HS SPPO Contacts Meeting

July 31, 2019
Agenda

- UC San Diego Updates & Reminders (Erika Wilson)
- NIH Updates & Reminders (Rachel Cook)
- ClinicalTrials.Gov Monitoring Updates (Monique Teixeira)
- International Engagement Considerations for Export Control and Conflict of Interest (COI) (Jennifer Ford & Brittany Whiting)
UC San Diego Updates & Reminders

- with Erika Wilson, Senior Director, HS SPPO
# Minimum Requirements for Incoming & Outgoing Subawards

**HS SPPO REQUIRES THE SAME DOCUMENTS EITHER WAY!!!**

<table>
<thead>
<tr>
<th>Incoming Subawards</th>
<th>Outgoing Subawards</th>
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<tbody>
<tr>
<td><strong>Sub’s Proposal</strong></td>
<td><strong>New or Resubmission</strong></td>
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<tr>
<td><strong>Package</strong></td>
<td><strong>Option 1</strong></td>
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<td>• PHS 398 Face Page*</td>
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<td>• Statement of Work</td>
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<td>• 395 Budget Form Pages</td>
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<td>• Budget Justification</td>
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<td>• PHS 398 Checklist</td>
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<td>Option 2</td>
<td>• PHS 398 Face Page*</td>
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<td>• Statement of Work</td>
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<td>• R&amp;R Budget Form Pages</td>
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<td>• Budget Form Pages (R&amp;R Budget)</td>
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| **Option 2**      | **New or Resubmission** | **RPPR (Progress Report)** |
|                   | • PHS 398 Face Page* | • PHS 398 Face Page*        |
|                   | • Statement of Work  | • Statement of Work          |
|                   | • 395 Budget Form Pages | • 395 Budget Form Pages |
|                   | • Budget Justification | • Budget Justification |
|                   | • PHS 398 Checklist  | • PHS 398 Checklist        |
|                   | • PHS Face Page* | • PHS Face Page*            |
|                   | • Statement of Work  | • Statement of Work          |
|                   | • R&R Budget Form Pages | • R&R Budget Form Pages |
|                   | • Budget Form Pages (R&R Budget) | • Budget Form Pages (R&R Budget) |

*HS SPPO prefers the signed NIH PHS 398 or 2590 Face Page to Letters of Consortium, Letters of Intent, MCAs, and/or Subrecipient Commitment Forms.*
When the need arises where you need to contact NIH, please initially discuss this with your HS SPPO Analyst. We will determine if we need to step in and act as an intermediary for you and the PI, or we will determine if the topic is generic enough where we do not need to become involved at this stage of the conversation.
Question: What IDC rate should be applied when there is an Electronic Non-Payroll Expense Transfers (ENPET)?

Answer: The rate applied is at the time of the transfer transaction and not at the time when expense was incurred.

Example: An internal proposal has a start date prior to 6/30/19 and was budgeted with an IDC rate of 57%. The proposal was set up on or after 7/1/19. Thus, the ENPET(s) will be charged at the current rate of 57.5%. There will be no manual adjustment to charge at the lower, proposed rate of 57%.
Freedom of Information Act (FOIA) Requests

Subject: Notification of FOIA Request, grant 1T32GM127235-01, case 51321 NIGMS

Dear Dr. Hwa,

My name is XXX and I work as a Government Information Specialist Intern for the National Heart, Lung, and Blood Institute (NHLBI) FOIA Service Center at the National Institutes of Health (NIH). My office also processes FOIA requests for NIH/NIGMS.

My office recently received a FOIA request asking for a copy of the SF424 (R&R) Other Project Information section and the PHS 398 Research Training Program Plan section of grant 1T32GMXXXXXX-01, awarded by NIH/NIGMS.

A copy of the FOIA request is attached.

My office has a copy of grant 1T32GMXXXXXX-01 and we have begun our review and redactions. See the attached “General Guidelines” for information that is automatically withheld by my office.

In order for our office to process the FOIA request, I need you to complete the following actions:

• Identify proprietary information (if any) located in your grant by using a translucent highlight and return a copy of the highlighted portions to me by email or fax.
• If proprietary information is identified, please include a detailed and thorough justification explaining how and why the information will result in substantial commercial or competitive harm if it is released.
• Sign the bottom of the attached Release Letter and return it to me by email or fax no later than Monday, July 22nd, 2019.

Please contact me if you have any questions. Thanks!

Best Regards
FOIA Requests & What Do You Do?

• If you or your PI receive a FOIA request for portions of a submitted application, please forward this request to Angie McMahill, Executive Director, Research Compliance and Integrity & Paula Johnson, Director, Policy and Records Administration.

<table>
<thead>
<tr>
<th>Angie McMahill</th>
<th>Paula Johnson</th>
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<tbody>
<tr>
<td><a href="mailto:amcmahill@ucsd.edu">amcmahill@ucsd.edu</a></td>
<td><a href="mailto:pjjohnson@ucsd.edu">pjjohnson@ucsd.edu</a></td>
</tr>
<tr>
<td>(858) 534-7321</td>
<td>(858) 534-2552</td>
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</tbody>
</table>


• The Freedom of Information Act (“FOIA”), 5 U.S.C. 552, provides individuals with a right to access to records in the possession of the federal government. The government may withhold information pursuant to the nine exemptions and three exclusions contained in the Act.
Introducing the HS SPPO Quarterly Newsletter!

We will be introducing the HS SPPO Newsletter next month!!!

The newsletter will cover topics such as UC and NIH updates; relevant policy, procedures, SOPs; and application, JIT, and RPPR tips.

It will be published quarterly, on the 15th of the following months:

- August
- February
- May
- November

If you are not already a listserv member of our HS Contacts group, please subscribe today in order to start receiving our HS SPPO Newsletter next month, please join at hscontacts-l listserv!
NIH Updates & Reminders

- with Rachel Cook, Senior Grant Analyst, Supervisor, HS SPPO
Reminder!!! RPPR & D.1 Participants Effort

- Last summer, NIH changed its RPPR format to allow effort reported in Progress Reports to include decimals. Before this change, the system only allowed whole numbers and rounded up or down accordingly. The lack of the ability to include decimals contributed to significant inaccurate reporting when a PD/PI had contributed 20% effort or 2.4 calendar months, and the previous system feature rounded said effort down to 2 calendar months.

[Table]

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<tr>
<th>Commons ID</th>
<th>S/K</th>
<th>Name</th>
<th>Degree(s)</th>
<th>Role</th>
<th>Person Months</th>
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<tr>
<td>UCSD-1B</td>
<td>Y</td>
<td>Flint, Keith</td>
<td>PHD</td>
<td>PD/PI</td>
<td>2.4</td>
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</table>

[Link]

NOT-OD-19-107: NIH Expanding Usage of Notices of Special Interest

- Succinctly highlight a specific topic of interest, for example a specific area of research or program
- Direct applicants to one or more active FOAs (often parent announcements) for submission of applications for the initiative described
- Applicants must also adhere to any additional submission guidance described in the Notice of Special Interest.
  - Most Notices of Special Interest require applicants to include the notice number in the Agency Routing Identifier field (4b) of the SF424 (R&R) form at time of submission so NIH can assign and track applications and awards for the described initiative. It is critical that applicants adhere to this notice instruction.

“NIH has NOT substantially changed its expectations of what should be reported. However, the recent cases of foreign influence have exposed activities and resources that should have been reported to institutions and NIH, and were not. This Notice and following FAQs are intended to make those requirements more clear,” Wendy D. Streitz, President, Council on Governmental Relations (COGR) and former Executive Director, UCOP RPAC.

- Notice Intent: “to remind the extramural community about the need to report foreign activities through documentation of other support, foreign components, and financial conflict of interest to prevent scientific, budgetary, or commitment overlap.”

International Engagement & Financial Conflict of Interest will be touched on by our guest speakers: Brittany Whiting and Jennifer Ford.

Other Support Reminder

NIH reminds applicants and recipients that 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. This includes resource 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.

1. List all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application;

2. Report all resources and other support for all individuals designated in an application as senior/key personnel;

3. Report all current projects and activities that involve senior/key personnel both domestic and foreign, even if the support received is only in-kind; and

4. Provide the total award amount for the entire award period covered, as well as the number of person-months per year (AKA: effort) to be devoted to the project by the senior/key personnel involved.
NIH requires recipients to determine whether activities it supports include a foreign component, defined as: the existence of any “significant scientific element or segment of a project” outside of the United States, in other words

1. Performance of work by a researcher or recipient in a foreign location, whether or not NIH grant funds are expended; and/or

2. Performance of work by a researcher in a foreign location employed or paid for by a foreign organization, whether or not NIH grant funds are expended.

- If a recipient determines that a portion of the project will be conducted outside of the U.S., the recipient then will need to determine if the activities are considered significant. If both criteria are met, then there is a foreign component.

- If an activity does not meet the definition of foreign component because all research is being conducted within the United States, but there is a non-U.S. resource that supports the research of an investigator and/or researcher, it must be reported as other support.
Foreign Components: Examples

Example #1
If a PD/PI of an NIH-funded grant has a collaborator outside of the U.S. who performs experiments in support of the PD/PI’s NIH-funded project, this would constitute a foreign component, regardless of whether the foreign collaborator receives funding from the PD/PI’s grant.

Example #2
Additional funding from a foreign source for the NIH-supported research of a PD/PI at a U.S. institution would not constitute a foreign component but would necessitate reporting as other support.
FAQs - Other Support and Foreign Components

The FAQs are broken out into three parts:

A. Other Support;
B. Foreign Components; and
C. Financial Conflict of Interest (FCOI).

Standout Other Support FAQs

https://grants.nih.gov/grants/faq-other-support-foreign-components.htm
2. What does NIH evaluate when reviewing Other Support submissions?

NIH scientific program and grants management staff review Other Support information 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

3. I am a PI on an NIH award to a domestic university and have an unpaid appointment at a foreign university. At the foreign site I have access to lab space, research materials, and staff. Should I report this as Other Support?

Yes. While the researcher is not receiving monetary compensation, the lab space, materials, and staff are resources made available to them in support of and/or related to their research efforts. Other payments, such as travel or living expenses must also be reported. NIH requires applicants to list all positions and scientific appointments both domestic and foreign held by senior/key personnel that are relevant to an application 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).

8. What should I do if I’m not sure if something needs to be included as Other Support?

In the interest of full transparency, recipients should err on the side of disclosure. Researchers should consult with their institutional officials for guidance to ensure compliance with institutional and NIH policies. NIH requires complete and accurate reporting of all sources of research support, financial interests and affiliations, both foreign and domestic.
CLINICALTRIALS.GOV MONITORING UPDATES

MONIQUE M. TEIXEIRA, JD, CHRC
SENIOR RESEARCH COMPLIANCE ANALYST
RESEARCH COMPLIANCE AND INTEGRITY OFFICE
UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

- Conflict of Interest (COI)
- Dual Use Research of Concern (DURC)
- Export Control and Facility Security
- Institutional Animal Care and Use Committee (IACUC)
- Research Ethics and Integrity (Research Misconduct)
- ClinicalTrials.gov, NIH Good Clinical Practices (GCP) and Responsible Conduct of Research (RCR) Compliance

Website: RCI.UCSD.EDU
Helpline: (858) 822-4939
Email: rci@ucsd.edu
Challenges

• There is not a systematic way to identify the applicable clinical trials that need to be registered

• UC San Diego does not have an Institutional account for the clinical trial registration

• There is no institutional or central office support for ClinicalTrials.gov
<table>
<thead>
<tr>
<th>Entity</th>
<th>Registration</th>
<th>Results</th>
<th>Penalties</th>
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<tbody>
<tr>
<td>Food and Drug Administration (FDA)</td>
<td>Within 21 days of enrollment</td>
<td>Within 365 of Primary Completion Date</td>
<td>$11,569/study/day and Criminal proceedings</td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
<td>Within 21 days of enrollment</td>
<td>Within 365 of Primary Completion Date</td>
<td>Loss of grant funding (to include the institution)</td>
</tr>
<tr>
<td>National Cancer Institute (NCI)</td>
<td>Not Specified</td>
<td>Within 365 of Primary Completion Date</td>
<td>Loss of grant funding</td>
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<tr>
<td>Centers for Medicare &amp; Medicaid Services (CMS)</td>
<td>Not Specified</td>
<td>Not Specified</td>
<td>Coverage denial and fraud investigations</td>
</tr>
<tr>
<td>International Committee of Medical Journal Editors (ICMJE)</td>
<td>Prior to enrollment of the first participant</td>
<td>Not Specified</td>
<td>Restricted from publishing in journals</td>
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</table>
Email Account

- `ctgov@ucsd.edu` is registered with ClinicalTrials.gov
- Monitored by Research Compliance and Integrity
- All ClinicalTrials.gov correspondence goes to this email
- Emails sent regarding problem records are sent from this address
UCSD Institutional Account

- Institutional Protocol Registration and Review System (PRS) account
  - UCSDMED

- Individuals are given user profiles under the institutional PRS account
  - Number of user accounts: 491

- Allows Administrator to track all study records and send notifications and follow up on “problem” records
New User Accounts

1. To gain a new user account, email ctgov@ucsd.edu and provide your full name and email address.

2. The PRS Administrator will send the profile request to ClinicalTrials.gov.

3. ClinicalTrials.gov will email the new user and notify them of their user name and provide temporary password. (within 2 days)

4. You may now log into the ClinicalTrials.gov Protocol Registration System.

5. Change temporary password to permanent one.
RESEARCH COMPLIANCE AND INTEGRITY WEBSITE UPDATES

https://blink.ucsd.edu/sponsor/rci/clinical-trials.html
Registration:

1. How to Register: ClinicalTrials.gov User's Guide and Registration (PDF)
2. Who is the Responsible Party?: Determining the Responsible Party decision tree
3. What to Register? Registration and Results Decision Tree (PDF)

Updating:

1. Annual Report and Updating the Study Record (PDF)

Results:

1. How to Publish Results: Publishing Results and Adverse Events Factsheet (PDF)
2. Study Document Upload: Clinicaltrials.gov Instructions for Uploading Study Documents and Redaction Guide (PDF)
FAQ: https://blink.ucsd.edu/sponsor/rci/clinical-trials-faq.html

General Questions

Registration Questions

Protocol Registration and Results System (PRS)

Problem Records

PRS Review and Reviewer Comments

Posting Results

Resources
Some Institutions allow Industry Sponsors to appoint either the Institution or the Principal Investigator as the Responsible Party. However, UCSD does not allow for this.

If a study is Industry Sponsored the Sponsor has the responsibility to register and maintain the record.
UC San Diego will be utilizing a tool created by UCLA, PROCoM, to help manage UC San Diego’s ClinicalTrials.gov registered studies.
Notification and reminder emails will come from “RCI ClinicalTrialsGov” however the email address is procom@mednet.ucla.edu.

These are legitimate emails used by the RCI Office to provide important messages regarding ClinicalTrials.gov study records.

When these emails are replied to they get sent to the RCI monitored email account.
LATE RESULTS – PER FDAAA

RCI maintains a detailed database of all studies registered on ClinicalTrials.gov.

If a study has a flag ‘Late Results – Per FDAAA’, the UCSD administrator will reach out to the study team to have the results uploaded.
Meetings

- Determine if a study is required to be registered
- Review how to respond to PRS reviewer comments
- Review how to upload results
- Determine how to describe outcome measures

RCI is happy to meet with departments, teams, and investigators to review ClinicalTrials.gov regulations.
Contacting ClinicalTrials.gov

register@clinicaltrials.gov

Researchers can contact the ClinicalTrials.gov team for assistance. Their support can be particularly helpful when it comes to complex study designs or issues with submitting summary results information into The Protocol Registration and Review System (PRS). In most cases, the ClinicalTrials.gov team provides guidance by email, but in some cases, they may also offer to set up a teleconference at a mutually convenient time to discuss study specifics and provide tailored guidance as to how to enter results into PRS.
SEOEP Trainings

The Research Compliance and Integrity (RCI) Office hosts the RCI Hot Topics and Training Program which coordinates educational and training programs for UCSD faculty, students and staff involved in research.

September 26, 2019 will be ClinicalTrials.gov

1.5 hours and will include a Question and Answer session

Announcement will go out to our ListServe to sign up
COMMUNICATIONS

- Research Compliance and Integrity Helpline: (858) 822-4939, rci@ucsd.edu
- Conflict of Interest Helpline: (858) 534-6465. info-coi@ucsd.edu
- Export Control Helpline: (858) 246-3300, export@ucsd.edu
- IACUC Helpline: (858) 534-6069, iacuc@ucsd.edu
- Hot Topics and Newsletters:

  - Website: http://blink.ucsd.edu/sponsor/rci/news.html
  - Research Compliance and Hot Topics Training Program
  - To be added to the RCI list serv, please email rci@ucsd.edu
RESOURCES:

**Research Compliance and Integrity:**
Phone: (858) 822-4939  
Email: rci@ucsd.edu  
Website: rci.ucsd.edu  
Executive Director: Angela Fornataro McMahill

**IACUC:**  
Phone: (858) 534-6069  
Email: iacuc@ucsd.edu  
Website: blink.ucsd.edu/sponsor/iacuc  
Director: Kristen Anderson-Vicino

**Conflict of Interest:**  
Phone: (858) 534-6465  
Email: info-coi@ucsd.edu  
Website: blink.ucsd.edu/sponsor/coi  
Director: Jennifer J. Ford

**Export Control, DURC and Facility Security:**  
Phone: (858) 246-3300  
Email: export@ucsd.edu  
Website: blink.ucsd.edu/sponsor/exportcontrol  
Director: Brittany Whiting
QUESTIONS?
THANK YOU
Helpful Links

1. How to Submit Your Results homepage

2. Basic Results Data Elements Definitions
   http://prsinfo.clinicaltrials.gov/results_definitions.html

3. 10 minute webinars for each results module
   http://clinicaltrials.gov/ct2/manage-recs/present

4. Helpful Hints (with common study designs examples)
   http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf

5. ClinicalTrials.gov Review of Protocol Submissions
   http://prsinfo.clinicaltrials.gov/fdaaa.html
1. ACT Wizard: http://grants.nih.gov/clinicaltrials_fdaaa/docs/Flow_chart-ACT_only.pdf
Select References – Final Rule

1. Federal Register Notice: HHS Final Rule
2. Federal Register Vol. 81, No 183, September 21, 2016
3. Federal Register Notice: NIH Policy
4. Summary Table: HHS Final Rule and NIH Policy
5. Summary of Changes: HHS Final Rule and NIH Policy
6. JAMA: Toward a New Era of Trust and Transparency in Clinical Trials
7. NEJM: The Final Rule for US Clinical Trial Registration and Results Information Submission
8. NIH Director’s Blog: Clinical Trials – Sharing of Data and Living Up to Our End of the Bargain
9. NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information
Select References –
NIH Definition of Clinical Trial

5. Case Studies (illustrate the differences between clinical trials and clinical studies)
6. Decision Tree
7. FAQs
8. NOT-OD-15-015 Notice of Revised NIH Definition of “Clinical Trial” (Released 10/23/14)
UC San Diego

RESEARCH COMPLIANCE AND INTEGRITY

- Conflict of Interest (COI)
- Dual Use Research of Concern (DURC)
- Export Control and Facility Security
- Institutional Animal Care and Use Committee (IACUC)
- Research Ethics and Integrity (Research Misconduct)
- ClinicalTrials.Gov, NIH GCP and RCR Compliance

Website: RCI.UCSD.EDU
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Email: rci@ucsd.edu
GOVERNMENT CONCERN OVER UNIVERSITIES & FOREIGN INFLUENCE

- Public cases of Export Violations involving Universities
- Increased scrutiny by Congress, White House, and Federal Agencies
- Increased visits by federal agencies to Universities, FBI, BIS, ICE
- Economic espionage concerns
Heightened concern at federal level that certain foreign entities may seek to influence U.S. research at all levels including:

- Peer review
- Diversion of intellectual property
- Sharing of confidential information and the use of resources originating outside the U.S. inconsistency in reporting drives federal concern
Percival Zhang, founded & Chief Scientific Officer of Cell-Free Bioinnovations, Inc. ("CFB"), was awarded SBIR/STTR by NSF
- Grad Student was listed at PI and CTO at CFB
- Postdoc was listed as Chief Scientist at CFB

Undisclosed external activity:
- Worked as a paid researcher for the Tianjin Institute of Industrial Biotechnology, Chinese Academy of Sciences
- Talents Program Funding

NSF grant funds fraudulently obtained for research, Zhang knew had already been done in China
- Zhang intended to use the grant funds for other CFB projects rather than for the projects for which the funds were requested
National Institutes of Health
The NIH issued a notice reminding the research community of their obligation to disclose Financial Conflict of Interest (FCOI). They specifically called out foreign financial interests as a concern (March 30, 2018)
- Over 55 academic and research institutions
- Publications listing foreign collaborations with support Contracts/Grants & COI
- Affiliations with or without support
- Comprehensive listing of other support (salary or non-salary)
- Research conducted outside U.S.
- Foreign talents programs

Department of Defense
- The National Defense Authorization Act requires the DOD to develop procedures limiting foreign access to technologies through grants, contracts, cooperative agreements or other transactions based on national security interest and to work with academic institutions to limit undue influence, including through foreign talent programs, by countries to exploit United States technology within the DOD research, science and technology, and innovation enterprise (August 13, 2018)
National Science Foundation
The National Science Board (NSB), which governs the NSF, issued a statement on national security and science. In it NSB Chair Diane Souvaine affirmed the board’s commitment to the free exchange of ideas and information, while also acknowledging the need to create new policies to protect national interests. (October 23, 2018)

Department of Energy
- The DOE issued memos stating:
  - Researchers in unspecified “emerging research areas and technologies” would no longer be allowed to collaborate with colleagues from unnamed “sensitive” countries, December 14, 2018
  - Restrictions on funded researchers from participating in any foreign talent-recruitment programs, January 31, 2019
  - DOE Order 486.1, June 7, 2019
    - DOE will take appropriate actions to prohibit DOE employees and DOE contractor employees, while employed by DOE or performing work under a contract, from the unauthorized transfer of scientific and technical information to foreign government entities through their participation in foreign government talent recruitment programs of countries designated by DOE as a foreign country of risk.
CHALLENGES WE HAVE IDENTIFIED

- Conflict of Commitment not filed annually
- Conflict of Interest not filed when needed
- “Other Support” reporting is incomplete
- Funding agencies are not updated on new foreign engagements
- Inconsistencies across campus
- Visitor support
- Lack of awareness
The US Government issues various lists of individuals & entities both in the U.S. & abroad that have committed export violations or other serious offenses.

- Terms & conditions require no debarred, disqualified or ineligible persons
- Part of funding awards, procurement and service agreements

Financial dealings or export transactions with Restricted or Prohibited parties is prohibited.

- Terrorists
- Weapons Proliferators
- Export Violators
- Drug Traffickers

Visual Compliance Screening Tool
RESTRICTED ENTITY EXAMPLES (NOT COMPREHENSIVE)

- BEIJING UNIVERSITY OF AERONAUTICS AND ASTRONAUTICS (BUAA) AKA BEIHANG UNIVERSITY
- NORTHWEST POLYTECHNICAL UNIVERSITY
- SICHUAN UNIVERSITY
- UNIVERSITY OF ELECTRONIC SCIENCE AND TECHNOLOGY OF CHINA
- NATIONAL UNIVERSITY OF DEFENSE TECHNOLOGY
- MALEK ASHTAR UNIVERSITY OF TECHNOLOGY
- BAQIYATTALLAH UNIVERSITY OF MEDICAL SCIENCES
- IMAM Hossein UNIVERSITY
- BEN GURION UNIVERSITY (BGU)
CONFLICT OF INTEREST (COI) AND CONFLICT OF COMMITMENT (COC)

Jennifer J. Ford,
Conflict Of Interest Director
<table>
<thead>
<tr>
<th>Category</th>
<th>Agency</th>
<th>Examples</th>
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<tr>
<td>Sponsored Research</td>
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<td>National Health Institute (NIH)</td>
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<td>National Science Foundation (NSF)</td>
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<td></td>
<td>Non-Federal</td>
<td>For-Profit</td>
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<td></td>
<td></td>
<td>Non-Profit*</td>
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<td>Non-Federal</td>
<td>For-Profit or Non-Profit*</td>
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<td></td>
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<td>• Gifts</td>
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<td>• Material Transfer Agreements (MTA)</td>
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<td>• Service</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Unfunded**</td>
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* There are non-profit sponsors exempt from the disclosure requirement
** Disclosure may be required for internal University clinical research projects when Human Subjects are involved
### What Constitutes a Potential Research COI?

<table>
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<tr>
<th>Type of Interests*</th>
<th>Examples</th>
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<tbody>
<tr>
<td>Income / Compensation</td>
<td>Salaries, Consulting, Honoraria</td>
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<tr>
<td>Ownership / Position</td>
<td>Founder, Partner, Board of Directors, Scientific Advisory Board, Employee</td>
</tr>
<tr>
<td>Equity / Ownership Interest</td>
<td>Stocks, Bonds, Stock Options</td>
</tr>
<tr>
<td>Gifts</td>
<td>From outside entity</td>
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<tr>
<td>Loans</td>
<td>Money loaned to outside entity</td>
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<tr>
<td>Travel Expenses / Reimbursement</td>
<td>Paid from outside entity</td>
</tr>
<tr>
<td>Intellectual Property / Patent</td>
<td>Non-UC royalties</td>
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*Applies to the Employee, Spouse, Registered Domestic Partner, and Dependent Children*
WHICH COI DISCLOSURE FORMS AND WHEN TO SUBMIT?

PHS Form submitted at time of proposal and PHS supplement at NOA. 9510 and 700U must be completed, signed and dated at time of proposal.

<table>
<thead>
<tr>
<th>Funding Entity / Sponsor</th>
<th>Disclosure Form Required with Initial Submission</th>
<th>Additional Form Required if Positive</th>
<th>When does COI Office review?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Services (PHS) (NIH and those who have adopted PHS)</td>
<td>PHS Form</td>
<td>Supplement</td>
<td>Notice of Award</td>
</tr>
<tr>
<td>Federal Non-PHS (NSF, CIRM, UC Programs)</td>
<td>9510</td>
<td>Addendum</td>
<td>Proposal submission</td>
</tr>
<tr>
<td>Non-Federal (For-Profit or Non-Profit)*</td>
<td>700U</td>
<td>Addendum</td>
<td>Proposal or equivalent</td>
</tr>
</tbody>
</table>

* There are non-profit sponsors exempt from the disclosure requirement.
## Thresholds for Disclosure?

<table>
<thead>
<tr>
<th>Funding Entity / Sponsor</th>
<th>Income / Compensation</th>
<th>Ownership / Position</th>
<th>Investment / Equity</th>
<th>Travel Expenses/Reimbursement</th>
<th>Loans</th>
<th>Gifts</th>
<th>Intellectual Property / Patent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Services (PHS)</td>
<td>publicly traded &gt; $5,000</td>
<td>Any</td>
<td>publicly traded &gt; $5,000</td>
<td>&gt; $5,000</td>
<td>&gt; $5,000</td>
<td>&gt; $5,000</td>
<td>&gt; $5,000 (excludes UC)</td>
</tr>
<tr>
<td></td>
<td>non-publicly traded &gt; $5,000</td>
<td>non-publicly traded ≥ $0</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Federal Non-PHS 9510</td>
<td>&gt; $10,000</td>
<td>Any</td>
<td>&gt; $10,000 or &gt; 5% owner</td>
<td>≥ $10,000</td>
<td>&gt; $10,000</td>
<td>&gt; $10,000</td>
<td>Any royalties (excludes UC)</td>
</tr>
<tr>
<td>Non-Federal 700U</td>
<td>&gt;$500</td>
<td>Any</td>
<td>&gt;$2,000</td>
<td>≥ $0</td>
<td>≥ $500</td>
<td>≥ $50</td>
<td>Any royalties (excludes UC)</td>
</tr>
</tbody>
</table>

Important: Update of Financial Interests for Sponsored Activities within 30 days.
EXAMPLES THAT MAY CREATE A CONFLICT OF INTEREST

- Starting a company
  - Founder and managerial position
- Employee position at a company
- Visiting appointment at a foreign University or foreign Government
- Being on a proposal or award for another entity
- Operating a lab at another entity
- Consulting for a company or foreign University
  - Being on the Scientific Advisory Board (SAB)
- Travel expenses or reimbursement paid by an outside entity
THE INTERSECTION BETWEEN CONFLICT OF INTEREST (COI) AND CONFLICT OF COMMITMENT (COC)?
## CONFLICT OF COMMITMENT (COC) AND CONFLICT OF INTEREST (COI)

<table>
<thead>
<tr>
<th></th>
<th>Conflict of Commitment</th>
<th>Conflict of Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Policies</strong></td>
<td>APM 025 / APM 671</td>
<td>UCSD PPM 200-13, APM 028, OP PHS and NSF*</td>
</tr>
<tr>
<td><strong>Disclosure Forms</strong></td>
<td>Category I (prior approval) and II</td>
<td>Dependent on outside funding entity**</td>
</tr>
<tr>
<td><strong>Timing</strong></td>
<td>Category I: Prior to Engagement</td>
<td>Proposal and/or award stages and then dependent on funding</td>
</tr>
<tr>
<td></td>
<td>Category II: Annually</td>
<td></td>
</tr>
<tr>
<td><strong>Responsible Offices</strong></td>
<td>Academic Affairs</td>
<td>Conflict of Interest Office</td>
</tr>
</tbody>
</table>

**Similarity:** Engagement with outside activities

* There are many COI policies, see http://blink.ucsd.edu/sponsor/coi/policies.html
* Disclosure may be required for internal funding when Human Subjects are involved
WHAT CAN WE DO TO PROTECT UC SAN DIEGO?

- Follow established UC and UC San Diego Procedures
- UC Policies on COI, COC and External Research outline responsibilities for reporting
  - For PHS, disclose Foreign Institutions and Governments:
    - Disclose financial interests including foreign Universities and foreign governments
    - Income OR travel expenses/reimbursement over $5,000 (disclose within 30 days)
- Our existing procedures for proposals, agreements, purchasing and visiting scholars are in place to comply with regulations and alert us to address risks
- Use visual compliance for screening foreign collaborators, including visitors, funding entities, purchases or shipments
  - Restricted parties lists are being updated every few days by the USG
- Be transparent with UCSD and Federal Agencies
- Escalate any requests for information from federal authorities on national security or export controls
A Good Rule of Thumb

- Any external support (whether financial or not) or engagement that you would acknowledge in public presentations or publications is something that you should also disclose in grant applications, annual reports and closeout summaries and in university-related COI and COC disclosure forms (as required).

- “Transparency and compliance with UC and federal requirements are mechanisms to support all investigators and faculty.”

- Resources Online: https://blink.ucsd.edu/research/foreign-engagements.html
<table>
<thead>
<tr>
<th>CONTACTS</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Compliance and Integrity (RCI)</td>
<td>Angie McMahill</td>
</tr>
<tr>
<td>Export Control</td>
<td>Brittany Whiting</td>
</tr>
<tr>
<td>Conflict of Interest (COI)</td>
<td>Jennifer J. Ford</td>
</tr>
<tr>
<td>Health Sciences Sponsored Projects Pre-award Office (HSSPPO)</td>
<td>Erika Wilson</td>
</tr>
<tr>
<td>Office of Postdoctoral and Research Scholar Affairs (OPRSA)</td>
<td>Jennifer (Oh) Bourque</td>
</tr>
<tr>
<td>Office of Contract and Grant Administration (OCGA)</td>
<td>Linda Collins</td>
</tr>
<tr>
<td>Office of Innovation and Commercialization (OIC)</td>
<td>Paul Roben</td>
</tr>
<tr>
<td>Graduate Division</td>
<td>Paul Yu</td>
</tr>
<tr>
<td>Academic Senate and Council on Research</td>
<td>Andrew Kehler, Robert Horwitz</td>
</tr>
<tr>
<td>Office of International Affairs (OIA)</td>
<td>Chip Schooley</td>
</tr>
</tbody>
</table>
UC San Diego can expect site visits by outside agencies as part of routine oversight activities and for specific ongoing investigations.

The University’s practice is to cooperate with outside investigating agencies, while protecting the rights and privacy of the students, faculty, staff and research subjects.

Promptly contact Research Compliance and Integrity who will provide assistance or alert appropriate institutional offices.

For additional information and FAQs, please see https://blink.ucsd.edu/research/policies-compliance-ethics/index.html
Research Compliance and Integrity Helpline: (858) 822-4939, rci@ucsd.edu
Conflict of Interest Helpline: (858) 534-6465, info-coi@ucsd.edu
Export Control Helpline: (858) 246-3300, export@ucsd.edu
IACUC Helpline: (858) 534-6069, iacuc@ucsd.edu
Hot Topics and Newsletters:

Website: http://blink.ucsd.edu/sponsor/rci/news.html
Research Compliance and Hot Topics Training Program
To be added to the RCI list serv, please email rci@ucsd.edu