

Quarterly Research Administration Meeting

May 19, 2021

Welcome and Housekeeping

- This is our 2nd virtual!
- We will be “spotlighting” our speakers
- All participants are on mute
- Please enter any questions and feedback into the chat
 - Or, send directly to Jonathan Lew in the chat
 - We will be facilitating questions at relevant times during presentations and in between topics



Agenda

- *General Updates*
- Exempt Self Determination – Recently Expanded & UROP
- ERA Updates
 - KR Protocols – Project Update
 - KR Protocols – Planned IRB Submission Pause
- NIH Biosketch and Other Support Changes
- Fiscal Close – Closing Steps for Contracts & Grants
- Conflict of Interest: Updated/New Forms and New Best Practices Procedure

New Employee Introductions

Krystene Carpenter, Contract and Grant Officer
Madison Friend, Office of Research

Agenda

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Exempt Self Determination – Recently Expanded & UROP

Beverley Alberola

Director, Human Research Protections

Program Update: UROP & Expanding the Exempt Self Determination Tool

- University policy requires that an Institutional Review Board (IRB) must review human research projects prior to the start of the research. Undergraduate students who wish to engage in faculty mentored exempt research through the Undergraduate Research Opportunities Program ([UROP](#)) may now use the [Exempt Self-Determination Tool](#).
- In addition, for all UCI researchers, the [Exempt Self-Determination Tool](#) has now been expanded to allow Exempt category # 4. *(cont.)*

Program Update: UROP & Expanding the Exempt Self Determination Tool

(cont.)

Exempt research may be confirmed as Exempt via use of the [Exempt Self-Determination Tool](#) for the following Exempt categories:

Exempt Category	Abbreviated Category Description
1	Established or commonly accepted educational settings that specifically involves normal educational practices
2	Interactions involving educational tests, survey, interview procedures, or observation of public behavior (including visual or auditory recording)
3	Benign behavioral interventions with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording
4	Secondary research uses of identifiable private information or identifiable biospecimens that are publicly available, for which consent is not required

Questions?

Agenda

- General Updates
- Exempt Self Determination – Recently Expanded & UROP
- *ERA Updates*
 - *KR Protocols – Project Update*
 - *KR Protocols – Planned IRB Submission Pause*
- NIH Biosketch and Other Support Changes
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ERA Updates

Barbara Inderwiesche
Director, ERA

KR Protocols – Project Update

- Non-Human Subject Research Determination module
 - Now Live! Launched 05/03/2021
 - Access via Zot!Portal or from IRB website

Kuali Research Protocols Options ▾

- **Non-Human Subjects Research (NHSR) Determination Module** 
Determine if your activities are human subject research
- **KR Protocols User Guide** 
Online user guide for KR Protocols and the new NHSR determination module
- **Live Demo of the NHSR Determination Module (Pre-Recorded)** 
View a live demo of how to submit a NHSR in KR Protocols

<https://www.research.uci.edu/compliance/human-research-protections/index.html>

<https://portal.uci.edu/>

Research Protections

Human Research Protections


- ▶ About HRP and the IRB
- ▶ Researchers
- ▶ IRB Members
- ▶ Participants
- ▶ Single IRB (sIRB) / Reliances
- ▶ Other UCI Committees

Animal Care & Use

Human Stem Cell Research

Institutional Biosafety


QUICK LINKS



IRB Fast Facts

Registration #s:
DHHS(FWA) #: 00004071
FDA (IRG) #: 0000236

Individual IRB #s:
IRB A: 00000353
IRB B: 00000394
IRB C: 00000395
IRB E: 00008624
IRB WB: 00011147



Regulatory Compliance
Human Research Protections (HRP)

ANNOUNCEMENTS ▾

HRP is responsible for managing the University's human research protections program. The HRP staff provides administrative support to UCI's four Institutional Review Boards (IRB). Research involving human subjects must undergo review by the Institutional Review Board (IRB). The IRB is charged with the responsibility of reviewing human subjects research and ensuring compliance with federal regulations, state laws, and UC/UCI policies. The primary role of the IRB is to protect the safety and welfare of human subjects. [Read more...](#)

Questions about human subjects research?
Contact us at IRB@research.uci.edu

IRB Meetings & Deadlines




Full Committee Calendar

News & Announcements:

- KR Protocols — Non-Human Subjects Research (NHSR) Determination module is LIVE!
- KR Protocols — Non-Human Subjects Research (NHSR) Determination Module launches in one week!

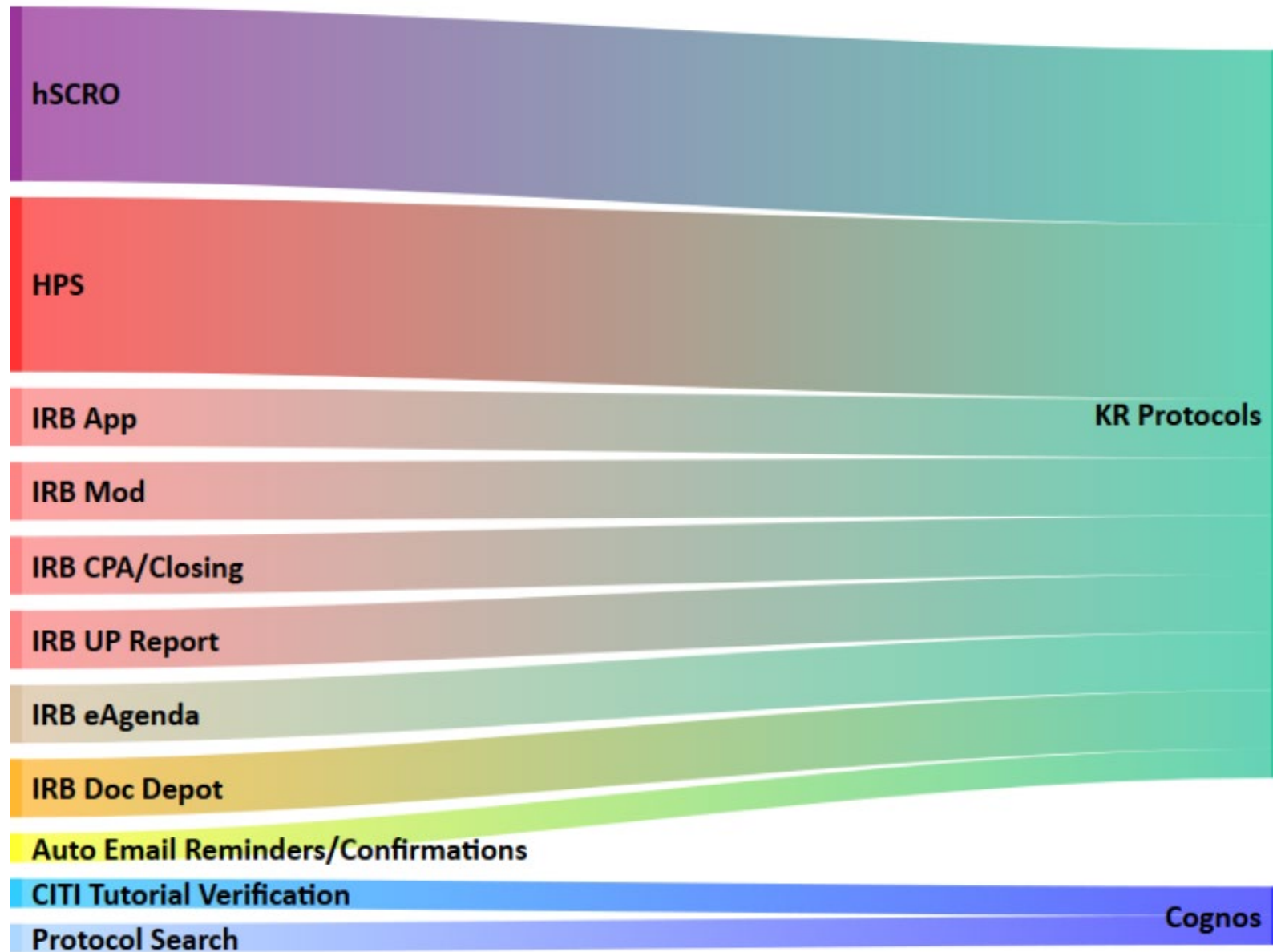
To subscribe to HRP **News & Announcements**, send a blank email to: or-irb-hrp-join@department-lists.uci.edu

Modules and Tools

- Non-Human Subjects Research Determination Module

[Go to KR](#)
- Exempt Self Determination Tool

[Open the Tool](#)
- IRB Application Module

[Go to the Module](#)

KR Protocols – Project Update (*cont.*)

- KR Protocols – **Full Launch 09/07/2021**
 - *Includes:*
 - All IRB **and** hSCRO transactions
 - Major Highlights:
 - A shared single point-of-entry for protocol submission/management for human subject and human stem cell researchers
 - A shared single point-of-entry for protocol tracking, processing, review and auditing for UCI IRB and hSCRO administrative staff
 - Full transparency for researchers on initial protocol submissions, protocol review and documentation of approved protocols





- **July 17, 2021 – September 6, 2021**
 - August 18th : data migration begins
- The pause allows for:
 - HRP Staff to clear the IRB review queue from old system
 - Existing data to merge to the new system
 - HRP staff to be trained on use and function of the new system
- What will be on pause:
 - All department funded protocols of any type unless required for a UCI dissertation or thesis
 - All modifications not necessary for the safety of human subjects

Questions?



Agenda

- General Updates
- Exempt Self Determination – Recently Expanded & UROP
- ERA Updates
 - KR Protocols – Project Update
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- *NIH Biosketch and Other Support Changes*
- Fiscal Close – Closing Steps for Contracts & Grants
- Conflict of Interest: Updated/New Forms and New Best Practices Procedure

NIH Biosketch and Other Support Changes

Nancy Lewis
Executive Director, SPA

Other Support

- NIH Other Support Defined
- NOT-OD-19-114
 - “other support includes **all resources** made available to a researcher in support of and/or related to **all** of their **research endeavors**, regardless of whether or not they have monetary value and regardless of whether they are based at the institution the researcher identifies for the current grant.
 - Includes resources and/or financial support from all foreign and domestic entities, including but not limited to, financial support for laboratory personnel, and provision of high-value materials that are not freely available (e.g., biologics, chemical, model systems, technology, etc.). ”

Other Support

- Other Support does not include:
 - Training awards
 - Prizes
 - Gifts: Resources provided where there is no expectation of anything (e.g. time, services, specific research activities, money, etc.) in return

An item or service given with the expectation of an associated time commitment **is not a gift** and **is instead an in-kind contribution** and must be reported as Other Support

Other Support

- When do we submit Other Support?
 - Just In Time (JIT)
 - Research Performance Progress Report (RPPR)
 - Change of PI (new PI) and adding key personnel
 - Some proposal applications, when specified in RFA
 - When Other Support was submitted without disclosing All required information

Reminder: Why Other Support Reviewed?



- NIH scientific program and grants management staff review Other Support to ensure that:
- All resources, domestic or foreign, directly supporting the individual's research endeavors have been reported
 - Sufficient levels of effort are committed to the project
 - There is no scientific, budgetary, or commitment overlap
 - Only funds necessary to the approved project are included in the award (example is subawards or multi- project awards)
 - Any foreign resources that meet the definition of a foreign component have received appropriate prior approval

Other Support Changes

NOT-OD-21-073

Applications due On or After January 25, 2022

- To promote full transparency and disclosure of all research activities, foreign and domestic.....
 - Applicable to PI, Other Senior Key Personnel
- Format
 - Revised Other Support reorganized to separate funded projects from in-kind contributions
 - Word Format page should be converted to PDF and electronically signed
 - Revised SciENCv template will be available the beginning of FY 2022

Other Support Changes

- Signature block added
 - Principal Investigator (PI) and Other Senior/Key Personnel must electronically sign the other support form to certify its accuracy
- Supporting documentation
 - If Other Support includes foreign activities or resources, the following must be submitted:
 - copies of contracts, grants, or any other agreement specific to:
 - foreign appointments and/or employment with a foreign institution
 - all foreign activities and resources reported must be submitted with Other Support
 - For documents that are not in English, translated copies must be provided

Other Support Changes

- Immediate notification of undisclosed Other Support
 - As soon as it becomes known to UCI that a PI/PD or Other Senior/Key personnel on an active NIH grant failed to disclose Other Support information, UCI must submit updated Other Support to NIH.

Even accidental oversight may have individual and/or institutional reputational consequences. Therefore, PIs/PDs and Other Senior/Key Personnel should take great care to ensure that Other Support is properly and completely disclosed.

Other Support Resources

- [Other Support Information](#)
- [Updated Other Support format page](#)
- [Updated Other Support Instructions](#)
- [Other Support FAQs](#)

Questions? Please contact your Contract and Grant Officer
in Sponsored Projects Administration

NOT-OD-21-073

R21 AA098075
Hunt (PI)
01/01/19-12/31/21

DMS No. 0025-0001 and 0025-0002 (Rev. 12/2020 Approved Through 02/28/2023)

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): 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/delete rows 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 addiction. 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. 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 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 competed 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)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older substance abusers

R01 MH922731
Mervin (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression and substance abuse in the elderly

4). Policy implications of genetic
ers. International Journal of Drug Policy,
sen, J.L. (2015). Early-life family and
Journal of Applied Gerontology, 28(2), 28-
A. (2018). Community-based
in the elderly. Addiction, 104(8), 1436-
laborators, I directly documented the
abusers and demonstrated the importance
actors in the etiology and maintenance
stance abuse treatment. This body of
iploid abuse in older adults and how
disorders.
social support networks on morbidity
leriatrics Society, 57(4), 15-23.
(2018). Aging out of methadone
, 134-149.
otinine in older nicotine addicts. Age
many years, but I led research that
themselves negatively and they
y narcotics users were shown in
tailored social support networks
into other forms of therapy. These
ted with these findings.
noe abusers. Journal of the
assessment. Journal Drug
ry systems by older nicotine
nographic profiles of the elderly
Ethnographic Society
Louis, MO
overlooked in older
ased drug and alcohol
he population ages.
stings or seek mental
document this emerging
to recognize symptoms,
viding evidence and
for addicted older
to the future. I served
sed participatory
15(3), 222-238.

NIH Biographical Sketch

Revised Biographical Sketch format is required for proposals submitted on or after January 25, 2022.

Notable Changes

- **Section A-** “Personal Statement”- updated to add that applicants may include details on ongoing and completed research projects from the past 3 years that they want to draw attention to (previously known as Research Support)
- **Section B** – ‘Positions and Honors’ -> Renamed ‘Positions, Scientific Appointments, and Honors’
 - Scientific Appointments

“List in *reverse* chronological order *all positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary)*”

NIH Biographical Sketch

Notable Changes

- **Section D**– ‘Research Support’ -> Removed & Replaced with ‘Scholastic Performance’
 - Only required for the specific applications
 - applicants for predoctoral and postdoctoral fellowships
 - applicants to dissertation research grants (e.g., R36)
 - candidates for research supplements to promote diversity in health-related research from the undergraduate through postdoctoral levels

Biographical Sketch Resources

- [Updated Biosketch Instructions](#)
- [Non-fellowship Biosketch template](#)
- [Fellowship Biosketch template](#)
- [SciENcv](#)
- [Biosketch FAQs](#)

Questions? Please contact your Contract and Grant Officer
in Sponsored Projects Administration

Office of Research's Efforts

- Outreach to keep the campus updated
- Workgroup of campus administrators to provide feedback and help develop resources and new procedures to address these changes
- Evaluating DocuSign for electronic signature requirement
- Developing a new reporting tool to help researchers
- Developing a new website on International Research Activities and Engagement

Questions?

Other Support Sample Pages

Other Support Format Page

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. [enter year 1]	
2. [enter year 2]	
3. [enter year 3]	
4. [enter year 4]	
5. [enter year 5]	

Note for Subs or Multi-Project Awards: Indicate the project number, Name of PD/PI, and source of Support for the overall project. Provide **all** other information (e.g. total award amount, person months) **for the subproject only**.

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. [enter year 1]	
2. [enter year 2]	
3. [enter year 3]	
4. [enter year 4]	
5. [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: _____

*This **specific form is mandatory** to use as it provides information on **ALL domestic & foreign** active, pending, and recently completed (w/in the last three years) **funded & unfunded** support for personnel on NIH funded projects as well as **in-kind contributions**.

For OS submitted in ASSIST, the PDF must be flattened after it has been signed electronically to avoid submission errors.

Other Support Format Page Example

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: Anderson, R.R.
Commons ID: ~~AndersonRR~~

Other Support – Project/Proposal

ACTIVE

*Title: Chloride and Sodium Transport in Airway Epithelial Cells

Major Goals: The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

*Status of Support: Active

Project Number: 2 R01 HL 00000 - 13

Name of PD/PI: Anderson, R.R.

*Source of Support: NHLBI

*Primary Place of Performance: University of California, Los Angeles

Project/Proposal Start and End Date: (MM/YYYY) (if available): 3/1/2021 – 2/28/2026

* Total Award Amount (including Indirect Costs): \$1,492,232

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

Year (YYYY)	Person Months (##.##)
1. 2021	3.6 calendar
2. 2022	3.6 calendar
3. 2023	3.6 calendar
4. 2024	3.6 calendar
5. 2025	3.6 calendar

*Title: Ion Transport in Lungs

Major Goals: The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

*Status of Support: Active

Project Number: 5 R01 HL 00000-07

Name of PD/PI: Baker, J.B.

*Source of Support: NHLBI

*Primary Place of Performance: University of California, Los Angeles

Project/Proposal Start and End Date: (MM/YYYY) (if available): 4/1/2017 – 3/31/2022

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

Name of Individual:
Commons ID:

* Total Award Amount (including Indirect Costs): \$981,736

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

Year (YYYY)	Person Months (##.##)
4. 2020	1.2 calendar
5. 2021	1.2 calendar

PENDING

*Title: Liposome Membrane Composition and Function

Major Goals: The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

*Status of Support: Pending

Project Number: DCB 950000

Name of PD/PI: Anderson, R.R.

*Source of Support: National Science Foundation

*Primary Place of Performance: University of California, Los Angeles

Project/Proposal Start and End Date: (MM/YYYY) (if available): 10/1/2021 – 9/30/2023

* Total Award Amount (including Indirect Costs): \$262,921

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

Year (YYYY)	Person Months (##.##)
1. 2021	2.4 calendar
2. 2022	2.4 calendar

COMPLETED

*Title: Gene Transfer of CFTR to the Airway Epithelium

Major Goals: The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

*Status of Support: Completed

Project Number: R000

Name of PD/PI: Anderson, R.R.

*Source of Support: Cystic Fibrosis Foundation

*Primary Place of Performance: University of California, Los Angeles

Project/Proposal Start and End Date: (MM/YYYY) (if available): 9/1/17 – 8/31/20

Other Support Format Page Example (*continued*)

Name of Individual:
Commons ID:

IN-KIND

*Summary of In-Kind Contribution: Post-doctoral fellow, Dr. John Smith, who conducts research activities in the Anderson lab. Salary supported by Oxford University.

*Status of Support: Active

*Primary Place of Performance: University of California, Los Angeles

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

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

*Estimated Dollar Value of In-Kind Information: \$80,000

*Summary of In-Kind Contribution: Cell line XYZ provided by Dr. Jennifer Smith at Cornell University.

*Status of Support: Active

*Primary Place of Performance: University of California, Los Angeles

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

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

*Estimated Dollar Value of In-Kind Information: estimate \$1,000

*Summary of In-Kind Contribution: C57BL/6-ABC^{tm1/bp} mice provided by Dr. Joseph Jones at the University of Texas at Austin.

*Status of Support: Active

*Primary Place of Performance: University of California, Los Angeles

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

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

*Estimated Dollar Value of In-Kind Information: estimate \$4,000

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

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff.

Name of Individual:
Commons ID:

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: Anderson, R.R.

Date: March 25, 2021

Biographical Sketch Sample Pages

Biographical Sketch Non-Fellowship Format Page

CURRENT FORMAT (as of July 2020)

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

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:

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

POSITION TITLE:

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

A. Personal Statement

B. Positions and Honors

C. Contributions to Science

D. Additional Information: Research Support and/or Scholastic Performance

Changes, effective on or after May 25, 2021 (in red)

DRAFT JULY 2020

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:

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

POSITION TITLE:

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

A. Personal Statement

B. Positions, **Scientific Appointments**, and Honors

← Updated Section B to capture ALL scientific positions and appointments, other foreign and domestic as well as both paid and not-paid.

C. Contributions to Science

Biographical Sketch Non-Fellowship Example

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

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): 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/delete rows 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 addiction. 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. 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 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 competed 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 DA942367
Hunt (PI)
09/01/16-08/31/21
Health trajectories and behavioral interventions among older substance abusers

R01 MH922731
Merryle (PI), Role: co-investigator
12/15/17-11/30/22
Physical disability, depression and substance abuse in the elderly

Key Personnel may include details on ongoing and completed research projects from the past three years that they want to draw attention to here.

R21 AA998075

Hunt (PI)

01/01/19-12/31/21

Community-based intervention for alcohol abuse

Citations:

1. Merryle, R.J. & Hunt, M.C. (2015). 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. (2018). 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. (2019). Predicting the substance-abuse treatment needs of an aging population. *American Journal of Public Health*, 45(2), 236-245. PMID: PMC9162292
4. Merryle, R. & Hunt, M.C. (2020). Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMID: PMC9002364

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 Addictions Study Section, members
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: Psychobiology 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, <i>Psychology and Aging</i>
2009 – Present	Member, American Geriatrics Society
2009 – Present	Member, Gerontological Society of America
2009 – 2013	Fellow, Division of Intramural Research, National Institute of Drug Abuse, Bethesda, 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 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 and 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. (2013). Community based participatory research with late-life addicts. *American Journal of Alcohol and Drug Abuse*, 15(3), 222-238.

B. List in **reverse** chronological order **all positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).**

Biographical Sketch Non-Fellowship Example (*continued*)

- b. Shaft, B.M., **Hunt, M.C.**, **Merryle, R.**, & Venturi, R. (2014). 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. (2015). 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.** (2018). Community-based intervention strategies for reducing alcohol and drug abuse in the elderly. *Addiction*, 104(9), 1436-1606. PMID: 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. (2015). 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. (2018). Aging out of methadone treatment. *American Journal of Alcohol and Drug Abuse*, 15(6), 134-149.
 - c. **Merryle, R.** & **Hunt, M.C.** (2020). Randomized clinical trial of cotinine in older nicotine addicts. *Age and Ageing*, 38(2), 9-23. PMID: 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. (2013). Morbidity among elderly substance abusers. *Journal of the Geriatrics*, 60(4), 45-61.
 - b. **Hunt, M.C.** & Pour, B. (2015). Methadone treatment and personal assessment. *Journal Drug Abuse*, 45(5), 15-26.
 - c. **Merryle, R.** & **Hunt, M.C.** (2018). The use of various nicotine delivery systems by older nicotine addicts. *Journal of Ageing*, 54(1), 24-41. PMID: PMC9112304
 - d. **Hunt, M.C.**, Jensen, J.L. & **Merryle, R.** (2020). The aging addict: ethnographic profiles of the elderly drug user. NY, NY: W. W. Norton & Company.

Complete List of Published Work in MyBibliography:
<https://www.ncbi.nlm.nih.gov/myncbi/1CifFFV4VYQZE/bibliography/public/>



D. 'Research Support' has been removed.
Section D is solely present on the fellowship version of the Biosketch, and no longer includes research support due to duplication of effort with Other Support & to harmonize format with NSF.

Biographical Sketch Fellowship Format Page

CURRENT FORMAT (as of July 2020)

OMB No. 0925-0001 and 0925-0002 (Rev. 03/2020 Approved Through 02/28/2023)

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:

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

POSITION TITLE:

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)	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions and Honors

C. Contributions to Science

D. Additional Information: Research Support and/or Scholastic Performance

YEAR	COURSE TITLE	GRADE
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Changes, effective on or after May 25, 2021 (in red)

DRAFT July 2020

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:

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

POSITION TITLE:

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)	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions, **Scientific Appointments**, and Honors

C. Contributions to Science

D. **Scholastic Performance**

YEAR	COURSE TITLE	GRADE
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Biographical Sketch Pre-Doctoral Fellowship Example

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

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: Simmons-Gonzales, Leilani

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

POSITION TITLE: Graduate Student Research Assistant

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)	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
Purdue University	BA	08/2014	05/2018	Biological Chemistry
UC San Diego	PHD	08/2018	05/2023 (Expected)	Molecular Biology

A. Personal Statement

I first became interested in human health and disease in high school when I was awarded an NIH Diversity Supplement to work as a research technician for two summers in Dr. Indira Creative's lab at the University of Hawaii. I continued to pursue this interest as an undergraduate at Purdue University, where I conducted research with Dr. Daniel Richardson on the mechanisms of action of a new class of small molecules for cancer treatment. This resulted in a co-authorship publication, as well as an invitation to present a poster at the annual Oncological meeting in Denver, Colorado. By the end of my undergraduate career, I knew that I wanted to pursue a long-term career in research. For my graduate training at UC San Diego, I have moved into the fields of genetics and biochemistry by studying the signaling and motility mechanisms of cancer cells, under the mentorship of Dr. Nani Green. Dr. Green is an internationally recognized leader in the field of cancer genetics and has an extensive record for training predoctoral and postdoctoral fellows. Along with giving me new conceptual and technical training, the proposed training plan outlines a comprehensive set of career development activities and workshops. I will have opportunities to engage in public speaking, conduct literature analysis, consider biomedical ethics, and learn about varied career options. For my initial project, I am currently developing a novel protocol for the identification of transcription complexes involved in cancer signaling pathways, which I hope to submit as a first author publication in the next few months. As a native Hawaiian, I am the first in my family to graduate from college, and I am excited to continue making great strides with my education. Overall, I believe that my current research setting in conjunction with my proposed training plan will provide a solid foundation for my long-term goal to become an academic researcher.

1. Nieman PY, Simmons-Gonzales L, Richardson, D. Gen Y: a novel small molecule with cytotoxic abilities targeting colon cancer cells. Cellular and Molecular Biology. 2018 June. 7(20):13672-78.

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2019 – 2020	Robertson Fellowship for Outstanding Graduate Students, Genetics Department, UC San Diego
2018 – Present	Graduate Research Assistant, UC San Diego
2018 – 2018	Lab Technician, University of Hawaii
2014 – Present	Member, Association for Women in Science

2014 – Present Member, Sigma Xi
2014 – 2018 Diversity Supplement, National Institutes of Health

Honors

2020 Virtual Poster Presenter, Genetics and Molecular Biology Meeting
2019 Poster Presenter, Advances in Cancer Research and Therapy Meeting
2018 Paula F. Laufenberg award for best senior project in the Biology Department, Purdue University
2014 – 2018 Scholarship, National Merit Scholarship Program
2014 Scholarship, Daughters of Hawaii Society

C. Contributions to Science

2. **High School Research:** I spent two summers doing research in the laboratory of Dr. Indira Creative at University of Hawaii, funded by a NIH Diversity Supplement award. Dr. Creative has developed several new anti-fungal drugs that might protect against skin infections. Over the course of two summers I set up in vitro cultures of skin cell lines and conducted a wide range of toxicity assays. We were excited to find that one of the new agents showed almost no toxicity, even at fairly high doses. Dr. Creative is now testing the drug in animals exposed to different types of fungal infections, including *Candida albicans*.
 1. Footman B, Eisser JK, Simmons-Gonzales, L, Creative IM. Testing XXH for toxicity in vitro. University of Hawaii Research Symposium; 2012 May; Manoa, HI.
3. **Undergraduate Research:** I was part of a project in the laboratory of Dr. Daniel Richardson at Purdue University. Dr. Richardson's laboratory studies the mechanisms of action of small molecules for cancer treatment. During my time in his lab I was looking at how a new small molecule, Gen Y, is able to target cancerous cells. My contributions to this work were included in a publication recently accepted in Cellular and Molecular Biology. The work was particularly exciting because it looks like the mechanism of action of Gen Y might be completely novel, making it a potential candidate for treating patients afflicted with colon cancer. Dr. Richardson was recently awarded a patent for this new drug.
 1. Nieman PY, Simmons-Gonzales L, Richardson, D. Gen Y: a novel small molecule with cytotoxic abilities targeting colon cancer cells. Cellular and Molecular Biology. 2018 June. 7(20):13672-78.
 2. Simmons-Gonzales, L, Richardson, D. Testing the ability of a small molecule, Gen Y, to target colon cancer cells. Advances in Cancer Research and Therapy; 2019 September; Denver, CO.
4. **Graduate Research:** My ongoing predoctoral research is focused on transcriptional gene regulation and signaling impacting motility of cancer cells. I believe the results from my research will likely be highly relevant to human health as they will provide new details into the workings of complex biological systems, which will allow for further extrapolations into the development of several types of cancer and their progression. I am currently developing a novel protocol for the identification of transcription complexes involved in cancer signaling pathways, which I hope to submit as a first author publication in the next few months.
 1. Simmons-Gonzales, L, Green, N. A tandem identification approach for transcriptional complexes involved in the signaling and motility of cancerous cells. Genetics and Molecular Biology Virtual Meeting; 2020 September

D. Scholastic Performance

YEAR	COURSE TITLE	GRADE
PURDUE UNIVERSITY		
2014	Introductory Biology	A
2014	Introductory Biology Lab	A
2014	Foundations of Chemical Principles	A
2014	French and Francophone World	A

B. List in **reverse** chronological order **all positions and scientific appointments both domestic and foreign, including affiliations with foreign entities or governments. This includes titled academic, professional, or institutional appointments whether or not remuneration is received, and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary).**

D. Scholastic Performance updated to remove 'Research Support' has been removed. Section D is solely present on the fellowship version of the Biosketch, and no longer includes research support.

Biographical Sketch Pre-Doctoral Fellowship Example (*continued*)

YEAR	COURSE TITLE	GRADE
2014	Ethics, Religion, and Culture Today	A
2015	Organismal and Population Biology	B
2015	Omics	B
2015	First Year Seminar: Nation and Migration	A
2015	Statistics, Probability, and Reliability	A
2015	Calculus I	B
2015	General Physics I	B
2015	Introductory Chemistry	A
2015	Population & Ecol Genetics	A
2015	Organic Chemistry	B
2016	American Literature	B
2016	General Physics II	B
2016	Organic Chemistry II	B
2016	Microbial Pathogenesis and the Immune Response	A
2016	Introduction to Cognitive Science	A
2016	Self Defense	P
2016	Biological Chemistry	B
2017	Anthropology of Childhood and the Family	A
2017	Disease, Culture, and Society in the Modern World	A
2017	Intro to Psychology	A
2017	Health & Fitness Walking	P
2017	State & Local Govt	A
2017	Human Genetic20	A
2017	Senior Project	A
2017	Bioinformatics	B
2018	Cell Biology	A
2018	Quantitative Analysis	B
2018	Quantitative Analysis Lab	A
2018	Physics in Modern Medicine	A
2018	Ethical Principles in Law and Economics	B
2018	Bowling	P
2018	Genomics and Systems Biology	A
2018	Senior Project	A
UC SAN DIEGO		
2018	Seminar in Genetics	P
2018	Statistics for the Life Sciences	P
2018	Ethics in Biological Research	CRE
2019	Seminar in Physiology and Behavior	P
2019	Cancer Immunology	P
2020	Mechanisms of Cell Motility	P
2020	Biochemical Mechanisms of Cancer Cells	P
2020	Toxicology	P
2020	Physiology for the Molecular Biologist	P

Except for the scientific ethics course, UC San Diego graduate courses are graded P (pass) or F (fail). Passing is C plus or better. The scientific ethics course is graded CRE (credit) or NC (no credit). Students must attend at least seven of the eight presentation/discussion sessions for credit.

Biographical Sketch Post-Doctoral Fellowship Example

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

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: Hayes, Susan

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

POSITION TITLE: Postdoctoral Fellow

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)	Start Date MM/YYYY	Completion Date MM/YYYY	FIELD OF STUDY
Wake Forest University	BS	08/2009	05/2013	Engineering
Georgetown University	PHD	08/2013	05/2019	Molecular Biology
Michigan State University	Postdoctoral Fellow	09/2019	Present	Bioinformatics/Immunology

A. Personal Statement

My academic training and research experience have provided me with an excellent background in multiple biological disciplines including molecular biology, microbiology, biochemistry, and genetics. As an undergraduate, I conducted research with Dr. Xavier Factor on the mechanisms of action of a new class of antibiotics. As a predoctoral student with Dr. Tanti Augusti, my research focused on the regulation of transcription in yeast, and I gained expertise in the isolation and biochemical characterization of transcription complexes. I developed a novel protocol for the purification of components of large transcription complexes. I was first author of the initial description of the Most Novel Complex. A subsequent first author publication challenged a key paradigm of transcription elongation and was a featured article in a major journal. During my undergraduate and graduate careers, I received several academic and teaching awards. For my postdoctoral training, I will continue to build on my previous training in transcriptional controls by moving into a mammalian system that will allow me to address additional questions regarding the regulation of differentiation and development. My sponsor Dr. I.M. Creative is an internationally recognized leader in the transcription/chromatin field and has an extensive record of training postdoctoral fellows. The proposed research will provide me with new conceptual and technical training in developmental biology and whole genome analysis. In addition, the proposed training plan outlines a set of career development activities and workshops – e.g. grant writing, public speaking, lab management, and mentoring students – designed to enhance my ability to become an independent investigator. My choice of sponsor, research project, and training will give me a solid foundation to reach my goal of studying developmental diseases in humans. During my second postdoctoral year in Dr. Creative's lab, my father had a severe stroke that eventually ended his life. I was out of the lab for six months dealing with my father's incapacitating illness and end-of-life issues. This hiatus in training reduced my scientific productivity. I am confident this proposed research project and training plan will enhance my scientific portfolio and will help recuperate my scientific productivity. My long-term research goals involve becoming an independent researcher and developing a comprehensive understanding of key developmental pathways and how alterations in gene expression contribute to human disease.

1. Hayes S, Schneider K, Chen M, Augusti T. Rapid isolation and characterization of a novel transcription complex in *Saccharomyces cerevisiae* and its role in transcription elongation. *Journal of Cell Biology*. 2016; 128:770.

2. Hayes S, Augusti T. A tandem affinity purification tag approach allows for isolation of interacting proteins in *Saccharomyces cerevisiae*. *Proceedings of the National Academy of Sciences of the United States of America*. 2019; 98:151.
3. Yao M, Dionne CF, Hayes S, Murray GC. Up-regulation of *Drosophila* innate immunity genes in response to stress. *Science (New York, N.Y.)*. 2020; 304:1754.
4. Hayes S, Casasnovas Q, Murray GC. Structural analysis of *Drosophila* Rtc. *Nature*. Forthcoming 2021.

B. Positions, Scientific Appointments, and Honors

Positions and Scientific Appointments

2019 – Present	Postdoctoral Researcher, Michigan State University
2015 – 2018	Predocotrual Fellowship for Minorities, Ford Foundation
2013 – 2019	Graduate Research Assistant, Georgetown University
2012 – Present	Member, National Society for Bioinformatics and Biotechnology
2010 – Present	Member, Association for Women in Science
2010 – 2012	Engineer, The IBeam Group Program
2009 – Present	Member, Sigma Xi

Honors

2013	B.S. awarded with high honors, Wake Forest University
2013	Paula F. Laufenberg Award for best senior project in the Department of Engineering, Wake Forest University
2013	STAR award for public service in engineering, The IBeam Group
2010 – 2011	Scholarship, National Merit Scholarship R
2009 – 2011	Scholarship, Daughters of Hawaii Society

C. Contributions to Science

1. **Early Career:** My early career contributions were focused on applying my knowledge of structural engineering to improving the design and integrity of tensile structures. More specifically, I worked with a team of engineers at the IBeam Group to develop concrete with a higher tensile strength that could be utilized in large structures such as suspension bridges. My particular role in the project was to identify candidate polymers, determine the ultimate tensile strength of these polymers, and make recommendations as to which polymer would afford concrete the most structural integrity under various stresses.
 - a. Hayes S, Janessa AJ. Redesigning the Golden Gate bridge. *National Undergraduate Symposium on Science and Engineering*; 2011; Baltimore, MD.
 - b. Lorentson C, Hayes S, Sauer N, Mehta S. Use of high-tensile concrete in cantilevered structures. *J Applied Engineering*. 2012; 63:413.
2. **Graduate Career:** My graduate research contributions focused on transcriptional gene regulation in *Saccharomyces cerevisiae*. Results from my research were highly relevant as they provided new details into the workings of complex biological systems and allowed for further extrapolations into the development of certain diseases and their progression. I originally developed a novel protocol for the purification of components of large protein complexes. A subsequent publication, in which I isolated and characterized a long sought-after transcription complex, challenged a key paradigm of transcription elongation and was a featured article in a major journal.
 - a. Hayes S, Schneider K, Chen M, Augusti T. Rapid isolation and characterization of the most novel transcription complex in *Saccharomyces cerevisiae* and its role in transcription elongation. *CSHL Meeting on Mechanisms of Eukaryotic Transcription*; 2015 August; Cold Spring Harbor, NY.
 - b. Hayes S, Schneider K, Chen M, Augusti T. Rapid isolation and characterization of a novel transcription complex in *Saccharomyces cerevisiae* and its role in transcription elongation. *Journal of Cell Biology*. 2016; 128:770.

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Biographical Sketch Post-Doctoral Fellowship Example (*continued*)

- c. Hayes S, ~~Auguri~~ T. A tandem affinity purification tag approach allows for isolation of interacting proteins in *Saccharomyces cerevisiae*. Yeast Genetics and Molecular Biology Meeting; 2017 September; Seattle, WA.
 - d. Hayes S, ~~Auguri~~ T. A tandem affinity purification tag approach allows for isolation of interacting proteins in *Saccharomyces cerevisiae*. Proceedings of the National Academy of Sciences of the United States of America. 2019; 98:151.
3. **Postdoctoral Career:** As a postdoctoral fellow, my research has provided a compelling link between mutations arising in stress response proteins and the development of various autoimmune diseases in humans. Previous studies have shown dysregulation in the innate immune response lead to autoimmune diseases in humans. A few ~~Rtc~~ homologues have now been identified in humans and appear to play a role in the regulation of genes in the innate immune response. My research is focused on the transcriptional regulator ~~Rtc~~ from *Drosophila melanogaster*.
- a. Hayes S, ~~Yager~~ LN, Murray GC. ~~Rtc~~ is an essential component of the *Drosophila* innate immune response. Genetics. 2019; 145:884.
 - b. Yao M, Dionne CF, Hayes S, Murray GC. Up-regulation of *Drosophila* innate immunity genes in response to stress. Science. 2020; 304:1754.
 - c. Hayes S, Murray GC. Stress, flies, and videotape: the *Drosophila* stress response. Annual review of physiology. 2020; 346:223.
 - d. Hayes S, ~~Cescaloo~~ Q, Murray GC. Structural analysis of *Drosophila* ~~Rtc~~. Nature. Forthcoming 2021.

Complete List of Published Work in My Bibliography:
<https://www.ncbi.nlm.nih.gov/myncbi/1VqYzYESn3Nke9/bibliography/public/>

D. Scholastic Performance

YEAR	COURSE TITLE	GRADE
GEORGETOWN UNIVERSITY		
2013	Seminar in Molecular Biology	P
2013	Basic Biomedical & Biological Sciences	P
2014	Model Systems	P
2014	Statistics for the Life Sciences	P
2014	Current Topics in Molecular Genetics	P
2015	Ethics in Biological Research	CRE
2015	Biochemistry	P
2015	Physiology	P
2016	Seminar in Systems Biology	P
2016	Protein Chemistry	P

Except for the scientific ethics course, Georgetown University graduate courses are graded P (pass) or F (fail). Passing is C plus or better. The scientific ethics course is graded CRE (credit) or NC (no credit). Students must attend at least seven of the eight presentation/discussion sessions for credit.

D. Scholastic Performance updated to remove 'Research Support' has been removed. Section D is solely present on the fellowship version of the Biosketch, and no longer includes research support.

Questions?

Agenda

- General Updates
- Exempt Self Determination – Recently Expanded & UROP
- ERA Updates
 - KR Protocols – Project Update
 - KR Protocols – Planned IRB Submission Pause
- NIH Biosketch and Other Support Changes
- *Fiscal Close – Closing Steps for Contracts & Grants*
- Conflict of Interest: Updated/New Forms and New Best Practices Procedure

Fiscal Close – Closing Steps for Contracts & Grants

Beata Najman

Director, Extramural Funds Accounting

Fiscal Close - Closing Steps for Contracts & Grants

Departmental Responsibilities

- At least once a month, run C&G Overdrafts by Org ID report in Decision Support and review accounts in overdraft
- Clear all overdrafts in awards not expected to receive additional funds
- Email fund accountant at C&G Accounting and request closing awards with a zero balance
- **Do not process any accruals and/or deferrals for C&G funds**

Fiscal Close - Closing Steps for Contracts & Grants

Expense Accruals for C&G Funds

- Expense accruals for contracts and grants will be processed by C&G Accounting
- Starting with July 10 and **no later than July 14**, departments are required to email Griselda Duran griseld@uci.edu and request expense accruals for goods and services received by June 30, 2021, and not reflected on the ledger for Period 12, if these expenses fall into one of the two categories specified below:
 - 1) Equipment with a transaction value of \$5,000 or more
 - 2) Goods and services with a transaction value of \$10,000 or more

Fiscal Close - Closing Steps for Contracts & Grants

Expense Accruals for C&G Funds

Emails requesting expense accruals on C&G funds have to include the following:

- Fund Number
- PO #
- A brief explanation
- A copy of the invoice

Fiscal Close - Closing Steps for Contracts & Grants

- All GECs involving C&G funds and processed after 120 days from the expense posting date require C&G Compliance review and approval.
- **July 16** is the final date for all FY2021 GECs. If C&G review and approval is required, GECs need to be fully approved by 4 p.m. by the Account Supervisor listed on the Expense Account being charged.
- Late GECs processed without proper departmental approvals will not be finalized by C&G Compliance until these approvals are recorded in KFS, and may miss the fiscal close deadline.

Questions?

Agenda

- General Updates
- Exempt Self Determination – Recently Expanded & UROP
- ERA Updates
 - KR Protocols – Project Update
 - KR Protocols – Planned IRB Submission Pause
- NIH Biosketch and Other Support Changes
- Fiscal Close – Closing Steps for Contracts & Grants
- *Conflict of Interest: Updated/New Forms and New Best Practices Procedure*



Conflict of Interest: Updated/New Forms and New Best Practices Procedure

Nadia Wong

Research Compliance and Outreach Manager

Updated Forms

To eliminate unnecessary or confusing questions and clarify the key information necessary for committee review

- Annual Form 810- For PHS
- Financial Disclosure Addendum for PHS- Funded Research (Form 820)- For PHS
- Addendum to Investigator's Disclosure of Economic Interests (Form COI-1)- For NSF and IRB
- Addendum to Investigator's Disclosure of Economic Interests for Gift Funding (Form COI-2)- For Gift Form 700U
- Addendum for Non-UCI Personnel (Form COI-3)- For PHS, NSF, and IRB
- COI Expedited Review Form- For PHS and IRB

New Form

To also reduce collecting redundant information

- Addendum to Investigator's Disclosure of Economic Interests for Form 700U disclosures (Form COI-1CA)- For Sponsored Research Agreement Form 700U

Paper Forms Untouched

- Statement of Economic Interests for Principal Investigators (Form 700U)
- Subrecipient/Non-UCI Investigator Disclosure for PHS-Funded Research (Form 800SR)
- Subrecipient/Non-UCI Investigator Disclosure for NSF Conflict of Interest Policy (Form 900SR)

Disclosure and Documentation- New Best Practices Procedure

COI Point Person (required for new studies requiring COIOC review)

- In light of the renewed focus on COI and transparency from the federal government, the COI Oversight Committee will now require researchers (being reviewed) disclose their financial interests to the study team and identify an individual (non-conflicted, non-junior to the researcher with the financial interests) for them to contact with any COI questions or concerns- “COI Point Person”
 - Documentation: Submit a copy of the email notification to the study team members including the identification of the COI Point Person, along with the applicable COI Addendum

For more information about the new procedures and template email disclosures, visit:

<https://research.uci.edu/ref/conflict-of-interest/research-disclosures/research-safeguards.html>

Disclosure and Documentation- New Best Practices Procedure

COI Liaison (as needed)

- In some higher risk cases, additional COI oversight from a non-conflicted, non-junior colleague to the researcher with the financial interest is required- “COI Liaison”. The COI Liaison would undertake additional specific tasks and responsibilities to help mitigate the potential conflict of interest.
 - Documentation: If needed, submit a [COI Liaison Acknowledgment Form](#) describing those additional responsibilities signed by the Disclosing Individual and the COI Liaison along with the applicable COI Addendum

For more information about the new procedures and template email disclosures, visit:
<https://research.uci.edu/ref/conflict-of-interest/research-disclosures/research-safeguards.html>

Implementation Date- June 1, 2021

- Starting June 1st, 2021, disclosures submitted will need to use the newest versions of the forms and new projects will also need to comply with the new Disclosure and Documentation Procedure. Changes to COI Forms were announced in April, which started the pilot phase.
 - COI Team will return incorrect versions of the forms if received on or after June 1st.
- For the current versions of the forms, please always refer to our [Forms page](#) online.
 - During this pilot phase, we have already made some additional revisions based on the responses received.

Questions?

COI Team Contact Information

- General: coioc@research.uci.edu
- Research Compliance Sr. Analyst: Kristine Thai, kthai2@uci.edu
- COI Administrator: Nadia Wong, nadiaw@uci.edu

Wrapping up

- Join us next time!
 - Wednesday, August 25, 2021, 10AM-11:30AM
 - Virtual
- Send us your feedback, request for content, questions!
 - era@research.uci.edu