UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

December 19, 2022

In This Issue

OIA Winter Closure 2022

On behalf of the OIA staff and IRB members, we wish you all the best. Happy Holidays!

Please note the following regarding the Office of IRB Administration (OIA) operating schedule in December. Please keep these adjustments in mind when preparing IRB submissions.

December 23-January 2: UC San Diego, including the OIA, will be closed for winter holidays and will re-open Tuesday, January 3, 2023.

As always, you may implement changes to research to eliminate an apparent immediate hazard to a subject without obtaining prospective IRB approval. Changes made in those circumstances must subsequently be reported to the IRB within 5 days.

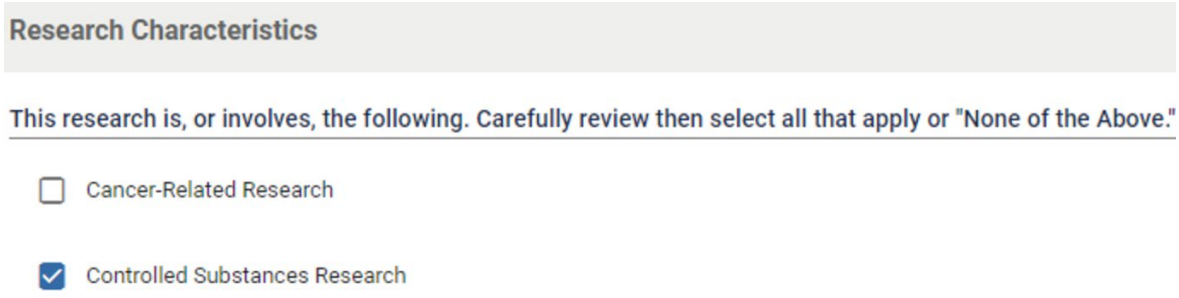
You may make emergency treatment use of investigational products according to the appropriate FDA instructions for drugs or devices (including permission from the FDA as required). If you are considering such use from December 23 – January 2, please contact the IRB at 858-229-8978. Such emergency uses must be reported to the IRB within 5 days.

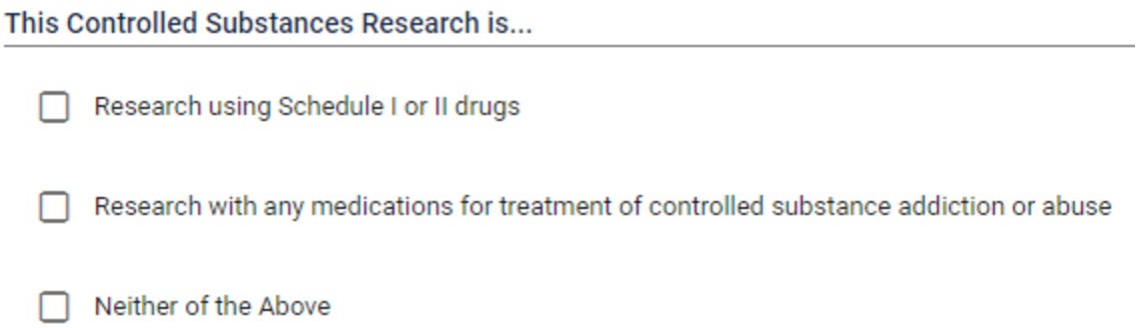
NEW: UCSD Investigational Drugs Service Rate Change for 2023

Please be aware that the Investigational Drug Service (IDS) has a new fee structure for 2023 which will become effective on January 1, 2023.
This fee structure will be utilized by all five UC IDS departments providing consistency among campuses. The new fees are based on current salaries, benefits and actual time required to perform given functions, and have been benchmarked against our peer institutions, to assure that they remain competitive.
Studies that are already in progress, or for which we have already provided a budget estimate, will continue to be charged the old fees.
For more detail, please refer to the new IDS 2023 Fee Structure or contact IDS directly.

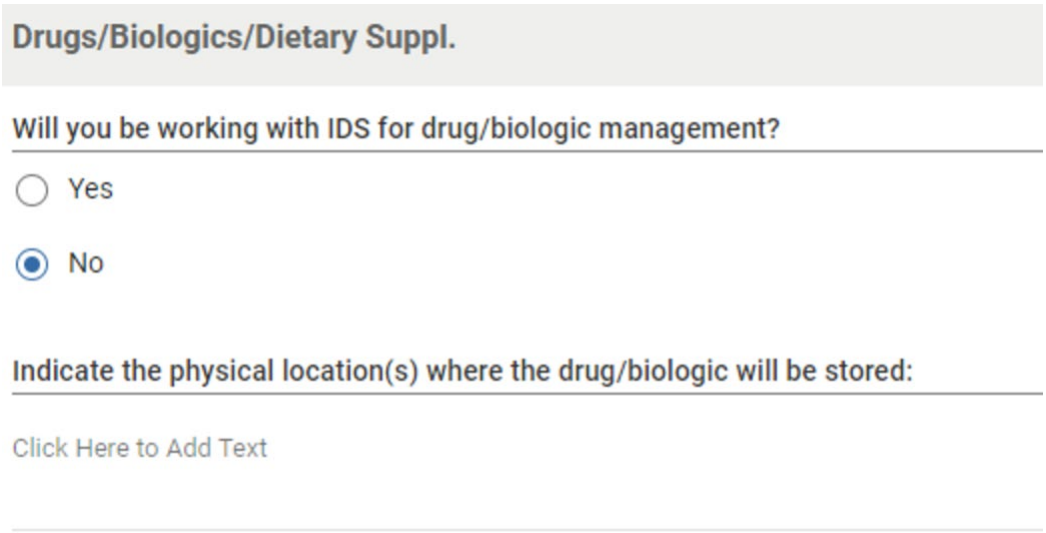
NEW: Reporting the Use of Controlled Substances in Human Subjects Research

As the research community is aware, we have successfully launched the Kuali system. The new system allows for greater detail in the registering of studies. One such feature is reporting the use of controlled substances in human subjects research. This new feature allows the Controlled Substance Committee to better track such use. Checking the "Controlled Substance Research" box on the Kuali application will trigger transmission of the information to the Controlled Substances Committee when it is also indicated that Investigational Drug Services (IDS) is not being utilized for the management of the controlled subst. Please see the snapshots below.





In addition, the Kuali section on Drugs/Biologics/Dietary Supplements includes a section to indicate if IDS will be utilized for the management of the controlled substance. If IDS is not used, indicate where the controlled substance will be physically stored. See snapshot below.



For additional information about the use of controlled substances in research, please contact the Controlled Substance Committee representative within the Office of Compliance and Privacy at hscomply@health.ucsd.edu or 858-657-7487 for human studies within Health Sciences or ehscs@ucsd.edu for studies involving tissues, cells, and *in vitro* research.

Any questions regarding the Kuali reporting requirements of controlled substances in a huamn subjects research study can be asked of the IRB by emailing irb@ucsd.edu.

Reminder: Kuali KBAs

Knowledge Base Articles (KBAs) are an important part of the transition from the legacy eIRB system to Kuali. These articles help provide additional instruction and guidance about how to use the Kuali system. The research knowledge base containing KBAs for all of UCSD research can be found here.

Administrative Determinations
The OIA generally has 5 types of administrative determinations it can make:

- A study is not human subjects research
- UCSD/RCHSD is not engaged in the human subjects research
- The research qualifies for an exempt determination
- The research will rely on a non-UCSD IRB for review
- The research involves indefinite plans or delayed onset

The KBA on this topic walks users through how to submit each of the 5 types of determination applications above.

Amendments
The KBA on this topic walks users through the process of submitting an amendment and some particular nuances of how to use the Kuali IRB system.

Renewals
The KBA on this topic walks users through the process of submitting a renewal application.

Not seeing a KBA to walk through a process and want to suggest OIA create one? Email us at irb@ucsd.edu to let us know.

Reminder: Updated RCHSD Consent and Assent Templates

The wait is over! Newly approved consent and assent templates for use when subjects will be enrolled at Rady Children's Hospital San Diego (RCHSD) are now available on our Forms and Instructions page. These new templates mirror the UCSD templates, with slight changes made to accomodate institutional requirements of RCHSD.

To ensure consistency among applications and ensure that subjects are appropriately fully informed about what will happen when the participate in research, these new templates will be required of all RCHSD studies submitted to OIA on or after **January 1, 2023**.

Reminder: Office of Compliance and Privacy HIPAA Training Requirements for Researchers

HIPAA Research Privacy training is offered by the CITI Program and is now available to UCSD faculty and staff. **This training will replace the legacy HIPAA training offered on OIA's old webpage which will be retired by August 2023.**

For researchers who potentially use Protected Health Information (PHI) or related data, completion of the following modules in CITI's Research Privacy curriculum is recommended:

Health Privacy Issues for Researchers

This module discusses data protection requirements for human subjects research that creates, obtains, uses, or discloses health data, principally the protections that derive from the Health Insurance Portability and Accountability Act (HIPAA).

Basics of Health Privacy

This module discusses the basic privacy protections for health information provided by HIPAA, and other legal-regulatory and non-government sources. It identifies the duties and responsibilities of persons with access to protected health information (PHI) in order to fulfill privacy protections.

For additional information on available CITI training and instructions for accessing the training modules, please see the Office of Compliance and Privacy's pulse page: Collaborative Institutional Training Initiative (CITI) Program

For technical questions about CITI training please see the CITI Support Center: https://support.citiprogram.org

For questions about the Office of Compliance and Privacy's HIPAA training requirements for researchers, please email hscomply@health.ucsd.edu.

For questions about UCSD OIA training requirements, please see the published guidance here.

Reminder: Renewal of Business Systems Accounts

As we approach the end of 2022 we are now past the one-year anniversary of the beginning of the Kuali transition. Since access to Kuali is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kuali. Those accounts are generally good for only a year and need to be renewed. As such, we want to remind everyone about this.

If you are a **user** who has a business systems account that you use to access Kuali, check in with the department who sponsored your account to see if there is anything they need you to do to ensure your account is renewed.

If you have **sponsored** someone for a business systems account, please be sure to follow your departmental policies on renewing (or not) accounts in a timely fashion so that researchers do not lose access to Kuali. Furthermore, please be on the lookout for automated emails asking you te renew access for these individuals throughout the course of the year.

Reminder: Getting Help

Kuali IRB Knowledge Base Articles (KBAs) are part of the growing Research Knowledge Base. We generate new articles and update older articles in response to trends in questions or problems submitted by the research community.

Install and enable the WalkMe extension in your browser to get contextual help as you navigate Kuali IRB. This includes tips about using the system as well as key regulatory background. The extension is approved for Campus and Health Sciences computers. Contact OIA by email at irb@ucsd.edu with questions or to report errors/issues. For questions about Kuali in relation to single IRB/reliance arrangements, contact irbrely@ucsd.edu.

Please be sure to include the protocol number, if available. This will help the OIA team triage and troubleshoot.