

January 24, 2024

---

## In This Issue

NEW: OIA February Office Hours

NEW: Outstanding Kuali Shells

NEW: External Reliance Post-Acceptance Submissions

NEW: Updated Reliance Webpage

Reminder: NHR Closures in Kuali IRB

Reminder: HSR Training Requirements

Reminder: Updated "Consent Minimums for External Reliance Studies"

Reminder: Submitting a Funding Proposal? Don't Wait to Submit to OIA

Reminder: Renewal of Business Systems Accounts

Reminder: Getting Help

---

## NEW: OIA February Office Hours

The next OIA office hours will be held on February 27, 2024 from 9-10 am and can be accessed at that time [here](#).

---

## NEW: Outstanding Kuali Shells

Now that OIA has fully transitioned to Kuali for more than a year, we're in the process of cleaning up records that were created in Kuali based on studies open in May 2021 in the legacy eIRB system. Some studies were closed in the legacy eIRB system

before being transferred, some have since closed without a closure submission in Kualu, and some are still active but were never transferred into Kualu.

To clean up these lingering "shell" records in Kualu, the OIA team has closed studies in Kualu which we were able to verify were closed in the legacy eIRB system. For the remaining "shells" our office will be reaching out to understand the study's current status and provide instruction on how to close or transfer the study in Kualu as necessary.

If there are questions about this process, feel free to contact us at [irb@ucsd.edu](mailto:irb@ucsd.edu) anytime.

---

## **NEW: External Reliance Post-Acceptance Submissions**

The OIA reliance team would like to remind all researchers that when they use an external IRB as the sIRB for their studies, they do retain certain obligations for post-acceptance submissions to the UCSD IRB as described on our [website](#) and in the attestation that was signed if using a commercial IRB.

### **Continuing Review**

One of the most often overlooked post-acceptance responsibilities is to submit continuing review information from the sIRB to the UCSD IRB. OIA has structured our continuing review application in Kualu so that if a study is relying on an external IRB, only a few brief questions about the study's status need to be answered. The team can then upload their approval letter and application submitted to the external IRB instead of completing the longer continuing review application required when the UCSD IRB is reviewing the study.

### **OCAA Submissions**

While the UCSD IRB needs to review some amendments before and after they are submitted to the external IRB as detailed on our [website](#), if a study has a coverage analysis managed by OCAA then a Kualu amendment submission is required every time there is a change to the study protocol/research plan, investigator's brochure (IB), or informed consent form (ICF).

If the amendment is solely submitted for the purpose of informing OCAA about these changes, OIA has built the application so that only two questions have to be answered. In addition, OIA typically processes such amendments in Kualu within 1 day or less so future amendments are not held up in the system.

If there are any questions about post-acceptance responsibilities when relying on an external IRB, please contact us at [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu) anytime.

---

## **NEW: Updated Reliance Webpage**

OIA has recently updated its [Reliance Webpage](#) to ensure that information is both current and easily accessible. Here is what we changed:

### **Post-Approval/Acceptance Responsibilities**

We created this [new section](#) of the webpage to provide easier access to researchers and their teams to this information. Previously it was buried in the Reliance Requests section which was not an intuitive place to look. We've also added the information above about OCAA submissions to this section to aid researchers.

### **Submitting Initial Reliance Requests**

[This section](#) (formerly called Reliance Requests) has had all post-approval/acceptance information removed and has been renamed to more accurately represent the information in this section.

### **Reliance Agreements**

[This section](#) has been updated to remove references to the UC Reliance Registry and reliance agreements through the MOU process.

As discussed in previous newsletters, the UC Reliance Registry is being sunset by UCOP later this year. As such, we are not accepting new reliances in that system any longer which is in line with the majority of the other UC campuses. Already executed reliances in the UC Reliance Registry will continue to persist under their current agreements.

Given the extensive use of commercial IRBs, adoption of the SMART IRB master agreement, and success in using our template IRB Authorization Agreement (IAA), the MOU pathway has been discontinued. We have updated the website to reflect this information so researchers and outside collaborators have the most current information.

As always, if there are any questions for our reliance team, please write to us anytime at [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu).

---

## **Reminder: NHR in Quali IRB**

Researchers conducting activities which are not human subjects research (NHR) may find themselves in need of official IRB determination that a project is NHR for a

variety of reasons. Maybe there is another UCSD office that requires an official determination, maybe a funding agency requires it, maybe a journal requires it. Whatever the reason, OIA is happy to review NHR applications in the Kuali IRB system and make NHR determinations.

**Note:** Historically, NHR projects may have been referred to colloquially as "Exempt" given that they do not require IRB review both by regulation and policy. This use of the term "Exempt" can become confusing as the IRB also makes formal Exemption determinations which means that a project is human subjects research but falls into one of the eight federally defined exempt categories found in the Common Rule at [45 CFR 46.104](#).

Because NHR projects are not regulated like studies that receive IRB approval, they are not required to be closed out in the Kuali system. NHR projects may carry on indefinitely, a few months, or only a day without further IRB review so long as they do not incorporate human subjects research activities.

While the Kuali system offers the ability to "Request Close" within the system for projects which have been determined to be NHR, this is not necessary and only serves to bog down OIA's review teams. As such, we kindly request that researchers do not submit closure applications for their NHR projects.

Not sure if your project is NHR? Questioning whether you need to close your project/study? The OIA team is here to help! Please email us at [irb@ucsd.edu](mailto:irb@ucsd.edu) with your study number and questions and we'll be happy to help.

---

## Reminder: HSR Training Requirements

OIA has long required that all study personnel working on human subjects research (HSR) receive training in the basics of working with human subjects through the CITI training modules designed for biomedical and social/behavioral researchers. In addition, all study personnel must also be specifically trained on the study protocol and the procedures to be followed.

OIA will review PI training at Initial and Continuing Review to ensure that the PI has completed the required CITI training. It is the PI's responsibility, as spelled out in our [OIA-103 IRB Handbook](#), to ensure that all other study personnel have completed the required CITI and protocol training.

Failure to ensure that staff are appropriately trained may result in findings of serious and/or continuing non-compliance on the part of the PI which are reportable to funding agencies, the FDA, and UCSD officials.

If there are questions about the PI's responsibility for study personnel training or other PI responsibilities, please contact OIA at [irb@ucsd.edu](mailto:irb@ucsd.edu).

---

## Reminder: Updated "Consent Minimums for External Reliance Studies"

OIA constantly strives to make sure that what we ask for in our reliance processes reflect what we ask of researchers when the UCSD IRBs review a study. To that end, it is necessary from time to time for us to update our consent minimums document to reflect any changes that may have occurred.

Recently, we published a new [consent minimums document](#) on our [reliance page](#).

These most recent updates reflect the following:

- Added new instructions to the beginning of the document to provide clarity for researchers and research teams.
- Updated radiation risks to be consistent with language requirements from HERC.
- Added Genetic Testing language to be used to align with the CalGINA requirements (more restrictive than federal GINA legislation).
- Clarified that the language about participant injury only applies to studies which are greater than minimal risk.
- Corrections of minor typos and formatting issues throughout.

Advarra and WCG IRB both have this new language on file and should be incorporating the language as appropriate into the consent forms they develop for UCSD/RCHSD sites. If research teams use another IRB as their IRB of record, they will need to incorporate this language into the consent form and submit the UCSD/RCHSD-specific consent template for review as a part of their reliance clearance submission.

Need more information about how to rely on an external IRB? Visit our [reliance page](#), view our [KBAs](#), or email us at [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu).

---

## Reminder: Submitting a Funding Proposal? Don't Wait to Submit to OIA

UCSD researchers collectively bring in an extraordinary amount of funding from outside sources to help support their research, but these funders need to see certain

things before they hand over any money. This includes IRB approvals or determinations when there are human subjects involved.

In OIA, we strive to be partners with our researchers and not stand in the way of getting research started. OIA often receives requests for rush approvals and reviews when Just In Time (JIT) notices come out. While we are happy to accommodate, these tend to bog down our review process for other researchers. In addition, there may be unforeseen complications with how research is proposed which means it cannot be easily approved even if it is moved to the front of the line.

As such, we ask that after researchers submit their proposals for funding, if the research will involve human subjects, go ahead and submit an application for review to OIA. That way, if something unforeseen arises there is time to deal with it without putting research funding in jeopardy.

Please keep in mind that the normal OIA review process can take from 6-8 weeks from the time of submission, so be sure to get those studies submitted with plenty of time for review. Our office (and your fellow researchers) thank you!

Need help with a submission? Contact us at [irb@ucsd.edu](mailto:irb@ucsd.edu) and one of our analysts will be happy to assist.

---

## Reminder: Renewal of Business Systems Accounts

Since access to Kualii is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kualii. 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 Kualii, 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 Kualii. 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.

Our [OIA FAQ page](#) answers the top questions our office receives from the research community. It covers everything from "Do I need to submit to the IRB?" to "How do I find my approval letter?"

Can't find what you're looking for? Contact OIA by email at [irb@ucsd.edu](mailto:irb@ucsd.edu) with questions or to report errors/issues. For questions in relation to single IRB/reliance arrangements, contact [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu).

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

---

University of California San Diego, 9500 Gilman Drive, La Jolla, CA, 92093

Share this email:



[Manage your preferences](#) | [Unsubscribe](#)

This email was sent to .  
*To continue receiving our emails, add us to your address book.*

**UC San Diego**

[Subscribe](#) to our email list.