouchers
- Cash Advances (MSU Manual of Business Procedures, Section 61: Cash Advances: Travel and Research Participants)

Questions?

HRPP Office Location

- Olds Hall, 408 West Circle Drive, Room 207, East Lansing, MI 48824
- Monday Friday, 8:00 A.M. 5:00 P.M. (office hours)

Phone

• 517-355-2180

Fax

• 517-432-4503

Email

- <u>irb@ora.msu.edu</u> (IRB project specific questions, website or training suggestions, FAQs, presentations)
- <u>irbdocs@ora.msu.edu</u> (IRB application and attachment submissions)
- <u>hrl@ora.msu.edu</u> (email contact for HRL office)
- <u>crbc@ora.msu.edu</u> (email contact for Clinical Research Billing Compliance)

Website

hrpp.msu.edu

Animal Care Program & Institutional Animal Care and Use Committee (IACUC)

http://animalcare.msu.edu/home

Sally Light
IACUC Administrator
421 West Fee Hall
517.353.9705
lights@msu.edu

Animal Research

• Animal research is as carefully regulated as human research.

 Most animal research is conducted primarily for the benefit of humans, not animals. But, unlike humans, animals cannot consent to participate in experiments or comment on their treatment, which creates special needs that should be taken into consideration in their care and use.

MSU's Animal Care Program

Institutional Animal Care and Use Committee (IACUC)

- Charged with oversight of all animals used in research, teaching, and testing at MSU.
 - 450 Protocols, 240 PIs
 - 20 Committee members, Dr. Susan Barman, Chair

Campus Animal Resources (CAR)

- Provides housing, husbandry, and veterinary care
- 40-50,000 average daily count

AAALAC accredited – next site visit late Spring 2016

Campus Animal Resources (CAR)

Animal Facilities:

- Biomedical Facilities (formerly ULAR) 9
- College of Veterinary Medicine Vivarium & Vet Research Farm
- University Farms (on and off campus)
 - On campus 8 Administered by Animal Science
 - Off Campus 4 Administered by Land Management
- **All animals must be housed in approved facilities.
- **Attending Veterinarian, Dr. Claire Hankenson, oversees veterinary care in all three areas of CAR.

IACUC

Animal Use Forms (AUF) - must be reviewed and approved by the IACUC for all work involving the use of live vertebrate animals in research, teaching, and testing.

- any activity (including clinical trials) that involves live animals and will be published.
- all hands-on course work, as well all activities related to or required for degree completion.
- If funded the title on AUF must match the grant title.

Exemptions http://animalcare.msu.edu/iacuc-forms

Timeline for Review

- AUFs submitted by email to <u>iacuc@msu.edu</u>
- AUFs are sent out for IACUC review every Monday
- Training verified before approval
- Allow 4-6 weeks for IACUC review.
- Once AUF approved, PIs notified and can order animals.

Animal Ordering

• All animals coming into Biomedical Facilities must be ordered through CARLOS.

https://login.msu.edu/?App=ULAR CARLOS

- PIs order animals online
 - Linked into AUF for approved animal numbers
 - Available amount of animals to order
 - Valid MSU account number
- Account numbers entered by department Fiscal Officers
- Farm animals on campus are ordered through the Animal Science Department.

Training

http://animalcare.msu.edu/animal-care-training

Mandatory Training:

- IACUC Online Tutorial
- Species Specific Training
- Biosafety Training
- Additional training available as needed
- Occupational Health Questionnaire required for all personnel who work with animals

Forms

IACUC Animal Use Form (AUF)
 http://animalcare.msu.edu/iacuc-forms

Animal Science

http://Web2.msue.msu.edu/AnimalUse, login with MSU Net ID and create a new project.

Campus Animal Resources

http://animalcare.msu.edu/CARforms

International Animal Use

- AUF is required for international research and classes.
- Permits must be obtained by PI if necessary.
- PIs and students must follow local laws & regulations.
- International Guiding Principles for Biomedical Research Involving Animals http://iclas.org/wp-content/uploads/2013/03/CIOMS-ICLAS-Principles-Final.pdf
- PHS requires a Foreign Assurance from institutions receiving PHS funding http://grants.nih.gov/grants/olaw/obtain_assurance. htm

Summary

- Animal work must be approved before use of animals is begun.
- CGA will not release grant funds until there is an approved AUF or exemption.
- Departments are responsible for making sure animals ordered, per diems, and supplies are charged to the appropriate account number.
- AAALAC is coming spring/early summer 2016.

Contacts & Information

- IACUC Office
 - Phone: 517-432-8103
 - email: <u>iacuc@msu.edu</u>
 - Web: http://animalcare.msu.edu/IACUC
- CAR
 - Phone: 517-353-5064
 - Web: http://animalcare.msu.edu/car
- Farms Animal Science Department
 - Web: http://www.ans.msu.edu/facilities

Networking Time



Sue Sipkovsky

Research Administrator, Department of Teacher Education

NIH Updates

Jessica Hauptman Research Administrator

Office of Research Facilitation - College of Veterinary Medicine

hauptma4@cvm.msu.edu

New NIH Biographical Sketch Format

Required for due dates on or after May 25, 2015

CHANGES:

- Length increased from 4 to 5 pages
- Personal Statement can now include up to 4 peer reviewed publications
- Section C "Peer Reviewed Publications" changed to "Contributions to Science"
 - Up to 5 most significant contributions to science
 - Each contribution can include 4 peer reviewed publications or research products (patents, etc)
 - Option to include a URL to a full list of publications via SciENcv or My Bibliography

New NIH Biographical Sketch Format

- Instructions and a sample Biosketch on the SF 424 Forms and Application page: http://grants.nih.gov/grants/funding/424/index.htm #format
- For more information: NOT-OD-15-032
 http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html

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.
- Hunt, M.C., Jensen, J.L. & Crenshaw, W. (2007). Substance abuse and mental health among communitydwelling elderly. International Journal of Geriatric Psychiatry, 24(9), 1124-1135.
- 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. & Eishbein, D. (2009). Brain imaging in methamphetamine abusers across the life-span. Gerontology, 46(3), 122-145.

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.
 - 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.
 - 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

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: Pl

OVPRGS Grant Assistance - NIH

- Program Split into Two Parts:
 - Peer-Review
 - Grant Consulting & Editing
- Cost Split: OVPRGS 60%, Dept/College 40%
- Information on OVPRGS website:
 https://vprgs.msu.edu/initiatives-office-vice-president-research-and-graduate-studies
- Questions: <u>RGS.review@campusad.msu.edu</u>

OVPRGS Grant Assistance - NIH

- Peer-Review: Connects investigators with colleagues on or off campus to provide a scientific review
 - PI must be an Assistant Professor, early stage investigator (seeking R, K, career development award)
 - \$500K+ total direct costs
 - Standard payment is \$250 per review up to 3 reviews.
 Anything above \$250 to be paid by Dept/College

OVPRGS Grant Assistance - NIH

- Consulting & Editing: Connects the PI to an NIH proposal specialist to help hone and "sell" the proposal
 - PI must be an Assistant Professor, early stage investigator (seeking R, K, career development award)
 - \$500K+ total direct costs
 - Costs average between \$1,500-\$3,000
 - Provide full proposal at least a month before internal submission deadline

OVPRGS Grant Assistance – Non-NIH

- New initiative to provide grant editing support for other disciplines (ie: NSF, DOE, DOD, USAID, USDA)
- Pilot program will help assess skills of potential consulting editors
- OVPRGS will cover all costs during the pilot program
- How to request assistance:
 - PIs should email Tom Hollon to set up a 20 minute appointment to discuss eligibility
 RGS.hollonappts@campusad.msu.edu
 - Include PI name and agency in the subject line

Upcoming Training & Events

- ERA Electives 18 classes offered between 4/28 &
 12/15 (https://sprout.vprgs.msu.edu/training/electives/)
- OVPRGS Workshop: Bias and Reproducible Research by Dr. John Ioannidis – 5/7 @ 3 p.m. (https://vprgs.msu.edu/event/loannidis)
- NCURA & SRA 2015

(https://sprout.vprgs.msu.edu/training/)

- NCURA Region IV Spring Meeting: 4/26-29 Chicago, IL
- NCURA Annual Meeting: 8/2-5 Washington, DC
- SRA Michigan Chapter Annual Meeting: 5/14-15 Grand Rapids, MI
- SRA Annual Meeting: 10/17-21 Las Vegas, NV

Thank You for Attending!



* BUSINESS CARD DRAWING *



- RAN Listserv Stay tuned for updates and future meeting notices!
- Contact Feel free to contact any of the committee members with questions!
- Website Please visit the website for presentation materials and committee contact information: https://sprout.vprgs.msu.edu/spartan-ran/