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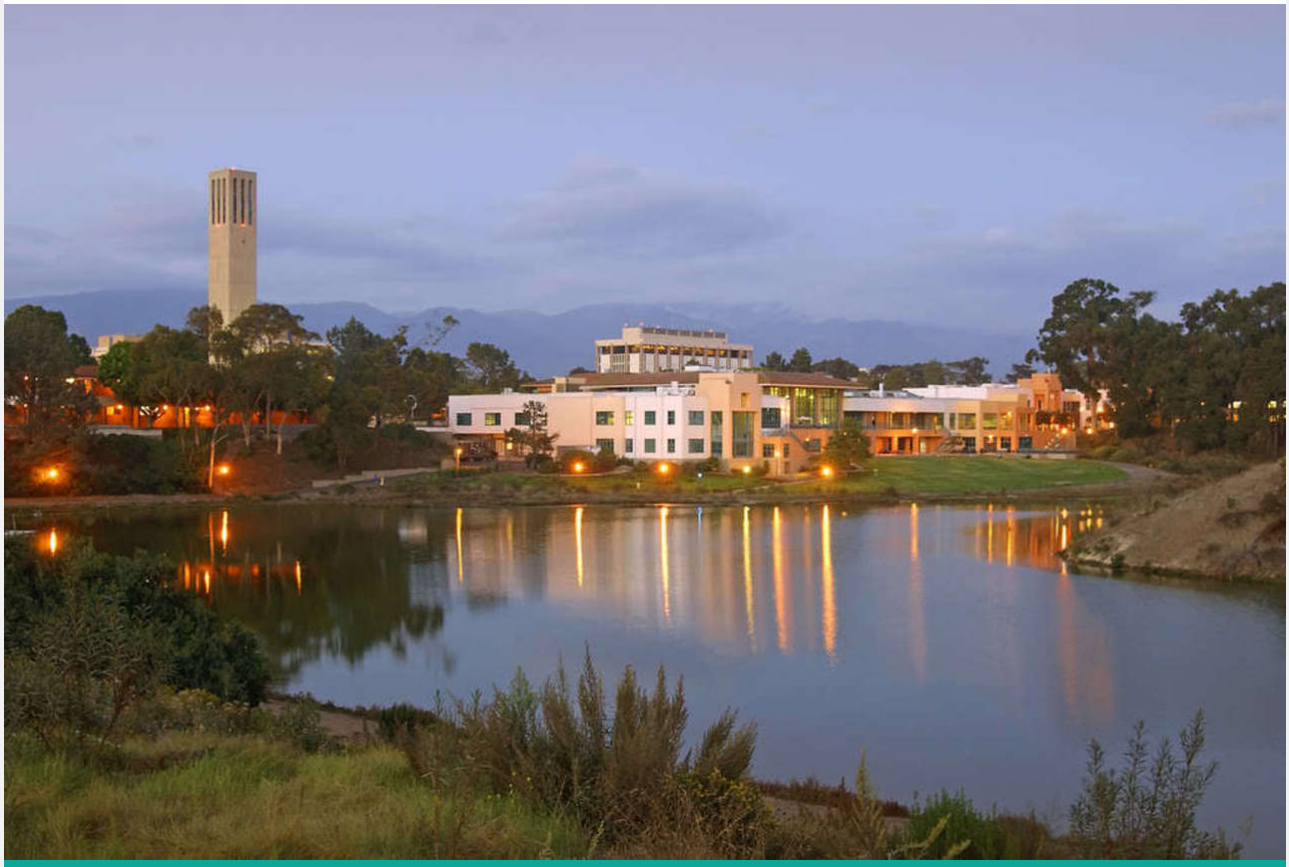


Research Integrity Newsletter - October 2022

News & Announcements

Conflict of Interest

NIH reminder of disclosure obligations

Recently, NIH posted a Notice reminding institutions and investigators of their responsibility in complying with the Public Health Service's Financial Conflict of Interest regulations. We would like to thank our current NIH-funded faculty and researchers for their high rate of compliance with this requirement.

As a reminder to all investigators and research staff, any significant financial interest (SFI) that is reasonably related to their institutional responsibilities must be disclosed, as well as those of their spouse and dependent children. At UCSB, NIH-

supported researchers are automatically contacted if they are subject to this disclosure requirement.

Investigators are also required to disclose all foreign SFIs received from any foreign entity, including foreign Institutions of higher education or foreign governments (which includes local, provincial, or equivalent governments of another country) when such income meets the threshold for disclosure, exceeding $5,000 in the trailing 12 months. (for a list of included activities please see the NIH notice at **Financial Conflict of Interest (FCOI) and Other Support: Reminders**).

One final reminder is to remember that before engaging in any NIH-funded research, investigators must complete FCOI training. This training must be renewed every four years as long as the investigator is receiving NIH (or any entity that adopts the NIH policy) funding. At UCSB, we use the UC-mandated Ethics and Compliance Briefing for Researchers to satisfy this training requirement. UC requires that this training be completed every other year. This means that a separate COI training is not required in order to meet the NIH policy requirements.

Human Subjects Research

When should a blanket (in concept only) protocol be submitted?

Blanket protocols are submitted when preliminary IRB approval is required, typically by the research sponsor; but when there are no immediate plans to conduct human subjects research. In such cases, the sponsor may require evidence of preliminary IRB approval before funding can be released. In other cases, the sponsor's just-in-time process may require that the University document compliance with §46.118 of the Federal regulations, which allows release of funding when a proposal lacks definite plans for the involvement of human subjects.

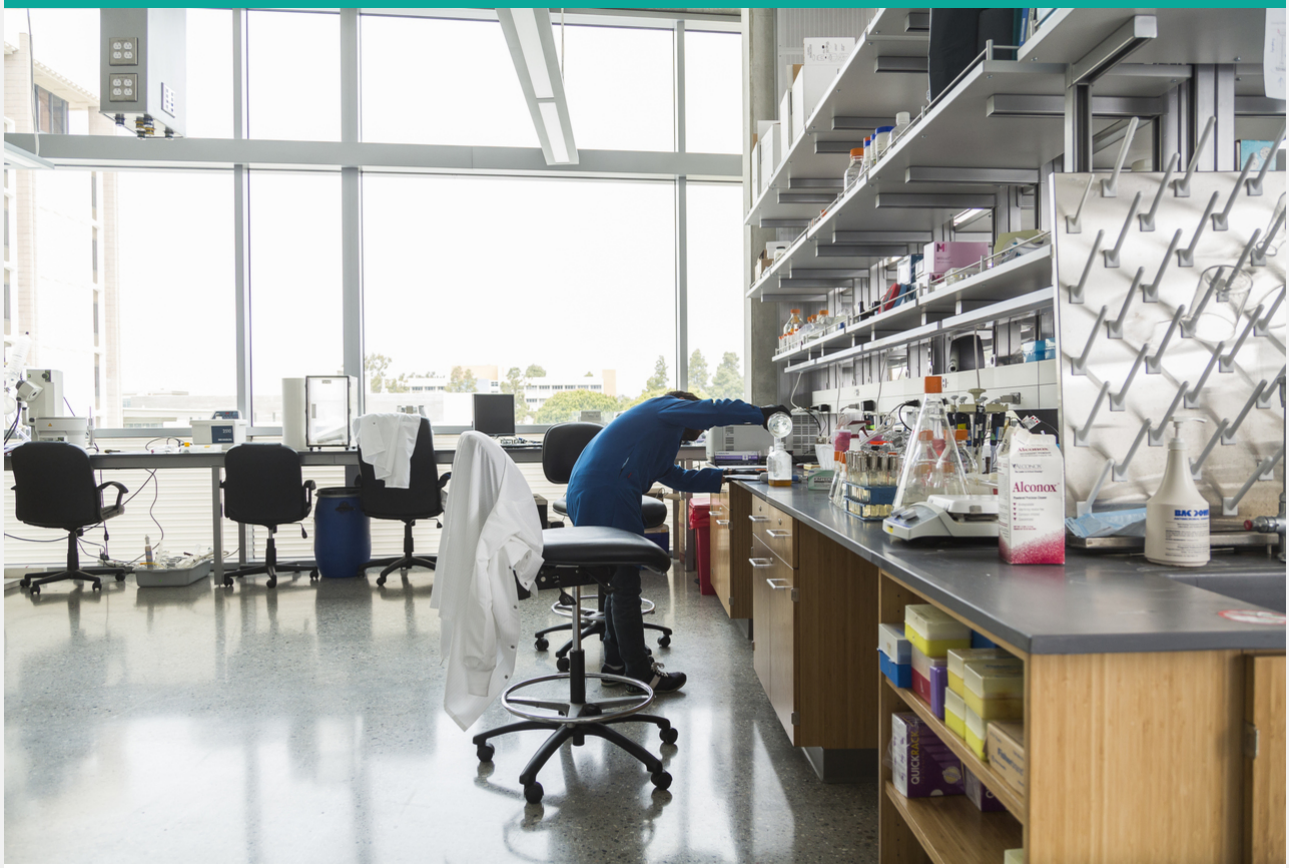
A Blanket *In Concept Only* protocol should only be selected when:

- There is an intent or plan to use human subjects in research
- The research methodologies or study instruments have not been fully developed, an
- A protocol must be in place in order to release funding.

Blanket protocols must contain sufficient information so that the IRB staff can determine whether the sponsor's requirements have been met. Researchers typically submit blanket protocols in response to a sponsor's funding decision. We encourage PIs to plan ahead and to begin the IRB process as soon as you have reason to believe that your proposal has received a fundable score.

Blanket protocols can NOT be used to conduct actual human subjects research, including recruitment and data collection. When the human subjects portion of the funded research is fully developed or is intended to begin immediately upon release of funding and there are definite plans to conduct human subjects research, then the normal submission and approval process must be followed. Since that process can

take several weeks, depending on review type and complexity, PIs should submit regular IRB protocols as early as possible.



Export Control

Understanding Fundamental Research and Export Controls

Do export control regulations apply to university research activities? You may have heard that export control regulations don't apply to basic research. This idea is **false** and leads to confusion and risks of non-compliance. The aim of this article is to dispel this idea by providing you with an understanding of where this idea comes from, why it is partially correct, and why it is partially incorrect.

The export control regulations exclude some types of information altogether. Information that is not "technology," such as general descriptions of items, is not subject to export controls. There are four other categories of information that are excluded based on how the information was developed or used.

1. **University classes:** Information shared in classes listed in a university's course catalog, and associated teaching laboratories, are not subject to export controls. Such information generally explains fundamental concepts and is typically publicly available, such as in textbooks.
2. **Fundamental Research:** Includes research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly

within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons.
3. **Published Information:** Information that is published, or intended to be published, is generally excluded from export controls. However, information that is already export controlled remains subject to export controls, even if published.
4. **Patent Information:**: This information is typically exempted from export controls unless the government has imposed an invention secrecy order.

The idea that university research is not subject to export controls emanates from an exception written into the export control regulations which exempts fundamental research from the scope of the regulations. The government recognizes the value of sharing research results broadly and includes a Fundamental Research Exclusion or FRE. The idea that universities are not subject to export control regulations comes from this exclusion. The Fundamental Research Exclusion is an essential mechanism which allows UCSB to openly share the results of its research and allows participation in research projects without regard for restrictions imposed by export control regulations.

A frequent misunderstanding about the Fundamental Research Exclusion is that it covers all aspects of university research. The Fundamental Research Exclusion only applies to the information that is produced from a funded research project. The Fundamental Research Exclusion does not apply when:

1. Inputs used in research are themselves controlled and are incorporated into the research results. This typically involves proprietary information obtained from a third-party under a Non-Disclosure Agreement (NDA)
2. Physical items produced in the course of fundamental research
3. Instrumentation or equipment used to conduct research
4. Specialized software that is subject to export controls
5. Fabrication services provided for outside entities

Let's dig a little deeper into the first example above. On occasion, UCSB engages with industry-partners in the conduct of fundamental research. An industry-partner may require the use of a NDA to allow UCSB personnel to access their intellectual property. Because UCSB is agreeing to keep the intellectual property confidential and will not disclose it to others it is not eligible for the Fundamental Research Exclusion. The intellectual property covered by an NDA is subject to export control regulations. It is critical for UCSB’s compliance with the export control regulations to understand how the intellectual property is controlled and to prevent the incorporation of controlled intellectual property into your research results. The Export Control Officer works closely with Technology and Industry Alliances to understand UCSB’s export control compliance obligations with respect to NDAs.

Conflict of Interest

Department of Energy financial disclosure requirements

Earlier this summer the Department of Energy instituted a new financial disclosure requirement. This disclosure requirement is very similar to the Public Health Service (e.g., NIH, CDC, FDA, etc.) requirement.

Individuals responsible for the design, conduct, or reporting of projects funded by DOE are required to disclose their significant financial interests (and those of the investigator's spouse and dependent children) to UCSB. All significant financial interests related to the Investigator's institutional responsibilities (teaching, research, and service) must be disclosed. These disclosures will be required for any new DOE funding opportunity announcements issued on or after June 18, 2022 or for new DOE awards after that date. Individuals listed as PI or identified as Key Personnel are automatically notified by email and directed to our electronic disclosure system **ORCOI**.

More detailed information about the disclosure requirements can be found in our **Research Circular D.6 or** our dedicated **DOE conflict of interest webpage**. UCOP has incorporated the DOE disclosure requirement into their policy on the **Disclosure of Financial Interests & Management of Conflicts of Interest, Public Health Service Research Awards** and have developed **interim guidance on the DOE policy**.

Human Subjects Research

New NIH Data Management & Sharing Policy

Beginning January 25, 2023, NIH will require researchers to submit a Data Management and Sharing Plan (DMS Plan) with all applications for funding. While this **new NIH policy** impacts all research, there are special considerations for research that involves human subjects. NIH has posted an **overview of the new policy** and many other resources. The Library, Strategic Research Initiatives, and Research Integrity are planning a webinar for faculty on this new requirement, scheduled for November 9th at noon. Registration information and a form to submit questions in advance will be available on the **SRI events webpage** prior to the event.

DMS Plans are expected to maximize the appropriate sharing of research data. However, there may be ethical, legal, and technical reasons to limit data sharing. These need to be explained in the DMS Plan. PIs conducting research with human subjects should consider the following when drafting their DMS Plan.

- Will the Informed Consent process limit the scope of sharing or use of data?
- Would the privacy or safety of research participants be compromised if data is shared?
- Are the available data protections insufficient to protect the privacy of participants?
- Do explicit federal, state, or Tribal law, regulation, or policy prohibit disclosure?
- Are there restrictions imposed by existing or anticipated agreements with other parties?

Since DMS Plans will typically be developed prior to submission of an IRB protocol, PIs should propose a consent and deidentification process in their DMS Plan which is likely to meet the IRB's standards. While DMS Plans can be modified after they are submitted, it will save time if the data protections listed in the plan align with any future IRB protocol. For our researchers, the most significant change will be to their consent forms. Participants must be fully informed about how their data will be shared and in what form. This includes describing how their data will be deidentified and any measures that will be taken to limit sharing of their data, if appropriate.

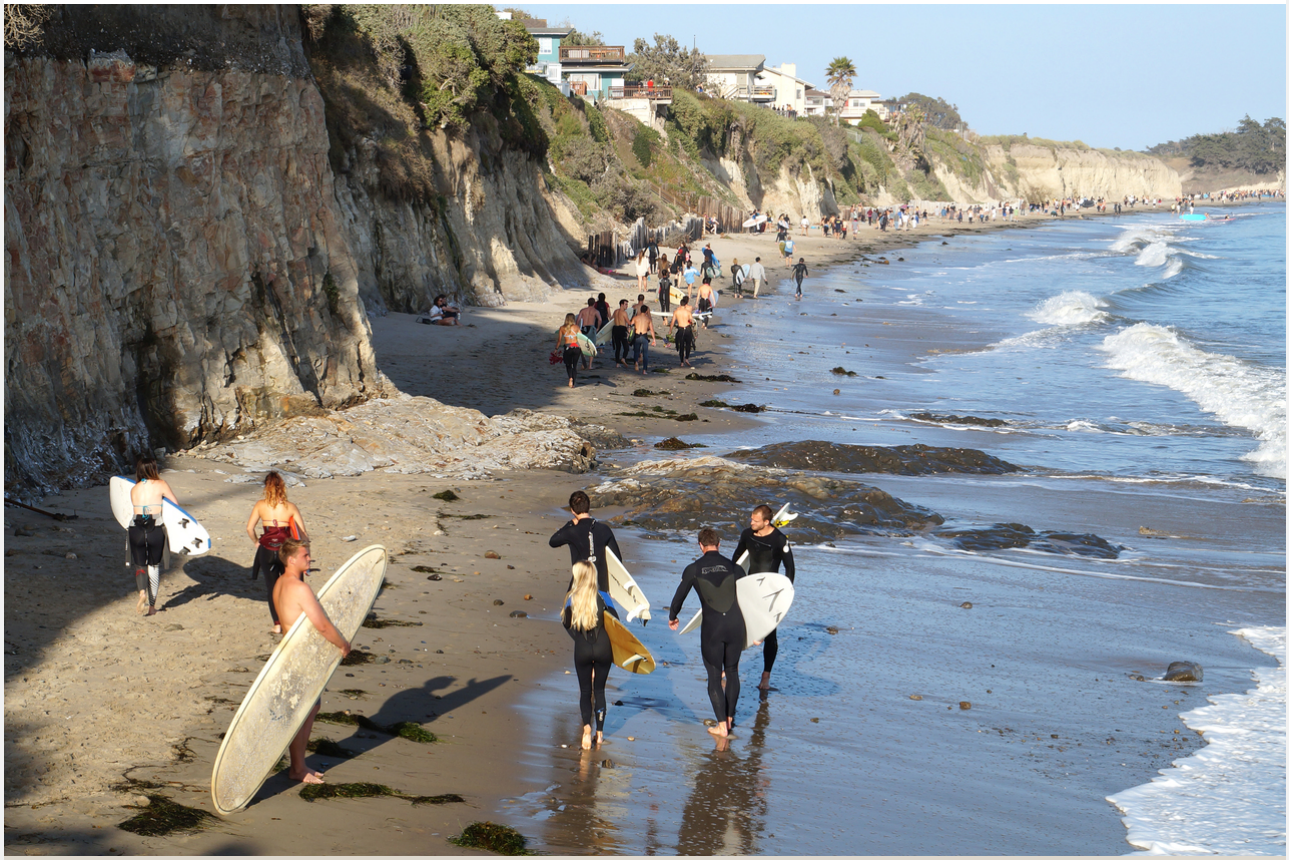
Please expect more information on this topic as we get closer to the January implementation date.

Institutional Animal Care and Use Committee
Disaster Plan Training

All animal users that provide husbandry to animals (including those working in satellite facilities), PIs that have at least one satellite facility where animals are housed, and PIs/Facility Directors that oversee centralized facilities (i.e., ARC, REEF, EEMB Aquarium, SNARL) need to complete the IACUC's training on the Animal Facilities Disaster Contingency Plan. The training requirement will be satisfied once an animal user completes the new **Disaster Contingency Planning for Research Animal Facilities course** through the UC Learning Center and reads the **Animal Facilities Disaster Contingency Plan**. PIs are responsible for ensuring that their lab personnel have completed the training. Training will need to be retaken if significant changes are made to the Animal Facilities Disaster Contingency Plan. The IACUC will notify labs of any changes.

Lab Safety Training

Per guidance from EH&S, personnel that work in a laboratory setting are required to annually complete a Refresher version of the **UC Learning Center Fundamentals of Laboratory Safety course**. The IACUC has modified its **Guideline on Training Requirements for Protocol Personnel** to align with the updated Laboratory Safety training requirements from EH&S.



Human Subects Research

Changes to the ORahs login process

To guard itself against cybercrime, UCSB is continuing the rollout of Multi-Factor Authentication (MFA) with Duo to campus applications. In the coming weeks ORahs, the Office of Research electronic application for human subjects research, will require the use of MFA via Duo. Faculty, students, and staff should all be familiar with this process and this change should not impact your ability to access the system.

This change will impact the ability of unaffiliated collaborators to access ORahs. Collaborators include individuals who are working on behalf of another institution/university or individuals without a formal appointment at UCSB. Once MFA is implemented, only individuals with a UCSB NetID will be able to access

ORahs. The Office of Research cannot request or create UCSB NetIDs. Individuals affiliated with a UCSB department are likely eligible for an affiliate account. Requests for affiliate NetIDs must be coordinated with your home department.

Since unaffiliated collaborators will not be able to directly access ORahs, PIs are encouraged to work with collaborators outside of ORahs to draft protocols, if needed. PIs continue to be responsible for sharing IRB-approved materials with the collaborators listed on their approved protocol. As always, HSC staff will work with the PI and collaborating institutions to ensure any necessary agreements are in place, such as reliance agreements.

Upcoming Events

New NIH Data Management & Sharing Policy Webinar

The Library, Strategic Research Initiatives, and Research Integrity are planning a webinar for faculty on this new requirement, scheduled for November 9th at noon. Registration information and a form to submit questions in advance will be available on the **SRI events webpage** prior to the event.

Human Subjects Webinar Offering

Interested in hosting a human subjects webinar for your department, class, or research team? We can present on a variety of topics from recruitment to informed consent. Contact us at **hsc@research.ucsb.edu** to schedule a webinar today!

Stay in Touch!

Questions? Contact us at:
Animal Subjects @ iacuc@lifesci.ucsb.edu
Human Subjects @ hsc@research.ucsb.edu
Conflict of Interest @ coi@research.ucsb.edu
Export Control @ exportcontrol@research.ucsb.edu
Stem Cell and Responsible Conduct of Research @ blakemore@research.ucsb.edu

If you have news or updates or feedback you'd like to share, please send to researchintegrity@research.ucsb.edu

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