UC San Diego — INSTITUTIONAL REVIEW BOARD ADMINISTRATION | human research news

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NEW: OIA April Office Hours

The next OIA office hours will be held on April 17, 2024 from 9-10 am and can be accessed at that time [here](#).

NEW: Student Research Projects

Spring is here and with it comes flowers, warmer weather, and the promise of Summer! Summer can be a great time to relax, hike, enjoy the beach, or take advantage of the academic break to do research.

OIA often sees an increase in student applications to conduct human subjects research in May and June with tight turnarounds requested. To ensure you (or any students you're mentoring) get IRB approval in time, consider these tips from OIA:

1. Get your application in as soon as possible. It can be tempting to wait until the last minute; however, OIA operates on a first come, first served basis so the sooner you submit, the sooner we can review. Keep in mind, our review times vary from 4-8 weeks depending on submission volume so submitting early helps ensure you'll be ready by Summer. Plus, beating the rush can allow you to get a head start on your project once Summer is here.

2. Review OIA resources as you're developing your application, informed consent, and protocol. The [OIA website](#) has all sorts of handy information like [FAQs](#), [what research needs IRB review](#), how to conduct [student research](#), [templates](#) for protocols and informed consent documents, and so much more.

3. Having trouble finding an answer to your specific question? Write to us at irb@ucsd.edu to ask. We're happy to answer any questions you might have!

4. Have a group of students who could all use the same information? OIA offers presentations. Write to us at irb@ucsd.edu and we'll be happy to arrange a training with our staff based on the content of interest. We cover everything from what an IRB is and why IRBs exist to common mistakes and how to submit in Kuali.

NEW: When to Choose Exempt vs. Expedited/Full Board Review

Choosing the right Kuali IRB submission type from the start is key to the application and review process as the submission type will dictate the information researchers are asked to provide. Knowing this, OIA has formatted the Kuali IRB application to provide specific instruction about when to choose which submission type.

But even with all that, it can sometimes be hard to know whether a study needs an administrative review as Exempt or IRB review as Expedited/Full Board. Every study is unique and the tiniest of nuances can sometimes push a study one way or the other. To help, OIA has developed a [website](#) which discusses the different levels of review and when each is appropriate. The most important thing to remember is that if any part of the research doesn't fit into one level, then the research has to be reviewed at a higher level.

For example, maybe you have a study where you want to do a survey, a chart review, and a blood draw. The survey and chart review potentially fit into the Exempt review level; however, the blood draw can't be reviewed as Exempt. Since the blood draw

doesn't fit into Exempt, we have to consider the next level up which is Expedited review. All three procedures can be reviewed Expedited so that will be the level of review for the study.

Every research project is unique. Sometimes it is clear which level of review is needed. Sometimes it isn't. If you need help determining the level of review you should select, write to us with as much detail about your project as possible at irb@ucsd.edu and we'll be happy to help. Important information to include in your email:

- How the study is funded (e.g. federal, industry, state, etc.) or if it's unfunded
- The specific research procedures to be done (e.g. surveys, chart reviews, blood draws, etc.)
- Whether any special populations will be involved (e.g. children, pregnant individuals, prisoners, cognitively impaired, etc.)

NEW: Searching for Study Personnel in Kuali IRB

Last month we talked about the importance of maintaining the Study Personnel list in Kuali IRB. If you missed it, that article is just below this one.

While it's important that the list be updated regularly and include all the individuals we mentioned in last month's article, it's also important that the list be accurate. Many of us on campus have the same or very similar names which can make selecting the right individual on the Study Personnel list a challenge. As a testament to this, OIA receives a number of emails each month of people who get a Kuali IRB notification even though they have no involvement in the study. Turns out, someone clicked the wrong person who had the same name.

To help with this, OIA recommends searching for people by their UCSD email address rather than their name. For example, if I have a study personnel Jane Smith and I search for "Jane, Smith" I might pull up 7 people where I have to figure out who the correct one is. However, if Jane's email is j7smith@ucsd.edu, I can search for "j7smith" and only the correct Jane Smith should appear. Of course, even then because email addresses were sometimes reused in the past this might give you two people so it always pays to be vigilant.

Have questions about completing the Study Personnel list in Kuali IRB? Email us at irb@ucsd.edu and we'll be happy to help!

Reminder: Study Peronnel Lists in Kuali IRB

OIA has recently observed an increase in audits showing that the Study Personnel list in Kuali 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!

Reminder: 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.

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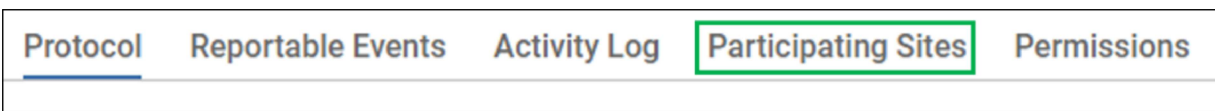
For studies where the UCSD IRB will review on behalf of non-UCSD/non-RCHSD sites, this tab is where information about each of those sites (e.g. name of site, local IRB contact, activities performed at site, etc.) is captured.

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!

Reminder: 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!

Don't Forget: 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 and one of our analysts will be happy to assist.

Don't Forget: 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 to renew access for these individuals throughout the course of the year.

Don't Forget: 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 with questions or to report errors/issues. For questions 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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