HS SPPO Contacts Meeting

October 1, 2018
Agenda

- HS SPPO & VCHS Updates: Erika Wilson
- Research Compliance & Integrity
  - Jennifer Ford, Director, Conflict of Interest
  - Kristen Anderson-Vicino, Director, IACUC
  - Brittany Whiting, Export Control Officer, Export Control
HS SPPO & VCHS Updates
Erika Wilson
Senior Director, HS SPPO
Clarification on Internal Proposals – Selecting a Due Date in ePD

If you are creating an ePD record for an internal proposal, please follow the HS SPPO Submission Timelines when selecting the proposal deadline date under the General Info tab.

- [https://medschool.ucsd.edu/vchs/research-services/hssppo/review/Pages/Submission-Timelines.aspx](https://medschool.ucsd.edu/vchs/research-services/hssppo/review/Pages/Submission-Timelines.aspx)

In addition, please make a note that this is an internal proposal in the internal comments section under the Abstract tab:

![Abstract Table with Internal Comments Section](image-url)
Clarification on Internal Proposals – Selecting a Due Date in ePD

OR

Please select “Internal Proposal” in the dropdown menu for ‘UCSD Proposal Type’ under the Others tab:

<table>
<thead>
<tr>
<th>Lookup Values</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Transfer Proposal</td>
<td>Transfer Proposal</td>
</tr>
<tr>
<td>2 Internal Proposal</td>
<td>Internal Proposal</td>
</tr>
<tr>
<td>3 NIH Minority Supplement</td>
<td>NIH Minority Supplement</td>
</tr>
<tr>
<td>4 Supplement (other than NIH Minority)</td>
<td>4 Supplement (other than NIH Minority)</td>
</tr>
<tr>
<td>5 N/A</td>
<td>None of the Above</td>
</tr>
</tbody>
</table>

Per our policy described above, HS SPPO advises against choosing a due date six-months out.
Go Paperless!

All handouts and brochures are available on our showcase website.

Scan QR Code or point your browser to:

rscshowcase.ucsd.edu

Visit the Showcase Online
Showcase Systems and Tools

Dashboard systems and tools that will be showcased are

NEW THIS YEAR
- Tableau reporting and visualizations integrated with UCSD Health Sciences Applications
- Integration of OnBase Document Management with UCSD Health Sciences Applications

OnBase® Enterprise Content Management
- A single enterprise information platform for document management and form creation, designed to enhance business processes and workflow

Research 360
- Single, unified dashboard system that reports on pre and post award research administration activities

Electronic Financial Status Report (eFSR)
- Combines automatically updated ledger data with projections to generate a systematic and comprehensive financial status report for PIs

Training Grant Resources
- Training Grant Resources and training offered by RSC include data table tracking and NIH xTRACT

RSC Help
- Web based electronic help desk system for automated routing and recording of client feedback
RSC Systems

NEW THIS YEAR

Tableau reporting and visualizations integrated with UCSD Health Sciences Applications
Integration of OnBase Document Management with UCSD Health Sciences Applications

OnBase®
A single enterprise information platform for document management and form creation, designed to enhance business processes and workflow

Research 360
Single, unified dashboard system for managing and reporting on pre and post award research administration activities, including: comprehensive proposal tracking, post award portfolio tracking, payroll reporting, and more!

Training Grant Resources
Training Grant Resources offer T32 resources on data tables, NIH xTRACT, xTRAIN, grant application support, trainee appointments and financial management

eFSR
Electronic Financial Status Report (eFSR)
Combines automatically updated ledger data with projections to generate a systematic and comprehensive financial status report for PIs

RSC Information
Welcoming site resource for new and existing staff that includes toolkits, process map resources, and project update and web based electronic help desk system for automated routing and recording of client feedback

Contact:
Isabella Bryant-Parkinson
ibryantparkinson@ucsd.edu

https://researchsystemsshowcase.eventbrite.com

UC San Diego Health
Oversight and Responsibility for:

- Conflict of Interest (COI)
- Dual Use Research of Concern (DURC)
- Export Control and Facility Security
- Institutional Animal Care and Use Committee (IACUC)
- Research Integrity

Website: RCI.UCSD.EDU
Research misconduct per the federal regulations includes:

- **Fabrication**: Making up data or results and recording or reporting them.
- **Falsification**: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism**: The appropriation of another person’s words, ideas, processes or research results without acknowledgement, and passing them off as one's own.

Questionable research practices should be resolved by the appropriate department/research group: Authorship disputes, attribution of credit, data access and use, differences of opinion or honest error.

For assistance, contact Angela McMahon, Executive Director, Research Compliance and Integrity at amcmahill@ucsd.edu, (858) 534-7321.
THE ROLE OF THE CONFLICT OF INTEREST OFFICE

The UC San Diego Conflict of Interest Office, also known as the COI Office, role is to provide faculty and staff assistance in assessing circumstances under which their outside activities or financial interests may inappropriately conflict with their responsibilities to the University.
CONFLICT OF INTEREST (COI) OFFICE SERVICES

- Reviews disclosures of financial interests from University faculty and staff
- Ensures compliance with all applicable regulations
- Serves as a resource to University faculty, staff and institutional offices
Faculty APM 025/671: Conflict of Commitment
- Not managed by the COI Office

Staff Conflict of Interest:
- PPSM-82

Provide guidance for COI
- Starting companies
- Consulting with companies
## WHEN ARE CONFLICT OF INTEREST (COI) DISCLOSURES REQUIRED?

<table>
<thead>
<tr>
<th>COI Research and Other Related Activity Disclosures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
</tr>
<tr>
<td>Sponsored Research</td>
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<tr>
<td>Other Related Activity</td>
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</tbody>
</table>

* There are sponsors exempt from the disclosure requirement
### WHAT CONSTITUTES A POTENTIAL RESEARCH COI?

<table>
<thead>
<tr>
<th>Type of Interests*</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Income/Payments</td>
<td>Salaries, Consulting, Honoraria</td>
</tr>
<tr>
<td>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>
</tr>
<tr>
<td>Loans</td>
<td>Money loaned to outside entity</td>
</tr>
<tr>
<td>Travel Reimbursement/Payments</td>
<td>From outside entity</td>
</tr>
<tr>
<td>Intellectual Property</td>
<td>Non-UC royalties</td>
</tr>
</tbody>
</table>

*Applies to the Employee, Spouse, Registered Domestic Partner, and Dependent Children*
<table>
<thead>
<tr>
<th>Funding Entity</th>
<th>Common Sponsors</th>
<th>When to Disclose</th>
<th>Who Must Disclose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Services (PHS)</td>
<td>NIH or those that have adopted FCOI</td>
<td>Initial submission, Change in funding, Addition of new personnel, Change in financial interest, No cost extension, At least annually</td>
<td>Principal Investigator (PI), Project Director, Senior/Key Personnel, and Others who direct or can materially influence the research, or who are responsible for the design, conduct, and reporting of such research</td>
</tr>
<tr>
<td>Federal Non-PHS*</td>
<td>NSF, CIRM and UC Programs</td>
<td>Initial submission, Change in funding, Change in financial interest</td>
<td>Principal Investigator (PI), and All other individuals who have the responsibility for the design, conduct or reporting of research</td>
</tr>
<tr>
<td>Non-Federal*</td>
<td>Non-Profit For-Profit</td>
<td>Initial submission, Additional funding, Renewal proposal Change in financial interest</td>
<td>Principal Investigator (PI) Studies involving human subjects, PI and any study personnel with a financial interest in an entity that would reasonably appear to be affected by the research</td>
</tr>
<tr>
<td>Unfunded Projects</td>
<td>Internal unrestricted</td>
<td>Initial submission to IRB</td>
<td>PI with a financial interest in an entity that would reasonably appear to be affected by the research</td>
</tr>
<tr>
<td>Clinical Research</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*There are sponsors exempt from the disclosure requirement: all non-profit, tax-exempt educational institutions, and those on the list (on COI Website).

**Important:** Update of Financial Interests for Sponsored Activities within 30 days.
<table>
<thead>
<tr>
<th>Who is the Sponsor?</th>
<th>Which Disclosure Form?</th>
<th>What to Disclose?</th>
<th>Who decides if the research and the interests are related?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Health Services (PHS) (i.e. NIH and those who have adopted PHS)</td>
<td>PHS</td>
<td>Disclose all interests related to the discloser’s Institutional Responsibilities*</td>
<td>Institution</td>
</tr>
<tr>
<td>Federal Non-PHS (i.e. NSF, CIRM, UC Programs)</td>
<td>9510</td>
<td>Disclose any interests related to the work to be conducted under the proposed project</td>
<td>Discloser</td>
</tr>
<tr>
<td>Non-Federal (For-Profit or Non-Profit)**</td>
<td>700U</td>
<td>Disclose any interests with the sponsor(s)</td>
<td>Institution</td>
</tr>
</tbody>
</table>

* Reasonably appears to be related to or is in the same field of expertise as your Institutional Responsibilities.

** Includes research and other related activities (gifts, service agreements, MTAs, unfunded projects, etc.)
**INITIAL SUBMISSION OF COI DISCLOSURE FORMS**

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

<table>
<thead>
<tr>
<th>Sponsor</th>
<th>Disclosure Form Required with Initial Proposal 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 Annually</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 submission</td>
</tr>
</tbody>
</table>
Special review line in ePD AND email completed, signed and dated COI Disclosure forms to coiforms@ucsd.edu with ePD #

STTR/SBIR if a University researcher wants to be the PI for the Company, contact the COI Office

Disclose financial interests including foreign Universities and foreign governments consistent with the regulations of the applicable COI form

Researchers need to provide updates of financial interest within 30 days

COI question for interests with Subrecipients in Marketplace
WHAT HAPPENS IF THERE IS A POSITIVE COI DISCLOSURE?

If a financial interest exists:

- Investigator’s financial disclosure forms must be reviewed by the COI Office
- Depending on the scope and nature of the disclosure and/or project the conflict of interest may be managed by the Independent Review Committee (IRC) on Conflict of Interest
- Various institutional offices receive notice that the COI review must be completed before the project can move forward and funds allocated
COMMON IRC MANAGEMENT STRATEGIES

- Disclosure of the financial interest(s) in presentations, publications of research results
- Disclosure of the financial interest(s) in the Informed Consent Form, if applicable
- Ensuring the protection of students and postdoctoral scholars by disclosure of interests or appointment of a co-advisor
- Discontinue consulting and any other recompensed activities during the course of a research project
- Monitoring of the project by the Conflict of Interest Management Subcommittee (COIMS)
CONTACT THE CONFLICT OF INTEREST (COI) OFFICE

Email Questions: info-coi@ucsd.edu
Email COI Forms: coiforms@ucsd.edu
Telephone: (858) 534-6465
COI Website: http://coi.ucsd.edu
Institutional Animal Care and Use Committee (IACUC) Office

Kristen Anderson-Vicino
Director
WHAT IS THE IACUC?

- Mandated by federal law that any institution doing animal research must have this committee
- Members include UCSD faculty members from all schools and departments using animals as well as non-affiliated members
- Oversees the University's animal care and use program
- Reviews and approves all animal research protocols
- Inspects animal facilities and laboratories
- Oversees the training and educational programs
- Investigates animal welfare concerns
IACUC OFFICE CONTACT INFORMATION

- http://blink.ucsd.edu/sponsor/iacuc/
- IACUC Office Phone: 858-534-6069
- IACUC Email: iacuc@ucsd.edu
- All information that a new Principal Investigator (PI) needs to register and use the online IACUC system is on the website
- Online website is SSO-secured
- If a PI wishes to begin working on his/her protocol prior to receiving his/her appointment, he/she will need to be sponsored by the department in order to receive an affiliate SSO account
Eligibility to serve as a PI on an animal use protocol is the same as the University’s requirements for eligibility to be a PI on a grant (PPM 150-10)

An approval for an exception must be approved by the appropriate Vice Chancellor prior to eligibility to be a PI on an animal use protocol

A fully executed copy of the PI exception form needs to be provided to the IACUC Office before the IACUC will approve the PI’s protocol
All PIs and personnel performing research and teaching involving animals at UCSD are required to complete the on-line "Orientation to Animal Research at UCSD" class.

The IACUC will also require additional training for each individual, depending on their prior training and experience with animals.

Refresher training is required of all PIs and personnel once every three years and usually coincides with the year of our triennial AAALAC accreditation site visit.
NIH, NSF and most federal extramural funding agencies require verification that the IACUC has approved all proposed animal studies before they will fund grant proposals - Termed “congruency verification”

OLAW defines congruence as “agreement between the animal activities described in a grant and the animal activities reviewed and approved by the IACUC”
The Sponsored Project Offices (OCGA, HSSPPO and SIO) work directly with the IACUC Office to provide assurance to the funding agency of “congruence”

IACUC Office compares grant proposal to approved animal use protocol (“side by side”) and provides feedback to the contracts and grants offices

The contracts and grants offices provide the assurance to the funding agency

Most of the time verification is not done until funding is imminent (JIT)
Please educate your PIs that they should routinely amend their animal protocol to match any new or supplemental grant proposals.

If they do that early in the process, there should be no delays at funding time.
Please educate your PIs that inter-institutional work using animals has very strict rules and they must carefully read the UCSD IACUC Inter-Institutional Policy at http://blink.ucsd.edu/_files/sponsor-tab/iacuc/Policy%2021%20Interinstitutional.pdf

Animals owned by UCSD (bought with funding to a UCSD PI) may only be used/housed at AAALAC-accredited institutions, see https://www.aaalac.org/accreditedorgsDirectorySearch/index.cfm
Subcontracts to other institutions that include animal work must have an MOU or contract with specific language.

Any animal work being conducted at other institutions (where the funding is coming through UCSD) must also be verified as congruent.

A copy of the animal use protocol and IACUC approval letter from other institution(s) must be provided to the IACUC Office.
Incoming subcontracted work does not require a congruency verification as the onus is on the prime institution to assure congruence.

An inter-institutional assurance is used for U.S. Institutions that receive PHS funding but do not have their own animal care and use program, facilities or IACUC.

Assures that the project will be conducted in compliance with PHS Policy and the PHS Assurance of the Assured Institution.
Completed PHS Interinstitutional Assurances should be routed to the IACUC Office with the relevant UC San Diego IACUC approved protocol number on which the animal work will be performed

The form should be sent to iacuc@ucsd.edu

The IACUC Office staff will confirm the approval date of the protocol and obtain the signatures of the IACUC Chairperson as well as the Institutional Official (Vice Chancellor for Research) and return the signed form as soon as possible
IACUC CONTACT INFORMATION

- IACUC Office Website: http://blink.ucsd.edu/sponsor/iacuc/
  Email Questions: iacuc@ucsd.edu
  Telephone: (858) 534-6069

- Kristen Anderson-Vicino, Director, kca002@ucsd.edu
Export Control Office

Brittany Whiting
Director
Identifies and manages export risks for U.S. national security & foreign policy to facilitate university research
- Export Controls
- Dual Use Research of Concern (DURC)
- Facility Security
Advises on and obtains export licenses for:
- International payments, shipments, travel and collaborations
- Sanctioned country activities with Cuba, Iran, North Korea, Syria & Sudan
- Restricted parties
Develops technology control plans with researchers for export restricted items
Export control is a shared responsibility

Policy applies to all UC Faculty, Academic Appointees, Staff, Students (including student employees), non-employee participants in University programs (e.g., visiting scholars, vendors and contractors) and to all University activities.

Export control reviews are required for certain transactions to ensure there are no unlicensed exports abroad or to foreign persons in the U.S. Transactions, items or activities may require export licenses, control plans or other approaches to ensure compliance with the export control regulations.

If you are involved in export transactions, you are responsible for ensuring export reviews are escalated to the UC San Diego Export Control Office, providing information required to complete the reviews or export licenses and complying with the terms of a technology control plan or export license conditions issued by the government.
UC SAN DIEGO’S EXPORT CONTROL PROGRAM

Export Control Office and Export Control Workgroup
Training
Reviews:

- Sanctioned country interactions (Cuba, Iran, North Korea, Syria and Sudan)
- Restricted party screening for international collaborators and visitors, exports and foreign financial transactions
- Agreements: (Sponsored Research, Unfunded (NDA/CDAs, MOUs, MTAs), Purchase, gifts, OIC)
- Export restricted technology reviews including foreign person license reviews for access to restricted technology
- Export Shipments or Hand carry of equipment or materials

Licensing/ Exceptions/ Control Plans
Recordkeeping: 5 years from the date of export or expiration of license
Auditing
Review, investigation, escalation of reported or suspected violations and disclosures of violations to federal agencies
Sec. 885 PROCESS TO LIMIT FOREIGN ACCESS TO TECHNOLOGY

Section 889 PROHIBITION ON CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT.
- Prohibits federal agencies from contracting with entities that use equipment from Huawei, ZTE, and certain other companies in specified capacities.
  - Includes video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Technology Company, or Dahua Technology Company (or any subsidiary or affiliate).
  - Replacement window is two years.

Sec. 1049 CRITICAL TECHNOLOGIES LIST.

SEC. 1286. INITIATIVE TO SUPPORT PROTECTION OF NATIONAL SECURITY ACADEMIC RESEARCHERS FROM UNDUE INFLUENCE AND OTHER SECURITY THREATS.
- to limit undue influence, including through foreign talent programs, by countries to exploit United States technology within the Department of Defense research, science and technology, and innovation enterprise;
- The capacity of government and academic institutions and institutions of higher education to assess whether individuals affiliated with Department of Defense programs have participated in or are currently participating in foreign talent programs or expert recruitment programs
- Policies to limit or prohibit funding provided by the Department of Defense for institutions or individual researchers who knowingly violate regulations developed under the initiative, including regulations relating to foreign talent programs.
UC SAN DIEGO PAUSE ON CHINESE RESTRICTED ENTITY AGREEMENTS AND FUNDING

Letter issued to Chancellor’s Cabinet and all Deans pause on agreements, funding and engagements for 6 month period until February 2019- review evolving regs for Huawei, ZTE, and Listed Chinese video surveillance companies

Likely next steps will be:

• definitions and guidance in contracts and grants or policy changes from USG
• Implementation of procurement restrictions
• removal of equipment, as required
NIH FOREIGN INFLUENCE CONCERNS

NIH Guide Notice and August 20, 2018 NIH Letter

1. **Diversion of intellectual property** (IP) in grant applications or produced by NIH supported biomedical research to other entities, including **other countries**;

2. Sharing of confidential information on grant applications by NIH peer reviewers with others, including foreign entities, or otherwise attempting to influence funding decisions; and

3. **Failure** by some researchers working at NIH-funded institutions in the U.S. to disclose substantial resources from other organizations, including **foreign governments**, which threatens to distort decisions about the appropriate use of NIH funds.

Additional guidance is expected in December from NIH, but researchers and sponsored project officers on campus are already receiving requests from NIH grants officers indicating all foreign affiliations be indicated in Biosketches, Other Support, Progress Reports and at Just in Time (JIT).

Town hall meeting with VCR Brown on October 17th at 8-9:00am
Export Control Office Website: http://blink.ucsd.edu/sponsor/exportcontrol/
Email: export@ucsd.edu
Telephone: 858-246-3300

Brittany Whiting, Director
Garrett Eaton, Sr. Export Analyst
Ryan Jordan, Export Analyst
UNANNOUNCED VISITS BY FEDERAL AND STATE AGENCIES

- 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](https://blink.ucsd.edu/research/policies-compliance-ethics/index.html)
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
  - 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

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