Quarterly Research Administration Meeting

February 17, 2021
Welcome and Housekeeping

• This is 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**
  - Cannabis Research, Committee and Role
  - NIH Loan Repayment Program
  - Federal Updates
  - C&G Accounting Updates
  - Applied Innovation Topics
  - Human Research Protections Updates
  - ERA Project Updates
Who is here?
General Updates – Staff Updates

Sponsored Projects Administration (SPA):

• Garrett Larsen
• Alison Dang
• Luis Cendejas
• Wanda Kao
• Jasmin Ramirez
General Updates - Staff Updates

Human Research Protections (HRP):

• Jessica Sheldon
• Boram (Bo) Choung
• Audrey Covarrubias-Aguilera
• Muzhgan Afzal
• Muriel Marroquín
General Updates

• Office of Research in the process of vacating 141 Innovation in Research Park
  – Campus-wide cost reduction efforts
  – Upcoming lease expiration
  – Continued remote work
  – Vacating incrementally
  – Address remains unchanged
    • Until further notice!
Agenda

• General Updates
• **Cannabis Research, Committee and Role**
• NIH Loan Repayment Program
• Federal Updates
• C&G Accounting Updates
• Applied Innovation Topics
• Human Research Protections Updates
• ERA Project Updates
Agenda

• General Updates
• Cannabis Research, Committee and Role
• **NIH Loan Repayment Program**
  • Federal Updates
  • C&G Accounting Updates
  • Applied Innovation Topics
• Human Research Protections Updates
• ERA Project Updates
NIH Loan Repayment Plan
February 17, 2021

Diana Stephens
Institute of Clinical and Translational Science
Education Director
About LRP

NIH Loan Repayment Programs (LRPs) are a vital component in our nation's effort to keep health professionals in research careers

**Researcher:** Commit to research for 2 years

**NIH:** Pays up to $50,000 of qualified debt and federal taxes

**OUTCOME:** Increase in nation's stock of biomedical research scientists
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<thead>
<tr>
<th>Category</th>
<th>Description</th>
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<tbody>
<tr>
<td>Clinical Research</td>
<td>Patient-oriented research w/ human subjects or materials of human origin on causes &amp; consequences of disease in humans. Accepted and reviewed by all participating NIH ICs</td>
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<tr>
<td>Pediatric Research</td>
<td>Research related to diseases or disorders in children. Basic research allowed. Accepted and reviewed by all participating NIH ICs.</td>
</tr>
<tr>
<td>Health Disparities Research</td>
<td>Research focusing on minority &amp; and other health disp. pop. Basic, clinical, social and behavioral research allowed. Accepted and reviewed by all participating NIH ICs.</td>
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<td>Contraception &amp; Infertility Research</td>
<td>Research focusing on conditions impacting ability to conceive/ bear children &amp; provide methods of preventing pregnancy. Applications reviewed solely by NICHD</td>
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<tr>
<td>Clinical Research DB</td>
<td>Same as Clinical Research LRP. Available for researchers from disadvantaged backgrounds. Applications reviewed solely by NIMHD.</td>
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<tr>
<td>September 1 – November 15</td>
<td>Application Cycle Open</td>
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<tr>
<td>November 15</td>
<td>Application, IBO &amp; Colleague Deadline</td>
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<tr>
<td>Jan – May</td>
<td>Application Review</td>
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<tr>
<td>May</td>
<td>IC Initial Selections</td>
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<td>May – July</td>
<td>Financial Vetting and Verifications</td>
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<tr>
<td>Mid-July – August</td>
<td>Final Funding Decisions/ Notification</td>
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<tr>
<td>November</td>
<td>First Lender Payments</td>
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Basic LRP Criteria

- **Doctoral Degree**
  - M.D., Ph.D., or equivalent
  - *Exception: Contraception & Infertility Research LRP

- **Research Funding**
  - Research Funding
  - Domestic nonprofit, university, or government.org

  *NIH grant support NOT required

- **Educational Loan Debt**
  - At least 20 percent of applicant's annual income

- **Research Time**
  - At least 20 hours/week

- **Citizenship**
  - U.S. Citizen or permanent resident
Application Process

ICTS can provide support and draft language contact

Diana Stephens
dvigil1@hs.uci.edu
UCI Resources

Grant Library
ICTS has a library of successful LRP grants

Affiliated Scholars Advancement Program
ICTS program to develop career development support

Statistical Support
Center of Statistical Consultation offers 1-hour free consultation

Grant Writing Support
ICTS offers a K grant writing program. UCI SOM offers an R01 boot camp.

https://www.icts.uci.edu/education/loan%20program.php
Questions?

Contact ICTS for Support

Diana Stephens, MBA
Institutional Business Officer
Education Director
Institute of Clinical and Translational Science
dvigil1@hs.uci.edu
KEEP CALM AND TAKE A BREATHER
Agenda

• General Updates
• Cannabis Research, Committee and Role
• NIH Loan Repayment Program

**Federal Updates**

• C&G Accounting Updates
• Applied Innovation Topics
• Human Research Protections Updates
• ERA Project Updates
National Defense Authorization Act (NDAA)
Section 889

Applies to Federal Grants and Contracts
• Prohibits using federal funds to purchase telecommunications and video surveillance services or equipment from Huawei, ZTE, Hytera, Hangzhou, and Dahua (2 CFR 200.216)
• Prohibits federal agencies from contracting with an entity that simply uses “covered telecommunications equipment or services” as a substantial or essential component of any system (FAR 52.204-24, 51.204-25)
• Effective on all expenditures charged to Federal awards as of August 13, 2020
Cybersecurity Clauses in Federal Contracts

- FAR 52.204-21 Basic Safeguarding for Federal Contract Information
  - 17 Controls
  - Applies to Federal Contract Information (FCI)
- DFARS 252.204-7012 Safeguarding Covered Defense Information
  - NIST 800-171 Standard
  - Applies to Covered Defense Information (CDI)
- DFARS 252.204-7019, 7020
NIH Update
Prohibition on Expending NIH Grant Funds for Covered Telecommunications Equipment or Services

- OMB revised 2 CFR Part 200 to align with Section 889 of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Public Law 115-232) and the revision was effective for all agencies on August 13, 2020.
  - Recipients and subrecipients are prohibited from expending grant funds to:
    Procure or obtain; extend or renew a contract to procure or obtain; or enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that use covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system.
- Learn more: NOT-OD-21-041 and FAQs
Requirement for Trainee Diversity Report to be Submitted Electronically

• Beginning October 30, 2020, recipients are required to submit Trainee Diversity Reports electronically
• Applies to awards that require appointments through the xTrain system, including the following:
  • T15, T32, T34, T35, T37, T42, T90, TL1, TU2, TL4, TU2, K12/KL2, R25, R38, R90, RL5, RL9
• RPPRs lacking an electronically generated report will not be accepted.
• For the K12/KL2, R25, KM1 and R90, eRA will check whether an appointment has been made. If an appointment was made, NIH will require an electronically generated report. If no appointment was made the system will not be able to generate a report and a manual upload will be required.
• Learn more: NOT-OD-20-178
• Salary limitation on direct salary for individuals under NIH grants, contracts and cooperative agreement awards has increased to the current Executive Level II salary of $199,300 effective January 3, 2021. This change is also applicable to the agencies under the Department of Health and Human Services (DHHS), including, Agency for Healthcare Research and Quality (AHRQ) and the Substance Abuse and Mental Health Service’s Administration (SAMHSA).

• For all federals awards subject to this increase, PIs may rebudget to accommodate the current Executive Level II salary level if adequate funds are available. Please note that no additional funds will be awarded by the federal government to cover this increase.

• For UCI, this increase becomes effective for pay periods beginning February 1, 2021. Please note that UCOP has submitted a request to the UC Path team to update the DHHS salary cap in UC Path.

• Learn More: NOT-OD-21-057
Notice of Legislative Mandates in Effect for FY 2021

• Provides current requirements outlined in statutory provisions that limits or conditions the use of funds on NIH grant, cooperative agreement, and contract awards for FY 2021.

• Review the notice for additional information regarding this policy update.

• Learn More: NOT-OD-21-056
Notice of Fiscal Policies in Effect for FY 2021

- Provides guidance about the NIH Fiscal Operations for Fiscal Year 2021 and implements the Consolidated Appropriations Act, 2021 (Public Law 116-260), signed into law on December 27, 2020.

- The following NIH fiscal policies are instituted in FY 2021:
  - **FY 2021 Funding Levels:** Non-competing continuation awards made in FY 2021 will generally be issued at the commitment level indicated on the Notice of Award. The NIH awarding Institutes/Centers (ICs) will develop and post their fiscal policies consistent with overall NIH goals and available FY 2021 funds.

  - **Next Generation Researchers Initiative Policy:** NIH will prioritize meritorious R01-equivalent applications from Early Stage Investor (ESI) PD/Pis. By providing funding priority for ESIs, NIH intends to encourage funding applications that involve researchers earlier in their career in accordance with the policy established in FY 2017 and described in NIH Guide Notice NOT-OD-17-101.
Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2021

• This Notice supersedes NOT-OD-20-070 and establishes stipend levels for fiscal year (FY) 2021 Kirschstein-NRSA awards for undergraduate, predoctoral, and postdoctoral trainees and fellows.

• The Training Related Expenses and Institutional Allowances for predoctoral and postdoctoral trainees and fellows and the Tuition and Fees for all educational levels remain unchanged from the prior budget year.

• The budgetary categories described in this Notice apply only to Kirschstein-NRSA awards made with FY 2021 funds.

• All FY 2021 awards previously issued using NOT-OD-20-070 will be revised to adjust funding to the FY 2021 levels.

• Appointments to institutional training grants that have already been awarded in FY 2021 must be amended to reflect the FY 2021 stipend levels once the training grant award has been adjusted by the awarding agency.

• Learn More: NOT-OD-21-049
Updated Guidelines for Enhancing Diversity and Creating Safe Environments in Conferences Supported by NIH Grants and Cooperative Agreements

• This Notice provides updated guidance on enhancing the diversity of conferences supported by the National Institutes of Health (NIH) (under the R13 and U13 activity codes) and replaces previous guidance in NOT-OD-03-066 Guidelines For Inclusion Of Women, Minorities, And Persons With Disabilities In NIH-Supported Conference Grants.

• It also reiterates the expectation that organizers of NIH-supported conferences maintain inclusive, safe, and respectful environments for all attendees and provides examples of strategies to accomplish this expectation.
Conference grant applicants (R13/U13) must include plans to enhance diversity during the selection of organizing committees, speakers, other invited participants, such as session chairs and panel discussants, and attendees.

Plans to enhance diversity will be assessed during the scientific and technical merit review of the application. Plans will be considered in the overall impact score.

Awardees will be required to report on the effectiveness of plans to enhance diversity of underrepresented groups in annual Research Performance Progress Reports (RPPR) and the Final-RPPR.

Learn more: NOT-OD-21-053
Notice of Changes in the Review Criteria for Applications Submitted for NIH Support for Scientific Conferences (R13 and U13)

- Changes to the review criteria for applications submitted to NIH for support of Scientific Conferences (R13 and U13) related to the implementation of guidelines announced in NOT-OD-21-053 Updated Guidelines for Enhancing Diversity and Creating Safe Environments in Conferences Supported by NIH Grants and Cooperative Agreements.
- All changes take effect for R13/U13 applications submitted for the April 12, 2021 application due date.
- Applications submitted to NIH for support of Scientific Conferences (R13 and U13) are required to include a Diversity Plan. Reviewers will consider the Diversity Plan in determining the scientific and technical merit of the application, and in providing an overall impact score. The Diversity Plan will be evaluated as an additional review criterion and not receive a separate criterion score.
Notice of Changes in the Review Criteria for Applications Submitted for NIH Support for Scientific Conferences (R13 and U13) (cont.)

- R13/U13 applicants should describe in the Personal Statement of the Biographical Sketch senior/key persons’ past experiences with enhancing diversity by increasing the participation of individuals from diverse backgrounds, including those from underrepresented groups, in biomedical sciences.
- Reviewers will be asked to evaluate:
  - Is(are) the PD(s)/PI(s) well suited for organizing and fulfilling the goals of this conference, including efforts to enhance diversity?
  - Are the qualifications and past performance of the PD(s)/PI(s) appropriate, and are they well suited for their described roles in the conference?
  - Are the key personnel and selected speakers appropriate and well suited for their described roles in the conference?
- Learn More: NOT-OD-21-055
Questions?

Nancy Lewis, Executive Director, Sponsored Projects Administration
nrlewis@uci.edu

Grace Park, Assistant Director, Sponsored Projects Administration
parkgj@uci.edu
HOLY SMOKES BATMAN!

THAT’S A LOT OF INFORMATION
Agenda

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- Federal Updates
- **C&G Accounting Updates**
- Applied Innovation Topics
- Human Research Protections Updates
- ERA Project Updates
Contracts & Grants Accounting

- General Updates
- UK No Longer Part of Open Skies
- Direct Retros
- New Fixed Price Award Closeout Process
- New Contracts and Grants Aging Report
UK No Longer Part of Open Skies

“As of January 1, 2021, The United Kingdom (U.K.) is no longer a member of the EU. Consequently, the Open Skies Agreement with the EU does not pertain to the U.K. Travelers must use a U.S. Flag Carrier to travel from the U.S. to the U.K. and not a U.K. airline (e.g., British Airways), unless they use a different Fly America Act exception. Travelers may continue to use an EU agreement for travel from the U.S. to the U.K. as long as the flight stops in the EU prior to arrival in the U.S. or the U.K.”

Direct Retros

- Explain how the error occurred and why the transfer is being requested. If partial transfer, explain the basis for proration and/or split.
- Who approved the transfer of funds? (e.g. Name of PI, Department CAO)
- The transfer benefits the award as the PI was budgeted for 10% effort and has been working continuously on this project.
- Explain the untimeliness if transfer is: > 120 days after original transaction date, and/or > 90 days after the fund end date.

Training in UCLC
Fixed Price Award Closeout Process

• **NEW Procedure**
  Within 90 to 120 days after the expiration of a fixed-price award, the department/unit administering the award completes the Fixed-Price Award Closeout Form and emails it to the appropriate accountant in the Contracts and Grants Accounting (CGA) Office.

• **NO CHANGE to the Form**
  IF THERE IS A LARGE UNEXPENDED BALANCE (GREATER THAN $10,000 OR GREATER THAN 25% OF THE TOTAL AMOUNT RECEIVED FROM THE SPONSOR), PLEASE EXPLAIN IN THE SPACE BELOW THE CIRCUMSTANCE(S) THAT LED TO IT AND/OR THE REASON(S) FOR IT.
New Contracts & Grants Aging Report

• We will be publishing the new report in ZotPortal
• Shows data as of the last business day
• Data will be shown by Fund
• Can search or filter by:
  – Org or rollup Org for the Award
  – UC Fund Number
  – Primary Project Director’s UCINetID
# Report Summary

## Contracts & Grants Aging Report

**Award Org or Org Rollup Code:**

**Primary Project Director UCINetID:**

**UC Fund Number:**

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Drill down to see history and details

- You can see what is Open
- You can see what has been Paid
Drill down to Contracts & Grants Invoice

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<th>TOTAL BUDGET</th>
<th>INVOICE AMOUNT</th>
<th>CUMULATIVE EXPENDITURES</th>
<th>BUDGET REMAINING</th>
<th>TOTAL PREVIOUSLY BILLED</th>
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Questions?

Beata Najman, Director, Extramural Funds Accounting

bnajman@uci.edu

Kevin Chung, Financial Management Support Manager

chungkb@uci.edu
Quarterly Research Administration Meeting, continued!

February 24, 2021
HOLY SMOKES BATMAN!

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Agenda

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Meet the Team

UCI Beall Applied Innovation
For a complete list of departmental assignments: https://innovation.uci.edu/about/industry-sponsored-research/
Industry Sponsored Research handles agreements involving research funded by or through for-profit industry sponsors. Our Industry Contract Officers support researchers in negotiating agreements with companies, including:

- Confidentiality / Non-Disclosure Agreements
- Collaboration agreements
- Federally funded subcontracts received through industry
- Industry funded subcontracts received through a university/non-profit
- Research contracts funded by major corporations

Note: ISR handles proposals and agreements with a for-profit component, excluding clinical trials and outgoing subcontracts (i.e. UCI to a company).
ISR receives frequent requests for sponsored research agreements (contracts) prior to submission of a proposal. Many of these requests become after-the-fact and the proposal process and any associated regulatory committee approvals can delay ISR’s final signature on a sponsored research agreement.

**Have you submitted a proposal in Kuali?**

**Has the proposal been reviewed, approved, and “submitted”?**

**Do you need regulatory committee review and approval (IRB, IACUC, COI, etc.)?**
Questions?

Industry Sponsored Research

David Gibbons, Director
Agenda

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Human Research Protections

Beverley Alberola
Director
Effective February 1:
IRB Documentation Sharing Update:

• IRB Documentation Sharing Update:

• Beginning this month, HRP will provide IRB Application and supporting documentation to Chao Family Comprehensive Cancer Center (CFCC) to help facilitate their Protocol Review and Monitoring Committee (PRMC) process. An update to the IRB Application text to reflect this practice is anticipated March 2021. Any questions, contact the PRM unit at CancerCenter_Committees@hs.uci.edu.
Effective February 1:
Surrogate Consent Update:

• The Investigator Certification of Surrogate Decision Makers for Potential Subject’s Participation in University of California Research Form has been updated to remove signature lines.
Effective February 1:
Translated Short Form Updates:

– Removal of errant Investigator signature line for all translated languages
– New Urdu translated Short Form available
– Certificate of Translations available
Effective February 1: Appendices Updates:

Appendices O, P:
– Instructional text is clarified and better organized
– Removed the requirement to justify minimal risk
– Open text fields replaced by appropriate response options

Appendix U:
– Prompts for additional necessary documentation related to adding a reliance
Effective February 15:
Consent Updates:

• Combining the UC HIPAA Research Form with the IRB Approved Consent Form as a single PDF, at the time of IRB approval. Upon UCI IRB approval, only a Word (editable) version of the UCI IRB Approved Consent Form will post to the UCI IRB Document Depot. A Word version of the UCI HIPAA Research Form will not post.
Effective February 15: 
More Consent Updates:

– New Certificate of Confidentiality language added to address possible access to Epic for UCI Health treatment purposes
– Template text added to prompt researchers to include, as applicable, suggested methods of birth control
– Template text added to prompt researchers to address subject reimbursement
– Template text updated to further define routine care medical costs during a clinical research study vs. standard of care medical costs that occur outside (absent) of a clinical research study
– Template text added to include more specificity when imaging is done for research purposes.
• *All referenced forms are available on the HRP Apps & Forms page!*
Questions?

Beverley Alberola, Director, Human Research Protections

beverley.alberola@uci.edu
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• **ERA Project Updates**
The *Dynamite*) ERA Team:

Barbara
Martin
Alison
Kim
Jonathan
Kavi
Maureen
ERA Tips and Reminders

• Denial Letters

• Login.gov
  – Users will be required to use two-factor authentication (2FA) through Login.gov to access eRA Commons, ASSIST, Internet Assisted Review (IAR), and Commons Mobile by September 15, 2021.
  – Users can register for a Login.gov account and start using 2FA now. This is recommended so you’ll be familiar with the process by the time it’s required in September

ERA Project Updates

• KR Protocols
  – Phase 1 – *April 2021*: Non-Human Subjects Research Determination
  – Phase 2 – *August 2021*: EVERYTHING ELSE! IRB and hSCRO: Full Committee, Minimal Risk, sIRB, Expanded Access…and more
ERA Project Updates

• KR Conflict of Interest (COI)
  – Preliminary work
  – Spring/Summer 2021: Implementation activities
Transition to KR S2S

Cayuse 424 (Proposals)

Kuali Research
System-to-System (S2S)
Including Budget
Report Updates

• COMING SOON!
  – Personnel Awards Credit by Role
    • Date range for “active” awards, proposal data, redesign
  – Awards by Campus Area
  – Date range instead FY
  – Proposals by Campus Area – NEW!
  – ATS Updates
  – Proposal Development number and link

• Did you know?
  – DW Query – Protocols
Research Administration Data Tools Training

- Increased number of questions related to RA data
- ERA will host training sessions and post materials

- Or, if you have a group, let us know and we’ll schedule a session.
  - Email: era@research.uci.edu to schedule time
Questions?
“See” you next time...

Spring Virtual QRAM
May 19, 2021
10:00-11:30 AM

Send us topics you want to hear about!