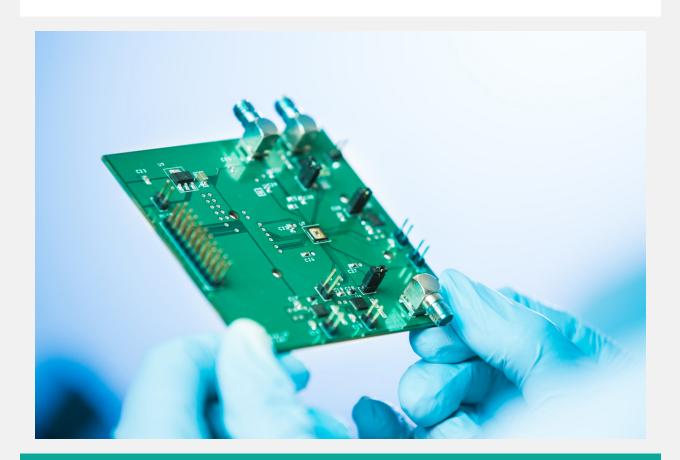
# UC SANTA BARBARA Office of Research



# **Research Integrity Newsletter - March 2022**

# News & Announcements

# **Conflict of Interest**

# **Department of Energry Interim Conflict of Interest Policy**

On December 20, 2021 the Department of Energy (DOE) published an **interim Conflict of Interest Policy**. This policy closely resembles the existing Financial Conflict of Interest program required for those applying for and receiving funding from Public Health Service agencies, such as the National Institutes of Health.

Our institution has 180 days to implement a process to collect and review disclosures from those applying for and receiving DOE funding. We are working on

developing a process to implement these new requirements and will provide more details for the campus research community in the coming months.

For PIs and Key Personnel applying for or currently receiving DOE funding, you should be aware of the following:

- The policy will require disclosure of Significant Financial interests that relate to your institutional responsibilities (e.g., research, teaching or service). This means that you may need to disclose financial interests that do not relate to your DOE funding, but are related to your professional responsibilities to UCSB.
- You are advised to keep track of any personal Significant Financial Interests.
   Since the initial disclosure period will cover the preceding 12 months, you will need to be able to accurately report on those financial interests.
- The definition of a Significant Financial Interest can be found within the interim DOE COI policy.
- Reimbursed or sponsored travel will also need to be reported. Since there
  may be a zero dollar reporting threshold, you should keep track of any such
  travel that is related to your institutional responsibilities.
- The existing UCOP Ethics & Compliance Briefing for Researchers satisfies the training requirement in the interim policy.
- DOE disclosures will not be required until a campus process is implemented and communicated to the research community.

# **Export Control**

## **New Expense Reimbursement Process and Export Control**

Business and Financial Services (BFS) are transitioning to a new travel expense reimbursement system called Concur,

https://www.bfs.ucsb.edu/travel\_entertainment/concur. Concur will replace the Web Travel Expense Voucher (TEV) and Online Form-5.

There are a variety of U.S. government restrictions that could impact your ability to be reimbursed for certain expenses.

International Travel to Sanctioned Countries – Traveling to/from comprehensively sanctioned countries (Iran, Cuba, North Korea, Syria, Crimean Region of the Ukraine) is subject to significant U.S. government restrictions. Travelers to/from these countries must work with the campus Export Control Officer prior to booking their travel, otherwise you will not be reimbursed for your travel. In rare cases,

Other Transactions - Certain other transactions will also be reviewed for export

control or federal contract requirements. These include expenses involving international recipients, purchases involving drones, and purchases of certain video surveillance and telecommunication devices. Purchases of this type of equipment should be made through campus Procurement whenever possible, so that the proper reviews can take place before the purchase is made.

If you have any questions about the role of export control compliance and the types of transactions listed above being screened by the ECO, please feel free to email exportcontrol@research.ucsb.edu.

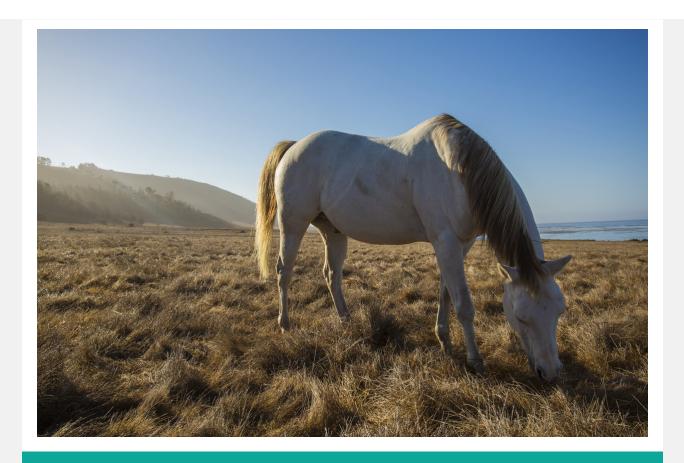
# **Export Control**

## **E-Learning Offerings**

Two new courses were recently added into the UCSB Learning Management System are "Export Controls" and "Restricted Party Screening". These training videos are the result of a collaborative effort across the UC system, and were produced by UCR's Risk & Safety Training Center of Excellence.

**Export Controls** – Export control regulations impact a wide range of UCSB activities. This course will provide audience members with an in-depth look at what the regulations cover, areas of compliance risk (international shipping, use of biological agents, ITAR-controlled work, international collaborations, and international travel, etc.) and provide UCSB resources for export controls.

Restricted Party Screening – Interactions with international partners pose risks to export controls compliance. This course provides an overview of the importance and requirements associated with conducting restricted party screening to manage the compliance risks. The course will include an overview of restricted party screening, convey the importance of restricted party screening, identify who is responsible for restricted party screening, and provide UCSB resources for restricted party screening. The campus utilizes a software tool to conduct restricted party screenings. The export control staff, exportcontrol@research.ucsb.edu, can provide access to the system if it is warranted.



#### **Institutional Animal Care and Use Committee**

#### **AAALAC Accreditation**

The Institutional Animal Care and Use Committee received notice from **AAALAC** International that they have decided to continue the full accreditation status for UCSB's Animal Care and Use Program. This vigorous process takes months of preparation and allows research programs to demonstrate that they meet the minimum standards required by law and go above and beyond the minimum standards to achieve excellence in animal care and use. Thank you to all of those who were involved in the re-accreditation process last year!

#### **Institutional Animal Care and Use Committee**

#### **New Occupational Health and Safety Process for Animal Users**

The Occupational Health and Safety (OHS) clearance notices for animal users will now be sent to the researchers and their PIs using the UCSB Box service. Hard copies of the clearance notices will no longer be mailed to animal users by the OHS Physician at Sansum. The IACUC Office will use the Box service share feature to

invite the animal user and their PI to view the clearance notification once it has been uploaded.

#### **Institutional Animal Care and Use Committee**

#### **IACUC Newsletter Archive**

The IACUC keeps all vertebrate animal users apprised of changes to our program by sending out newsletters with important updates, including revisions to our IACUC Guidelines and Procedures documents. Newsletters are usually sent twice a year from iacucnews@lifesci.ucsb.edu. All issues of the IACUC Newsletter can be accessed from the Office of Research website.



**Human Subjects Research** 

#### Use of Exempt Category 4 (iii) for Secondary Research

Per the **UC Guidance Memo 20-04**, the Institutional Review Board (IRB) Human Subjects Committee does not permit the use of 45 CFR 46.104(d)(4)(iii) as exempt under category 4 for secondary research uses of identifiable private information or identifiable biospecimens if the following criteria is met:

The research involves only information collection and analysis involving the investigator's use of identifiable health information when that Use is regulated under

45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b).

Due to UC's hybrid entity status under HIPAA as a Single Health Care Component, and since research is not a covered function under the HIPAA Privacy Rule, the use of this category for IRB exemption is not permissible.

What this means to our human subjects researchers is any protocol applications that include a request to use Protected Health Information (PHI) as part of the research will need to be submitted as a regular non-exempt protocol application. The IRB staff will administratively switch exempt applications which contain the use of PHI to non-exempt applications and ask the PI to complete all sections of the protocol.

Please note that UCSB can only use, house, or access PHI under limited circumstances, such as completely de-identified datasets, or limited datasets (i.e.,only dates such as admission, discharge, service, DOB, DOD; city, state, five digit or more zip code; and ages in years, months or days or hours), or when accessed through a providing entity's secure system.

#### **Human Subects Research**

#### California Information Practices Act and California Public Health Service

Any personally identifiable information that is collected or used for human subjects research purposes from a CA state agency is subject to the California Information Practices Act (CA Civil Code §1798). UC is considered a state agency and therefore must follow this privacy law.

What this means is that if a researcher is obtaining personally identifiable information from a state agency, other than another UC or state university, the researcher must obtain IRB review from the **Committee for the Protection of Human Subjects** (CPHS) in addition to, and before obtaining UCSB IRB review

The researcher will need to disclose in the protocol application all data elements they expect to, or will be receiving or have access to. **CA law** requires CPHS review and approval before personal information (linkable to any individual) that is held by any state agency or department can be released for research purposes.

Since this approval process may take time, researchers should plan their projects accordingly, to allow for the review of their protocol applications by both IRBs.

#### **Human Subects Research**

# **Human Subjects Website Updates and More!**

**Definitions** - Updated and new definitions, including definitions on ORahs user roles, data sets, adverse events, and more can be found on the Office of Research **website for human subjects** and within the ORahs protocol application by going to the "help" feature and selecting "glossary".

**Secondary Research Uses Flow Chart** - Researchers are encouraged to use this **flow chart** to assist in determining whether the secondary use of data constitutes human subjects research requiring IRB review.

MRI Scanning Addendum - Researchers who conduct fMRI studies and have multiple MRI sessions should complete this scanning addendum and attach the document to the ORahs protocol application. The addendum was created to assist in breaking down scanning time and decibel exposure over multiple sessions to facilitate a more efficient IRB review of the proposed research.

**Updated Human Subjects Standard Operating Procedures** - Over the past several months, the IRB has updated many Standard Operating Procedures (SOPs) to reflect current regulatory information, including updating definitions and procedural expectations, as well as to increase transparency in its current practices.

#### **Upcoming Events**

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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