UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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NEW: Spotlight on 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.

In this month's newsletter we wanted to highlight 3 new KBA documents published by OIA to help users better navigate the Kuali IRB system. These KBAs are related to Administrative Determinations, Amendments, and Renewals. As always, these KBAs provide step-by-step directions and tips to using the Kuali IRB system. They do not provide guidance on submission types or when a submission might be necessary. For guidance questions, please review our guidance web page or submit a ticket by emailing irb@ucsd.edu.

Administrative Determinations

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

- A study is not human subjects research
  - This determination means that the study either does not qualify as "research" according to the Federal definitions that IRBs use or that it does not involve "human subjects" as defined in the same Federal regulations. Thus, IRB review is not required.
- UCSD/RCHSD is not engaged in the human subjects research
  - This determination means that while the study is human subjects research, the activities being performed by UCSD/RCHSD personnel do not engage the institution(s) in the research. Thus, IRB review is not required.
- The research qualifies for an exempt determination
  - This determination means that the study is human subjects research, but all of the activities fall into at least one of the six Federal categories of Exemption. Per UCSD PPM 100-5, the UCSD IRB is required to review these studies to make sure that they meet Exempt criteria and conform to local requirements.
- The research will rely on a non-UCSD IRB for review
  - This determination allows the UCSD IRB to cede our review to a non-UCSD IRB for the oversight of the study.
- The research involves indefinite plans or delayed onset
  - This determination means that the study PI has certified to the UCSD IRB that their study will involve human subjects research and that they won't involve human subjects until IRB approval has been granted, but they can't make a full submission to the IRB because there is preparatory work that has to be done first. These are most appropriate when there is an impending funding deadline, just-in-time request, or an award needs to be released so that non-human subjects research activities can take place.

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

Amendments

Throughout the life of a study, it may be necessary to make changes to the study application or any of the study documents (e.g. protocol, consent form, recruitment materials, etc.). The process by which these changes are submitted to the IRB for review is called an amendment. The newly developed 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

Some studies require ongoing review by the IRB to ensure the safety of subjects. In order to facilitate this ongoing review, researchers must submit a renewal application to the OIA. The newly developed 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.

New: 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: Deadline to Begin Using New ICF, Assent, and Protocol Templates

Protocol Templates

Back in December 2021, OIA quietly rolled out three new protocol templates and made them available on our forms webpage here. These templates were designed to complement the Kuali application and not require duplicative information.

Starting **September 1st**, all new studies (except for secondary use studies which only require the Kuali application) will be required to use the master protocol if one exists (e.g. from an industry sponsor, cooperative group, etc.). Otherwise, you must use one of the three new protocol templates.

UCSD Consent and Assent Templates

All new UCSD studies requiring an informed consent or assent document will be required to use the new ICF and assent templates starting **September 1st**.

RCHSD Consent and Assent Templates

All new RCHSD studies requiring an informed consent or assent document will be required to use the new ICF and assent templates starting **January 1st, 2023**.

Reminder: OIA Winter Closure 2022

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.

As always, IRB meeting dates are available here. For information about handling urgent changes or emergency use of investigational products without IRB approval, please see the end of this message.

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

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

Please submit all renewals that need to occur prior to January 16, 2023 by November 30, 2022 to ensure that they are renewed in a timely fashion and do not expire.

Note: 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.

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 to 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.