
Research Integrity Fall 2021 Quarterly Newsletter

1 message

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UC SANTA BARBARA Office of Research

Research Integrity Newsletter - Fall 2021



News & Announcements

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- OR Information for Campus Researchers

Human Subjects Research - Genomic Data Sharing and Institutional Certifications

The Genomic Data Sharing (GDS) Policy applies to all competing NIH grant applications and proposals for NIH contracts, or other Programs following this policy if the proposed research will generate large-scale human or non-human genomic data or will use these data for subsequent research.

Research Integrity has developed guidance to assist investigators for obtaining Institutional Certifications when it is required by NIH.

Read more about **Genomic Data Sharing**

Conflict of Interest - New ORCOI System Online!

We are excited to share that our new Office of Research Conflict of Interest disclosure system (ORCOI) successfully launched this summer. Researchers may access the system at <https://orcoi.research.ucsb.edu/> and can view a user guide in the ORCOI section of our website: <https://www.research.ucsb.edu/coi/orcoi-electronic-disclosure-system>. The new system has been designed to streamline the disclosure process and allow us to move away from the old DCR form.

As of September 10th, ORCOI automatically assigns a National Science Foundation or Public Health Service annual disclosure to all individuals that are listed as “key personnel” in the ORBiT datasheet and who do not already have an active annual disclosure. This takes place at time of proposal submission for NSF and PHS awards and is continuously checked through the life-cycle of the project. As of this week, ORCOI also automatically assigns 700-U project specific disclosures.



Foreign Travel and Export Control

With the University transitioning back to normal and as international travel restrictions begin to ease, we would like to remind all UCSB personnel of their obligations in regards to foreign travel.

Travelers are strongly encouraged to notify our office as early as possible if traveling to an embargoed or sanctioned country (Cuba, Iran, Syria, North Korea, and the Crimean region of the Ukraine). UCSB cannot reimburse travel to these countries if the traveller did not receive advance approval from the Export Control Officer. All travelers are encouraged to book their international travel through Connexxus. Doing so will help our office provide timely guidance for those traveling to sensitive or restricted destinations.

Nearly all University activities within embargoed or sanctioned countries will require a license from the U.S. government, which can take many months to obtain and are not guaranteed to be granted. Many routine financial transactions with these countries also require a license. Due to these restrictions and the potential for significant penalties, those intending to travel to these countries must contact the campus Export Control Officer (exportcontrol@research.ucsb.edu) before booking their trip.

For more guidance on the impacts of export control laws and regulations on international travel, please visit our [International Travel webpage](#).

Animal Care and Use - IACUC Google Share Drive Now Available!

In an effort to increase compliance with UCSB's vertebrate Animal Care and Use Program, the IACUC has created a mechanism for PIs and Lab Managers to share their lab's approved IACUC protocols and associated documents (modifications, SOPs, etc.) with the other personnel on the project roster. Each PI will have a Google Shared Drive with PDF versions of the current version of their protocols and associated documents. The PI will be the Manager of this folder and is able to give access to anyone with a UCSB email account. Additionally, each PI may select one person (e.g., Lab Manager) who will also be given Manager permissions for the folder and can also give access to lab members. Once an individual is no longer working on an IACUC protocol, the PI and Lab Manager are responsible for removing that individual's access. Please follow the [link for instructions on how to set this up](#).



Some Important Changes are Happening to the Datasheet Assurances!

Human Subjects Research datasheet changes:

Datasheet Assurance #2 has been expanded to include all studies funded by a Common Rule Agency (e.g., NIH, NSF, DOD, DOE, etc.) which may require a Single IRB Review. If a project involves multiple U.S. institutions conducting non-exempt research within the United States then single IRB review requirements may be applicable. Researchers are expected to budget for single IRB expenses at proposal stage and should consult with the Human Subjects Staff to determine which institution may be appropriate to serve as the Reviewing IRB.

Datasheet Assurance #3 is a new question on the datasheet. For certain federally funded studies or studies regulated by the FDA that meet the definition of a clinical trial (which includes social-behavioral research), investigators will be required to register and report their studies, including posting a copy of the consent form on a public website such as ClinicalTrials.gov or other federal website (e.g., Open Science).

Datasheet Assurance #4 and #5 have been updated to clarify the use of Protected Health Information and/or Personally Identifiable Information in research. Due to UC's hybrid status as a health care entity, unless completely de-identified and non-federally funded, review of Protected Health Information cannot be conducted via exempt level review and research involving health information must be reviewed via a non-exempt protocol application.

Datasheet Assurance #6 pertains to the use of large scale genomic data. For studies that are funded by NIH and involve human genomic data, an Institutional Certification may be required to be submitted along with the data sharing plan to NIH. Investigators should be aware that Institutional Certifications may take some time to complete and plan accordingly.

Animal Subjects Research datasheet changes:

Earlier this year, SPO and the Office of Research made some changes to the datasheet that gets filled out for awards and entered into Orbit. For Datasheet Assurance #7, additional instructions have been added for awards that include the use of vertebrate animals. Additionally, there is a new question that asks whether the award includes a subawardee that will be working with vertebrate animals. The UCSB IACUC Office is responsible for ensuring that all subawardee PIs working with vertebrate animals have the required approvals in place before an award may be processed.

Stem Cell datasheet changes:

Datasheet Assurance #8 has been updated for NIH-funded research and the use of human fetal tissue derived from elective abortions. Investigators will be required to

provide additional documentation to NIH confirming that individuals were consented for providing their specimens for research purposes.

Export Control datasheet changes:

We have recently updated the questions in Datasheet assurance #11. These questions cover export control related matters and are intended to identify situations requiring review by the Export Control Officer. The changes made to these questions were intended to focus more narrowly on higher-risk areas of export control compliance, rather than trying to identify all potential export control matters.

The text of the assurance has been revised and the question expands to three sub-questions if the answer to the assurance is ‘Yes’. The sub-questions allow department administrators to identify specifically why the assurance is being marked ‘Yes’. The comment box should be used to explain all ‘Yes’ responses. The comment should provide relevant details about the activity that has resulted in a ‘Yes’ response to the assurance. If a project is funded, the Export Control Officer will follow up. In cases involving proposed research in a sanctioned country, the Export Control Officer may contact you during the proposal submission process.

Conflict of Interest datasheet changes:

Datasheet Assurance #16

We have automated the assigning of 700-U disclosures related to contracts and grants effective 10/20/2021. At the award stage, ORCOI will automatically assign 700-U disclosures to PIs on records with assurance 16 marked non-exempt for any sponsor. Responding to this assurance incorrectly could result in the inappropriate completion or non-completion of disclosures as well as time delay in award processing. Due to this, we request that department administrators double check the accuracy of their responses to assurance 16 prior to the submission of the datasheet.

As a quick reminder:

All non-profit tax-exempt educational institutions are exempt from the 700-U disclosure requirement (i.e., Harvard, UCLA, Duke, etc.).

UCOP maintains a list of organizations that are exempt from the 700-U disclosure requirement [here](#).

General Reminders

Human Subjects Research

Modifications - Any change in the design, conduct, or key personnel of this research must be reviewed by the UCSB HSC prior to implementation. This includes changes to the study procedures and/or documents (e.g., protocol, consent form, recruitment materials, addition of data points, addition or change of research sites) and changes to the research team. If you are unsure whether your changes constitute a protocol modification, contact the HSC for guidance.

Blanket In Concept Protocols - See our new **ORahs Tutorial** on Blanket In Concept Protocols and transitioning the study to a regular protocol application.

Use of One's Own Students or Subordinates as Research Subjects - See our **updated FAQ** on additional protections for when using one's own students or using lab members, individuals who are in a lower position of authority as research subjects.

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

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