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## NEW: OIA March Office Hours

The next OIA office hours will be held on March 22, 2024 from 9-10 am and can be accessed at that time [here](#).

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## NEW: Study Personnel Lists in Kualii IRB

OIA has recently observed an increase in audits showing that the Study Personnel list in Kualii IRB is not being consistently maintained. Per the OIA's [IRB Handbook](#),

the PI is responsible for ensuring all appropriate personnel are listed in the Study Personnel section in KualI IRB. The people who must be listed are:

- The Principal Investigator
- Any Co-Investigators
- Anyone obtaining the informed consent of research participants
- Anyone who interacts with or intervenes with human subjects or their identifiable data
- Anyone named as a contact person on the informed consent document and/or recruitment materials for the study

Each individual is entered in their own row with their name, home unit (i.e. department), institutional title (e.g. associate professor, staff research associate, clinical research coordinator, etc.), researcher role (i.e. principal investigator (PI), co-investigator, or key personnel), and the permissions they should have for the study in KualI IRB (i.e. full access or read-only).

OIA recognizes that it may be unwieldy or not possible for certain individuals to be listed in the Study Personnel section by name, and so we have created an “Unnamed Personnel” sub-section to allow inclusion of study team members who will not have an account in KualI IRB. The types of individuals that can be included in this section include residents or students who will rotate on and off the study for a short period of time, volunteers with formal UCSD/RCHSD appointments, and outside contractors who will conduct human subjects research activities (e.g. survey firms).

Additionally, OIA recognizes that studies which retained their previous HRPP study number from the eIRB legacy system will not have the Unnamed Personnel section described above and will have a section in their Research Plan discussing personnel. For these studies (study numbers starting with a 1 or 2), the PI may update only the Research Plan rather than the KualI IRB Study Personnel section to satisfy the requirement to list appropriate personnel working on the study.

It is imperative that PIs keep the Study Personnel section of KualI IRB or their Research Plan (only for studies with a study number starting with a 1 or 2) up to date at all times. OIA has implemented a very quick process for reviewing amendments which involve only personnel changes so as to ensure that study teams are not otherwise held up by completing this important update to their IRB applications.

For answers to common questions on this topic, we encourage you to visit our [FAQ section on Study Personnel](#).

Not finding the answer to your question? Write to us at [irb@ucsd.edu](mailto:irb@ucsd.edu)!

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## NEW: Using the Participating Sites Tab in Kuali IRB

Kuali IRB comes with many features and not all of them get used in every submission to OIA. One feature we want to highlight is the "Participating Sites" tab.



For studies where the UCSD IRB will review on behalf of non-UCSD/non-RCHSD sites, this tab is where information about each of those sites (e.g. name of site, local IRB contact, activities performed at site, etc.) is captured.

Unlike other sections of Kuali IRB, the Participating Sites tab isn't locked upon submission to OIA or once approval is issued by OIA. As such, it is possible for researchers or their teams to make changes on this tab without initiating an amendment.

**Please note** that any changes made to the participating sites tab and not submitted for approval, reviewed by OIA, and approved by OIA are not considered approved. Just like any other change to a research protocol, changes to Participating Sites may not be enacted without prior IRB approval except to eliminate an apparent immediate hazard to subjects.

If changes to the Participating Sites tab are needed (e.g. adding a site, removing a site, changing information about a site, etc.) please remember that you'll both need to make the change on the Participating Sites tab **and** submit an amendment as normal for the change to be reviewed.

Questions about using the Participating Sites tab? Questions about reliance processes in general? Email us at [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu)!

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## NEW: Clearance is Required Before Submitting to External IRBs

As a part of the process for OIA to cede its responsibility for review to an External IRB, OIA requires a two step process.

The first step in the process is called "clearance" and is when OIA will perform an administrative review of the study to make sure it is acceptable in terms of local context. During this administrative review, OIA may check that our [consent minimums](#) have been incorporated into any consent documents, that the External IRB's determinations are consistent with California law, and that any ancillary reviews have been appropriately triggered.

It is important that researchers and their teams submit to OIA for clearance **before** submitting for approval from the External IRB. In some cases (e.g. WCG IRB and Advarra IRB) the External IRB will not initiate review of the UCSD/RCHSD site until we provide clearance. In other cases, a failure to submit for clearance may result in significant delays in getting the study started here at UCSD/RCHSD if OIA later finds that there are issues with the study (e.g. missing consent language, HIPAA language in the consent, study procedures which are incongruent with California law, etc.).

As such, we want to remind all study teams considering having their studies approved by an External IRB that they need to submit to OIA for clearance first. Our Knowledge Base Article (KBA) on [submitting for administrative determinations](#) provides step-by-step directions on how to submit to OIA for clearance. In addition, our reliance team is committed to responding to all clearance submissions within 5-10 business days so as to not hold studies up unnecessarily.

Have questions about getting clearance? Have questions about reliances generally? Contact us at [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu)!

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## Reminder: 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 KualI, and some are still active but were never transferred into KualI.

To clean up these lingering "shell" records in KualI, the OIA team has closed studies in KualI 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 KualI as necessary.

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

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# Reminder: 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.

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## Reminder: 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).

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## **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.

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## Reminder: Renewal of Business Systems Accounts

Since access to Kualu is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kualu. 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 Kualu, 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 Kualu. Furthermore, please be on the lookout for automated emails asking you to renew access for these individuals throughout the course of the year.

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## Reminder: Getting Help

[Kualu 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.

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