UC San Diego
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NEW: OIA Recently Added Resources

Consent Guidance

Recently, the Office of IRB Administration (OIA) has been seeing an uptick in requests for "delayed consent" and so we wanted to provide some clarity about the waivers of consent that are available, what they mean, and what isn't possible. Because we expect that such information will be useful for more than just a one-time publication, we have posted the information about Consent Waivers on our website.

New Kuali KBAs

Subscribe to our email list.

In addition, OIA has added two new Knowledge Base Articles (KBAs) to our knowledge base. These KBAs provide step-by-step instructions on how to do various actions or make certain types of submissions. For guidance on when a submission is needed or action should be taken, please refer to our guidance webpage.

The first new KBA OIA has added is a set of instructions for how to submit a reportable event in the Kuali IRB system. Reportable events include non-compliance, new risk information, OCP monitoring reports, and similar issues/events that require prompt reporting to our office. Of all the submissions in Kuali IRB, this one is the most unlike any of the others and so we encourage researchers to review our Reportable Event KBA.

The second new KBA OIA has added is a set of instructions for how to submit a study closure in the Kuali IRB system. Submitting a closure application to the IRB is often the last step in the compliance lifecycle of any study and not one to be overlooked. OIA has provided two sets of instructions in this one KBA document. The first set of instructions detail how researchers can submit a closure for a study currently in an "approved" status in Kuali. The second set of instructions detail how researchers can submit a closure for a study currently in an "expired" status in Kuali. We encourage all researchers to review our Closure KBA.

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

Have IRB Questions?

OIA is here to help! Contact us at irb@ucsd.edu for assistance.

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

- 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.

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

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.

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