Quarterly Research Administration Meeting

May 15, 2024
• Welcome
• Federal Update
• Malign Foreign Talent Recruitment Program
• Award Closeout-Stepped Up Enforcement by the Federal Government
• Award Closeout Process in the School of Biological Sciences
• Reportable Event Submission
• Clinical Research Transition
• Q&A and Closing
Honoring 40 Years of Service
Join Us in Celebrating Bruce Morgan's Retirement

Dear friends and colleagues:

After four decades of unwavering commitment and invaluable service, Associate Vice Chancellor for Research Administration Bruce Morgan, is retiring from the University of California. It's with great joy, yet a hint of sadness, that we announce his well-deserved retirement.

To honor Bruce's incredible career, we cordially invite you to join us for a celebratory event on Monday, June 17, 3-5pm at The Commons**, where we'll gather to reminisce on fond memories, share stories, and extend our heartfelt gratitude to Bruce for his years of service.

Please RSVP by May 31st to ensure we can properly accommodate all attendees.

Warm regards,

UCI Office of Research

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Have fond memories of time with Bruce? Want to share?

Leave a comment on Kudoboard: LEAVE KUDOS

Upload a photo for our slideshow: SHARE A PHOTO
Breakouts

• 5 minutes
• 4-5 people
• Cameras on!
  • Introduce yourself
• What are you most looking forward to this Summer?
• Welcome

• **Federal Update**
  • Malign Foreign Talent Recruitment Program
  • Award Closeout-Stepped Up Enforcement by the Federal Government
  • Award Closeout Process in the School of Biological Sciences
  • Reportable Event Submission
  • Clinical Research Transition
  • Q&A and Closing
Federal Update

Nancy Lewis
Spring 2024 QRAM
NIH Update
New 90-Day Closeout Reminder Notification (NOT-OD-24-047)

- NIH recipients must submit a Final Federal Financial Report (FFR), Final Research Performance Progress Report (F-RPPR), and Final Invention Statement and Certification (FIS) within 120 calendar days of the end of the period of performance (project period), as required in
  - Reference Section 8.6 of the NIH Grants Policy Statement.

- NIH currently sends reminder emails to recipients 10, 120, and 150 days after the project period end date.

- Beginning January 2024, NIH will begin sending an additional reminder closeout email notification 90 days after the project period end date.
Common Forms for Biographical Sketch and Current and Pending (Other) Support

- NIH has been working closely with the National Science Foundation (NSF) and other federal agencies on the Common Forms for the Biosketch and Current and Pending (Other) Support
  - Common Forms are posted on the NSF website: https://www.nsf.gov/bfa/dias/policy/nstc_disclosure.jsp
- NIH is implementing the Common Forms (Biosketch and Current and Pending (Other) Support) in a phased approach as part of Forms I
  - Until the Common Forms are fully adopted by NIH, NIH requires use of the current NIH Biosketch and Other Support formats for applications, Just-in-Time (JIT) Reports, and Research Performance Progress Reports (RPPRs)
    - Electronic signatures and supporting documentation are required
    - Failure to follow the appropriate formats may cause NIH to withdraw applications from or delay consideration of funding

• Informs the extramural research community of planned changes to the Research Performance Progress Report (RPPR) instructions to address the NIH Data Management and Sharing Policy

• Updated NIH RPPR Instruction Guide will be posted to the Research Performance Progress Report (RPPR) page

• NIH plans to implement new questions to address this requirement for RPPRs submitted on or after October 1, 2024
Notice of Fiscal Policies in Effect for FY 2024 (NOT-OD-24-109)

- Notice provides guidance about the NIH Fiscal Operations for Fiscal Year 2024 and implements the *Further Consolidated Appropriations Act, 2024* (Public Law 118-47), signed into law on March 23, 2024
- The categories covered by the Notice are as follows:
  - FY 2024 Funding Levels
  - Ruth L. Kirschstein National Research Service Awards (NRSA) Stipends
  - Salary Limits
- Additional Information: Additional details on Fiscal Operations, including specific funding strategies for ICs, will be posted on the NIH Funding Strategies webpage
Publication of the Revised NIH Grants Policy Statement (Rev. April 2024) for Fiscal Year 2024 (NOT-OD-24-115)

• Publication of the updated NIH Grants Policy Statement (NIHGPS, rev. April 2024)

• NIHGPS provides both up-to-date policy guidance that serves as NIH standard terms and conditions of award for all NIH grants and cooperative agreements, and extensive guidance to those who are interested in pursuing NIH grants

• Update is applicable to all NIH grants and cooperative agreements with budget periods beginning on or after October 1, 2023. This update supersedes, in its entirety, the NIHGPS dated December 2022
Publication of the Revised NIH Grants Policy Statement (Rev. April 2024) for Fiscal Year 2024 (NOT-OD-24-115)

• **Update** incorporates new and modified requirements, clarifies certain policies, and implements changes in statutes, regulations, and policies that have been implemented through appropriate legal and/or policy processes (e.g., Federal Register Notices, where appropriate) since the previous version of the NIHGPS dated December 2022.

• The Office of Management and Budget (OMB) has issued updates to 2 CFR Part 200 (Uniform Guidance), with an implementation date of October 1, 2024.

• NIH will include the changes to 2 CFR Part 200 in the FY 2025 release of the NIHGPS, in line with the implementation date set by OMB.
Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2024 (NOT-OD-24-104)

- Increase in annual pay levels for NRSA predoctoral and postdoctoral scholars:
  - Predoctoral scholars will receive an approximate 4% increase in their pay level bringing it to $28,224
  - Postdoctoral scholars will receive an approximate increase of 8%, with pay levels beginning at $61,008 and upwardly adjusted based on years of experience

- Eligible scholars will receive a $500 increase in subsidies for childcare and an additional $200 for training-related expenses.

- Includes a reminder that the maximum amount that NIH will award to support the compensation package for a graduate student researcher remains at the zero level postdoctoral stipend, as described in the NIH Grants Policy Statement 2.3.7.9.
Overview of Grant Application and Review Changes for Due Dates on or after January 25, 2025 (NOT-OD-24-084)

• Provides an overview of application and peer review changes impacting grant applications submitted for due dates on or after January 25, 2025, including:
  – Simplified Review Framework for Most Research Project Grant Applications
  – Revisions to the NIH Fellowship Application and Review Process
  – Updates to Reference Letter Guidance
  – Updates to NRSA Training Grant Applications
  – Updated Application Forms (FORMS-I)
  – Common Forms for Biographical Sketch and Current and Pending (Other) Support
New NIH "FORMS-I" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2025 (NOT-OD-24-086)

• Provides information regarding changes to grant application forms and application guide instructions for due dates on or after January 25, 2025

• **Key Changes:**
  – New attachment field for the Recruitment Plan to Enhance Diversity on the PHS 398 Research Training Program Plan
  – Modifications to some sections of the PHS Fellowship Supplement Form to improve the peer review process for NRSA Fellowship applications
  – NIH adoption and required use of the Common Forms for Biographical Sketch and Current and Pending (Other) Support by May 2025
NSF Update
Summary of Changes

• Seeking and Obtaining Tribal Nation Approval for Proposals that May Impact Tribal Resources or Interests
  • Proposers must
    • Seek guidance from the potentially impacted Tribal Nation
    • Submit a written request to the relevant Tribal Nation(s) for approval to carry out the activities that require review and approval
  • Information is included as a supplementary document
  • New checkbox on the Cover Sheet to indicate if there are “Potential Impacts on Tribal Nations.”
PAPPG (NSF 24-1)
Summary of Changes

- Biographical Sketch no longer has a page limitation, and the Synergistic Activities section has been removed.
  - New Common Disclosure form
  - Biographical Sketch will continue to be created in SciENcv, which will produce a pdf compliant version that can be attached to the proposal in Research.gov
- Synergistic Activities has been moved to a separate document.
  - Senior/Key personnel must include a one-page document with up to five examples of the broader impact of their professional and scholarly activities.
PAPPG (NSF 24-1)
Summary of Changes

- **Foreign Organizations:**
  - Updated guidance for justifying the inclusion of a foreign organization (subaward) or foreign individual (consultant) in a proposal budget
  - The justification must be included in the project description section of the proposal
  - The box for “Funding of a Foreign Organization or Foreign Individual” must be checked on the Cover Sheet
PAPPG (NSF 24-1)
Summary of Changes

CHIPS and Science Act of 2022

• **Current and Pending (Other) Support**
  
  • New [Common Disclosure form](https://www.nsf.gov/bfa/dias/policy/nstc_disclosure.jsp) will be implemented
    

  • Current and Pending Support form will continue to be created in SciENcv, which will produce a pdf compliant version that can be attached to the proposal in Research.gov
CHIPS and Science Act of 2022

• Postdoctoral scholars or graduate students who receive substantial NSF support must have an Individual Development Plan which is required to be updated annually

• Proposals that request funding for graduate students (new) or postdoctoral scholars must include a mentoring plan in the supplementary documentation section of Research.gov
CHIPS and Science Act of 2022

- **Foreign influence and Malign Foreign Talent Recruitment related policies**
  - NSF’s implementation of the National Security Presidential Memorandum-33 (NSPM-33).
  - Individuals who are a party to a Malign Foreign Talent Recruitment are not eligible to serve as a Senior/Key Person on NSF proposals and awards.
  - As part of the proposal submission, the University of California, Irvine **must certify** that all individuals identified as senior/key persons have been made aware of and have complied with their responsibility to certify that they are not party to a Malign Foreign Talent Recruitment Program.
NSF Resources and Helpful Websites


• NSF Policy Office Outreach webpage: https://nsfpolicyoutreach.com/

• NSF Policy Outreach Resource Center: https://nsfpolicyoutreach.com/resource-center/
Questions?
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FOREIGN (NON-US) TALENT RECRUITMENT PROGRAM
FOREIGN TALENT RECRUITMENT PROGRAM
FEDERAL GOVERNMENT’S DEFINITION

Any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the foreign country, to an individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue.

Consistent with Section 10632(d) of the Act, a foreign talent recruitment program does not include the following international collaboration activities, so long as the activity is not funded, organized, or managed by an academic institution or a foreign talent recruitment program on the lists developed under paragraphs (8) and (9) of Section 1286(c) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 4001 note; Public Law 115-232):

1. Making scholarly presentations and publishing written materials regarding scientific information not otherwise controlled under current law;
2. Participating in international conferences or other international exchanges, research projects or programs that involve open and reciprocal exchange of scientific information, and which are aimed at advancing international scientific understanding and not otherwise controlled under current law;
3. Advising a foreign student enrolled at an institution of higher education or writing a recommendation for such a student, at such student’s request; and
4. Engaging in the following international activities:
   a. Activities that are partly sponsored or otherwise supported by the United States such as serving as a government appointee to the board of a joint scientific fund (e.g., the U.S. Israel Binational Industrial Research and Development Foundation), providing advice to or otherwise participating in international technical organizations, multilateral scientific organizations, and standards setting bodies (e.g., the International Telecommunications Union, Intergovernmental Panel on Climate Change, etc.), participating in a Fulbright Commission program funded in whole or in part by a host country government; or other routine international scientific exchanges and interactions such as providing invited lectures or participating in international peer review panels.
   b. Involvement in national or international academies or professional societies that produce publications in the open scientific literature that are not in conflict with the interests of the federal research agency (e.g., membership in the Pontifical Academy of Sciences or The Royal Society).
   c. Taking a sabbatical, serving as a visiting scholar, or engaging in continuing education activities such as receiving a doctorate or professional certification at an institution of higher education (e.g., the University of Oxford, McGill University) that are not in conflict with the interests of the federal research agency.
   d. Receiving awards for research and development which serve to enhance the prestige of the federal research agency (e.g., the Nobel Prize).
   e. Other international activities determined appropriate by the federal research agency head or designee.

Summary
• Program, position, or activity
• With compensation including but not limited to: cash, honorific titles, research funding, complimentary foreign travel
• Provided by a foreign country or their designee, or an entity based in, funded by or affiliated with a foreign country, whether or not directly sponsored by foreign country

Some exclusions (see definition)
NON-US TALENT RECRUITMENT PROGRAM
UC GUIDANCE

An initiative aimed at recruiting experts in academia and other sectors to cultivate a non-U.S. nation’s domestic talent pool in support of that nation’s strategic civil and military goals. The arrangement will typically include a non-U.S. university and a UC researcher but will not ordinarily include UC.

Indicators of a Non-US Talent Recruitment Program:
- A written or verbal agreement such as an employment agreement or memorandum of understanding.
- Promised compensation that might include such things as cash or in-kind compensation, research support, complimentary travel, and honorific titles.
- An arrangement that typically includes a non-U.S. university and UC researcher, but doesn’t always include the UC researcher’s institution.
- Support that might be from a non-U.S. government national, provincial, or local sector or include a private entity.
- Requirement that the researcher comply with the laws of the non-U.S. nation.
- Requirement that the researcher commit effort/time in the talent program resulting in conflict of commitment or interest in excess of the standard UC and/or U.S. federal agency requirements.
MALIGN FOREIGN TALENT RECRUITMENT PROGRAM
FEDERAL GOVERNMENT’S DEFINITION

(A) any program, position, or activity that includes compensation in the form of cash, in-kind compensation, including research funding, promised future compensation, complimentary foreign travel, things of non de minimis value, honorific titles, career advancement opportunities, or other types of remuneration or consideration directly provided by a foreign country at any level (national, provincial, or local) or their designee, or an entity based in, funded by, or affiliated with a foreign country, whether or not directly sponsored by the foreign country, to the targeted individual, whether directly or indirectly stated in the arrangement, contract, or other documentation at issue, in exchange for the individual—

(A) engaging in the unauthorized transfer of intellectual property, materials, data products, or other nonpublic information owned by a United States entity or developed with a Federal research and development award to the government of a foreign country or an entity based in, funded by, or affiliated with a foreign country regardless of whether that government or entity provided support for the development of the intellectual property, materials, or data products;

(B) being required to recruit trainees or researchers to enroll in such program, position, or activity;

(C) establishing a laboratory or company, accepting a faculty position, or undertaking any other employment or appointment in a foreign country or with an entity based in, funded by, or affiliated with a foreign country if such activities are in violation of the standard terms and conditions of a Federal research and development award;

(D) being unable to terminate the foreign talent recruitment program contract or agreement except in extraordinary circumstances;

(E) through funding or effort related to the foreign talent recruitment program contract or agreement except in extraordinary circumstances;

(F) being required to apply for and successfully receive funding from the sponsoring foreign government’s funding agencies with the sponsoring foreign organization as the recipient;

(G) being required to omit acknowledgment of the recipient institution with which the individual is affiliated, or the Federal research agency sponsoring the research and development award, contrary to the institutional policies or standard terms and conditions of the Federal research and development award;

(H) being required to not disclose to the Federal research agency or employing institution the participation of such individual in such program, position, or activity; or

(I) having a conflict of interest or conflict of commitment contrary to the standard terms and conditions of the Federal research and development award; and

(B) a program that is sponsored by—

(A) a foreign country of concern or an entity based in a foreign country of concern, whether or not directly sponsored by the foreign country of concern;

(B) an academic institution on the list developed under section 1286(c)(8) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 4001 note; Public Law 115-232);

(C) a foreign talent recruitment program on the list developed under section 1286(c)(9) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (10 U.S.C. 4001 note; Public Law 115-232)."
FOREIGN (NON-US) TALENT RECRUITMENT PROGRAMS AND MALIGN FOREIGN TALENT RECRUITMENT PROGRAMS

Federal Government

- CHIPS and Science Act of 2022 defined Foreign Talent Recruitment Program (FTRP) and Malign Foreign Talent Recruitment Program (MFTRP)
- Guidelines for Federal Research Agencies Regarding Foreign Talent Recruitment Programs prohibits “covered individuals” (certain individuals substantively involved with preparing award applications or carrying out awards) from participating MFTRPs
- Beginning May 20, 2024, National Science Foundation established that individuals who are a party to a MFTRP are not eligible to serve as a senior/key person on an NSF proposal
- Beginning August 9, 2024, Department of Defense is prohibited from providing funding to or making an award of a fundamental research project proposal in which a covered individual is participating in a MFTRP or to a proposing institution that does not have a policy addressing MFTRP

University of California

- Beginning July 1, 2024), updated Academic Personnel’s Conflict of Commitment Policies APM-025 and APM-671 to clarify application to or participation in a non-US talent recruitment program is a Category I activity that requires prior approval through UC OATS goes into effect
- Implementing revisions to the UC Contracts & Grants Manual to comply with DOD policy requirement and other federal agencies as appropriate
DISCLOSURE REQUIREMENTS

Federal Government

• Disclose in biographical sketches and if applicable, other/current & pending support in proposal applications and annual progress reports
• Certifications in proposals and annually that covered individual is not participating in a malign foreign talent recruitment program

University of California

• Starting July 1, 2024, through UC OATS:
  • Prior approval request for participating in foreign talent requirement program
  • Annual disclosure of time spent participating in foreign talent recruitment program along with other professional activities
BEST PRACTICES

• Review FTRP and MFTRP definitions
• Ask questions about the opportunity (requirements, expectations, duration, sponsor)
• Submit prior approval request as required through UC OATS
POTENTIAL RED FLAGS

• Foreign entity may not explicitly indicate the foreign opportunity is part of a FTRP
• May be an unsolicited opportunity or referred by another participant in the program
• Typically longer-term, ongoing position, project, or affiliation
• Arrangement typically includes a non-US university and UCI researcher, but doesn’t always include UCI
• May not provide specific details regarding the nature of the opportunity
• May require UCI researcher to not disclose participation to UCI and/or federal agencies
RESOURCES

• **UC OATS**- to submit annual disclosures of outside professional activities and prior approval requests
  • [Academic Personnel](#)

• Research Security and International Engagement
  • [Website](#)
  • International Engagement Tool- coming soon

• University of California Office of President
  • [How to Identify a Non-US Talent Recruitment Program](#)
  • [New Clarifications & Policy Revisions: Academic Conflict of Commitment & Outside Activities](#)
Agenda

- Welcome
- Federal Update
- Malign Foreign Talent Recruitment Program
  - **Award Closeout-Stepped Up Enforcement by the Federal Government**
- Award Closeout Process in the School of Biological Sciences
- Reportable Event Submission
- Clinical Research Transition
- Q&A and Closing
Timely Submission of Final Technical Reports and Deliverables to Federal Sponsors

Nancy Lewis
Senior Director, Sponsored Projects Administration
Important Reminder:
Timely Submission of Final Technical Reports and Deliverables to Federal Sponsors

Dear UCI Researcher Community,

Recently, delays in submitting final technical reports to federal government sponsors have had significant consequences for UC Irvine. One Principal Investigator’s failure to adhere to the prescribed reporting deadlines resulted in UC Irvine being listed on SAM.gov’s non-compliance list, a list monitored by all federal agencies, and significant delays in NIH and Department of Defense awards.
NIH Enforcement of Unilateral Closeout Reporting in the System for Award Management Responsibility/Qualification (formerly Federal Awardee Performance and Integrity Information System (FAPIIS)) (NOT-OD-24-055)

- Final Federal Financial Report (FFR), **Final Research Performance Progress Report (F-RPPR)**, and Final Invention Statement and Certification (FIS) **must be submitted** within 120 calendar days of the end of the award.
- Reports become overdue the day after the 120 calendar day period ends.
- NIH will initiate unilateral closeout if all required closeout reports and not submitted within a year of the award end date.
- NIH will also report the recipient's failure to comply with the terms and conditions of award in SAM.gov.
- Failure to correct recurring reporting problems may cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding of further awards, suspension or termination per **Section 8.5.2** of the NIH GPS.
UCI’s Unilateral Closeout Case Study

• NIH award unilaterally closed because of a PI’s failure to submit a final RPPR
• NIH submitted a non-compliance report in SAM.gov
  – The report is visible to federal sponsors and the public
• As a result of the non-compliance report, awards from NIH and Department of Defense were delayed
• UCI filed a management corrective action plan in response to the non-compliance report.
### UNIVERSITY OF CALIFORNIA IRVINE

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### AWARDEE INFORMATION

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Key Takeaways

• Timely submission of final reports and deliverables under federal awards is the primary responsibility of the Principal Investigator however it is up to all of us to ensure that reports are submitted timely

• SPA is enhancing its monitoring of final reports by:
  – Closely monitoring the final report lists for federal sponsors and providing reminders to faculty regarding the due dates for final reports
  – Escalating cases where awards are in danger of going into unilateral close to leadership
    • PI’s may lose proposal submission privileges
  – Collaborating with ERA to develop tools and dashboard for monitoring final report due dates
Questions?
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Award Closeout - a Collaborative Effort

Jason Park
Director, Contracts and Grants
- NIH enforcement of unilateral closeout policy
- How do I do this? Where to find the closeout report
- Annual RPPR ≠ Interim RPPR ≠ Final RPPR
- BioSci process to address closeouts and stories
NIH Grants Policy Statement
8.6 Closeout
The requirement for timely closeout is generally a recipient responsibility. However, NIH may initiate unilateral closeout if a recipient does not provide timely accurate closeout reports or does not respond timely to NIH requests to reconcile discrepancies in grant records. Failure to submit timely and accurate closeout documents may affect future funding to the organization. Failure to correct recurring reporting problems may cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding or further awards, suspension or termination.
NIH enforcement

- NOT-OD-24-047 reminder of NOT-OD-18-107

- As a long-standing policy, NIH recipients must submit a Final Federal Financial Report (FFR), Final Research Performance Progress Report (F-RPPR), and Final Invention Statement and Certification (FIS) within 120 calendar days of the end of the period of performance (project period), as required in section 8.6 of the NIH Grants Policy Statement. The reports become overdue the day after the 120-calendar day period ends. It is the recipient's responsibility to accurately reconcile their FFRs that are submitted to the Payment Management System (PMS) and to ensure that all required closeout documents are submitted in a timely manner.
NIH enforcement

- NOT-OD-24-047 reminder of NOT-OD-18-107

  NIH currently sends reminder emails to recipients 10, 120, and 150 days after the project period end date. To increase outreach efforts to recipients prior to final reports becoming delinquent, starting in January 2024 NIH will begin to send an additional reminder closeout email notification 90 days after the project period end date. As with the 120- and 150-days reminders, recipients will only receive this notification if there is at least one required closeout report that has not been submitted as of the date of the notification.
NOT-OD-24-055

The purpose of this Notice is to alert the NIH extramural community that NIH is strengthening enforcement of longstanding closeout requirements, outlined in the NIH Grants Policy Statement (NIH GPS) Section 8.6, Closeout. NIH has consistently reminded recipients of their responsibility to submit timely, accurate final grant expenditure, progress and invention reports. In order to fulfill agency requirements under the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards at 2 CFR 200, NIH will report all unilateral closeouts of NIH awards as a Responsibility/Qualification (formerly FAPIIS) record in the entity’s information in the System for Award Management (SAM.gov). Please be reminded that, without prior approval from the awarding institute or center for a delay in closeout, NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days as required by Section 8.6 of the NIH GPS.
NOT-OD-24-055

NIH Actions

NIH is committed to addressing and reducing grant closeout delays and to enhance compliance with Federal regulations and NIH policies. Therefore, NIH will strictly enforce its closeout policies. When recipients fail to submit timely reports, NIH will initiate unilateral closeout. If a recipient does not submit all required closeout reports within a year of the period of performance end date, NIH will unilaterally close the award and report the recipient's failure to comply with the terms and conditions of award in SAM.gov. In addition, failure to correct recurring reporting problems may cause NIH to take one or more actions that may include, but are not limited to, corrective actions, withholding of further awards, suspension or termination per Section 8.5.2 of the NIH GPS.
Closeout Enforcement

NIH is strengthening enforcement of longstanding closeout requirements.

- Recipients must submit timely, accurate closeout reports
- Reports are LATE after 120 calendar days
  - NIH may allow late submission with prior approval (i.e., acceptable written justification)
  - Cash transaction data is submitted directly to PMS
  - Recipient responsibility to reconcile FFR and FCTR data

When recipients fail to submit timely reports NIH will initiate unilateral closeout.

- When no FFR is submitted, HHS policy directs NIH to close the grant using the last accepted FCTR
- This could be considered a debt or result in disallowed costs

See [NOT-OD-18-107](https://example.com/NOT-OD-18-107)
2. Final Project Report

The final project report should address progress in all activities of the project, including any activities intended to address the Broader Impacts criterion that are not intrinsic to the research. This report is not cumulative; it is the last annual report of the project and should be written specifically for the most recently completed budget period. By submitting the final project report, the PI is signifying that the scope of work for the project has been completed and that he/she does not anticipate that any further research activities (including a no-cost extension, supplemental funding, or transfer of the grant) need to be completed on the project. Submission of the final project report, however, does not preclude the grantee from requesting any further payments for costs incurred during the period of performance.

Unless otherwise specified in the award, the final project report should be submitted electronically no later than.

4. Compliance with Technical Reporting Requirements

PIs must submit final technical reports within the time period specified. Failure to provide these reports on a timely basis delay NSF review and processing of pending proposals for all for all identified PIs and co-PIs on a given grant.
**Where do we find the closeout section?**

- Not under RPPR section!

- Under status, last year of the award. e.g. 1R01GM012345-05

- RPPR submitted for yr 4 is not the final report.

Closeout has 3 components.

1. **FFR** Final financial report (C&G accounting)
2. **FRPPR** Final progress reports (PI and award manager)
3. **FIS** Final Invention Statement
Root cause of overdue reports?

- Procrastination by PI
- Lack of oversight by Post Award Admin
- PI unavailable / unreachable – i.e. left institution
- Assumption that it was completed by ???
Implemented Processes

• Upon project end date, courtesy email sent to PI from Post-awards staff regarding closeout deadline.

• The Post-Awards staff will then monitor the progress of the report and advise the PI on the requirements of the report.

• 2 weeks before deadline, Associate Dean for Research emails PI

• 1 week before Deadline - Personal visit to PI
  • aka initiate “Manhunt and Quarantine” protocol

• Once the PI has completed the report, the Post-Award staff reviews for accuracy and consistency with prior annual reports.

• Final Invention Statement- Research Translation Group validates, SO verifies – should be done well before 120 day mark.

Fellowship award equivalent

• Xtrain – Termination notices
Results from Implementation

• Submission of final RPPR well before the 120 day deadline

• Post Award administration and Faculty more cognizant of deadlines and requirements

• Same practices followed on annual / interim RPPRs and other Federal/ Non-Federal reports

• Remain in compliance
Know Role versus Responsibility

Sure glad the hole isn’t at our end.

Jason Park – jpark@uci.edu
https://research.bio.uci.edu/

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Agenda

- Welcome
- Federal Update
- Malign Foreign Talent Recruitment Program
- Award Closeout-Stepped Up Enforcement by the Federal Government
- Award Closeout Process in the School of Biological Sciences
- **Reportable Event Submission**
- Clinical Research Transition
- Q&A and Closing
Noncompliance & Unanticipated Problems

Presented by: Rachna Basu, MS, CCRP, CIP
Compliance Manager, Human Research Protections
<table>
<thead>
<tr>
<th>Noncompliance</th>
<th>Serious Noncompliance</th>
<th>Continuing Noncompliance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to comply with:</td>
<td>Significant adverse impact on:</td>
<td>Pattern of noncompliance that indicates an inability or unwillingness to comply</td>
</tr>
<tr>
<td>• laws, regulations, policies re: protection of human subjects, and/or</td>
<td>• rights or welfare of participants or</td>
<td></td>
</tr>
<tr>
<td>• IRB requirements/determinations</td>
<td>• on the integrity of the data</td>
<td>Report within 5 business days</td>
</tr>
</tbody>
</table>

Not Reportable

Report within 5 business days

Report within 5 business days
Unanticipated Problem (UP)

Report within 5 Days

Unexpected

(Possibly) Related

Greater Risk of Harm
AEs Not UP

Unanticipated Problems (UPs)

AEs Are UPs

UPs Not AEs

Adverse Events (AEs)
<table>
<thead>
<tr>
<th>Type of Event</th>
<th>Reporting Process</th>
</tr>
</thead>
<tbody>
<tr>
<td>Noncompliance</td>
<td>Follow External IRB policy; do not submit to UCI IRB</td>
</tr>
<tr>
<td>Serious/Continuing Noncompliance</td>
<td>Submit to External IRB + UCI IRB</td>
</tr>
<tr>
<td>Unanticipated Problem (UP)</td>
<td>Submit to External IRB + UCI IRB</td>
</tr>
<tr>
<td>Hold/suspension issued by External IRB, FDA, Sponsor, or DSMB risk to human subjects</td>
<td>Submit as an UP to UCI IRB</td>
</tr>
</tbody>
</table>
# How to Report

The image shows a screenshot of a webpage from the UCI Office of Research Administration. The focus is on the 'Reportable Events' section of the page. The page contains a table listing reportable events, with columns for Event Type, Description, Status, Event Date, and Recorded Date. The table is empty, indicating that there are no reportable events currently listed.

## Reportable Events Table

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Description</th>
<th>Status</th>
<th>Event Date</th>
<th>Recorded Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 of 0 reportable events</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Human Research Protections Policies:

- 19 Reporting of Adverse Events and Unanticipated Problems
- 52 Research Non-compliance
- 55 Protocol Deviation and Violation Reporting

Protocol Events Table

Reporting a Problem
Questions?
• Welcome
• Federal Update
• Malign Foreign Talent Recruitment Program
• Award Closeout-Stepped Up Enforcement by the Federal Government
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Transition of Industry Clinical Research

Effective 5/1/24

Presented by Sponsored Projects Administration, Industry Clinical Research Contracting (ICRC)
Effective May 1, 2024, all Industry Clinical Research proposals and agreements will be reviewed and negotiated by Sponsored Project Administration’s (SPA) Industry Clinical Research Contracting (ICRC) team to provide process clarity for faculty and sponsors, streamline workflows, and consolidate clinical research contracting expertise in a single administrative unit.

Clinical Research is any research involving human subjects (clinical trials), their data or biologic specimens, even if Institutional Review Board (IRB) approval is not required.

Beall Applied Innovation (BAI) will continue to process and negotiate proposals and awards for clinical education and training projects sponsored by industry.
Industry Clinical Research Contracting (ICRC)  
(formerly Clinical Trials Team)

Tam Tran, Director  
Alison Dang, Principal Contract Officer  
Shabana Durrani, Principal Contract Officer  
Nolan Imamura, Principal Contract Officer  
Garrett Larsen, Principal Contract Officer  
Lisa Marks, Principal Contract Officer  
Laura Moss, Principal Contract Officer  
Rosa Hernandez, Contract Officer  
Rean Du, Student Assistant  
Miki Lam, Student Assistant (Beginning June 2024)  
Serena Wu, Student Assistant (Graduating June 2024)

Contact us: or-ctcontracts@uci.edu
Officer Assignments

• As part of the transition, Industry Clinical Research proposals and agreements that were previously negotiated by BAI will now be negotiated by the following officers:

Nolan Imamura, Principal Contract Officer
• Joined UCI in 2023; transferred to Office of Research in 2024
• Department Assignments
  • CCR
  • Stem Cell Center
• Contact Information
  • Email: nimamura@uci.edu
  • Phone: (949) 824-1037

Laura Moss, Principal Contract Officer
• Joined UCI in 2018; transferred to Office of Research in 2024
• Department Assignments
  • Cancer Center
  • All Other Departments/Schools/Units
• Contact Information
  • Email: lmoss@uci.edu
  • Phone: (949) 824-2430

Questions? Email: or-ctcontracts@uci.edu
As a result of this change, Kuali Research (KR) has been updated to add the “Clinical Research” Activity Type (for human subject, clinical research that is not a clinical trial) in KR Proposal Development. Previously, the activity types such as “Basic Research” or “Other Sponsored Activity” were used to capture this subset of clinical research.

Please continue to select “Clinical Trial Research” for studies that are Clinical Trials.

New awards for Clinical Research will be reflected in the Award Transaction Summary (ATS). The new Activity Type will be available in DW Query as well as all of OR’s standard reports.

To assist users in selecting the correct Activity Type, a help link has been added on the KR Proposal Development document on the first page. Please review the Activity Type definitions there to ensure the correct Activity Type is selected.
Which SPA Team to Contact About Your Clinical Research?

1. Clinical Research
   - Clinical trials involving investigational drugs, devices or any other intervention on human subjects

2. Funding Source
   - Industry
   - Non-Profit
   - Federal/CIRM Flow-Through
   - Federal
   - CIRM

   - Industry
   - Non-Profit
   - Federal/CIRM Flow-Through
   - Federal
   - CIRM

3. Lead SPA Team
   - Industry Clinical Research Officer
   - Federal Officer
   - Principal Officer
   - Industry Clinical Research Officer
   - Non-Federal Officer
   - Federal Officer
   - Principal Officer

For a complete contact list of SPA staff, please visit https://research.uci.edu/sponsored-projects/contact-spa/
Questions?
See you next time!

Wednesday, August 21, 2024
10:00AM-11:30AM
Agenda ideas? Email us at era@research.uci.edu