# UC San Diego
## INSTITUTIONAL REVIEW BOARD ADMINISTRATION

## human research news

**April 29, 2024**

---

## In This Issue

NEW: OIA May Office Hours

NEW: Updated Sponsor Letter

NEW: Reportable Event Letters

NEW: What to do When All Human Subjects Research is Conducted at an External Site

NEW: The IRB Review Process

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

Reminder: Searching for Study Personnel in Kuali IRB

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

Don't Forget: Renewal of Business Systems Accounts

Don't Forget: Getting Help

---

## NEW: OIA May Office Hours

The next OIA office hours will be held on May 23, 2024 from 9-10 am and can be accessed at that time [here](#).

---

## NEW: Updated Sponsor Letter

OIA recently updated the [Sponsor Letter](#) available on our website. The new letter is dated April 8, 2024 and incorporates a minor change to the section "Compliance with

FDA Regulations and International Conference on Harmonization (ICH) Guidelines" which starts at the end of the first page.

If you use this letter in discussing studies or OIA policies with your sponsors, please ensure you're using the most current version.

---

# NEW: Reportable Event Letters

Kuali has recently enabled a new feature allowing OIA to create determination letters in Kuali IRB for reportable events similar to how we have created approval letters for years.

The change is not retroactive (no letters will be created for previously reviewed events); however, new reportable events submitted on new or old studies will have this feature enabled.

Because the process is not exactly the same as locating an approval letter, we have created this Knowledge Base Article (KBA) to provide step-by-step directions to locating the letter.

Having troubles navigating Kuali IRB? The OIA team is here to help! Please email us at irb@ucsd.edu.

---

# NEW: What to do When All Human Subjects Research is Conducted at an External Site

Often the process for getting IRB review is pretty straightforward. A researcher conducting human subjects research decides whether they'll use the UCSD IRB or an External IRB and then follows the appropriate process.

**But what happens when UCSD/RCHSD gets a grant for a human subjects research project even though no one at UCSD/RCHSD will actually do any human subjects research?**

This could happen for a variety of reasons: all the human subjects research will be done by collaborators, all the human subjects research will be done in a foreign country, the grant is transferring to UCSD/RCHSD but all the human subjects research is done at a different institution.

In all these cases, the one constant is that UCSD/RCHSD is receiving a federal award under which human subjects research will be conducted, albeit likely through subawards. As the prime awardee, UCSD/RCHSD is responsible for ensuring that

the rights and welfare of the participants are protected according to the regulations set out in the Common Rule. This is accomplished, in part, by receiving IRB approval and IRB approval is a term of the award.

However, in addition to merely ensuring there has been IRB approval, most federal funders also consider the prime awardee institution (UCSD/RCHSD in this case) to be engaged in the human subjects research even if a participant will never come to UCSD/RCHSD, talk to UCSD/RCHSD staff, or have their identifiable data sent to UCSD/RCHSD. This means that UCSD/RCHSD, as a performance site, needs IRB review.

In the case where there is another US site also engaged in the human subjects research, the UCSD IRB will typically cede its review to another site through a reliance agreement or the UCSD IRB will serve as the single IRB (sIRB) for the other US sites.

**But what happens when UCSD/RCHSD is the only US site and all the human subjects research is conducted abroad?**

Even in such cases, the UCSD IRB must review the study (along with the foreign IRB(s), depending on the country/ies) to ensure the regulatory requirements (e.g. informed consent, criteria for approval, etc.) are met; however, because no human subjects research will actually be conducted at UCSD/RCHSD, these submissions are not the same as the usual process.

**So what process is used instead?**

The UCSD IRB will still need to receive the study protocol and informed consent document(s) in Kuali IRB for review and approval; however, these need not use the OIA templates and UCSD/RCHSD specific language (e.g. injury language, the Moore clause, HIPAA language, etc.) need not be included. The UCSD IRB will also need to see any supporting documentation like Investigator Brochures (IBs), surveys/questionnaires, recruitment materials, and anything meant to be seen or heard by participants. Additionally, the Kuali IRB application should indicate that all study procedures are conducted outside of UCSD/RCHSD.

**What if I still have questions?**

The OIA team is always here to help. Email us at irb@ucsd.edu and we'll be happy to answer any questions!

---

# NEW: The IRB Review Process

For those unfamiliar with submitting to an IRB for approval, the process can seem both daunting and be a bit of a "black box" in terms of processing. When can I expect

to hear back? I received some questions early on and then crickets, why? When will my study be reviewed? What does the IRB look for?

In order to be more transparent with the research community, we have posted all our SOPs, Worksheets, and Checklists on our [Guidance](#) page. These documents cover the vast majority of the IRB review process and the various aspects that will be reviewed. Mid level flowcharts describing both the [OIA review process](#) and the [External IRB Reliance process](#) are also available on our webpage for those who prefer a more graphical representation of workflows.

Of course, we don't expect our researchers to be experts in the human subjects research process and so while we provide very detailed information on our website for those interested, we also wanted to provide this more general overview of the process:

- **Triage** - This is where it all starts!
  - When a new study, amendment, continuing review, or reportable event is submitted, our triage team is notified by the system.
  - Triage checks for general completeness, PI CITI training, common errors (e.g. negative subject numbers, non-UCSD/RCHSD personnel, etc.), and determines the likely level of review needed.
  - If there are errors or missing information identified, the submission will be returned to the research team to address the errors and provide the missing information.
  - Once the submission is complete, the triage team will send the submission to one of OIA's three review teams.
- **Non-Committee** - Review team for Not Human Subjects Research (NHSR) determinations as well as Exempt and Expedited reviews
  - Submissions qualifying for NHSR determinations as well as submissions of new Exempt and Expedited projects are reviewed for the criteria for approval.
  - Submissions of amendments and continuing reviews for studies previously reviewed by the non-committee team are also reviewed for the criteria for approval.
  - If a submission of a new study, amendment, or continuing review is found to need full board review either through review (less likely) or because more information is disclosed during the review process (more likely), the non-committee team will assign the submission to the appropriate committee team member for review.
  - Submissions of reportable events for studies previously reviewed by the non-committee team are reviewed for whether they can be accepted

by the non-committee team or require review by the full board according to our SOP.

- If a submission needs more information or changes in order to be approvable, the non-committee team will return the submission to the research team with action items.

- If a submission can be approved, the non-committee team will issue the approval in the Kuali IRB system.

- **Committee** - Review team for studies requiring review by the Full Board.
  - Submissions of new human subjects research which are not exempt and don't qualify for expedited review (either because of the procedures involved or the risk level) will be sent to this team.

  - Submissions of amendments, continuing reviews, and reportable events in studies previously reviewed by the full board will also be sent to this team.

  - New studies will undergo a pre-review process to identify as many issues as possible prior to review by the full board. If issues are identified, the submission is sent back to the research team to address prior to scheduling for a full board review.

  - Amendments, continuing reviews, and reportable events are assessed as to whether they can be reviewed by the committee team member or must be scheduled for full board review and a preliminary review is conducted. Again, if issues are identified, the submission is sent back to the research team to address prior to approval by the committee team member or scheduling for a full board review.

  - If a submission is being reviewed by the full board, the committee team member will reach out ahead of the meeting if a member prospectively identifies any issues likely to cause a deferral.

  - Following the full board meeting, the committee team member will communicate the board's decision through Kuali. Possible determinations include Approval, Approve Pending, Deferred, or Disapproved. Reportable events can have a variety of outcomes including accepted, determined to be non-compliance (may be serious or continuing), determined to be an unanticipated problem involving risk to subjects or others (UPIRSO/UPR), or result in a suspension or termination.

  - If a submission is able to be reviewed by the committee team member, once the submission meets criteria for approval they will issue approval in the Kuali IRB system.

- **Reliance** - When review will be conducted by an external IRB.

- Submissions with a request to rely on an external IRB are sent to the reliance team for clearance to submit to the external IRB.
- The reliance team will conduct an administrative review to ensure appropriate local context will be applied (e.g. California Laws, UC policies, etc.).
- If issues are identified, the reliance team will return the submission to the research team for more information or changes, as needed.
- Once clearance can be issued, the reliance team will issue a clearance notice in the Kuali IRB system.
- Following approval by the external IRB, research teams resubmit the application in the Kuali IRB system with the external IRB's approval and approved documents for acceptance.
- The reliance team again ensures the local context was adhered to and requests revisions as necessary.
- If all local context considerations are satisfied, the reliance team will issue an acceptance letter in the Kuali IRB system.

While this is a general overview about the steps in the review process, there are many nuances and special circumstances that aren't covered in the above.

Want to learn more? Email us at irb@ucsd.edu with your questions!

---

# Reminder: 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.)

## Reminder: Searching for Study Personnel in Kuali IRB

Back in February we talked about the importance of maintaining the Study Personnel list in Kuali IRB. If you missed it, that article is available on our website.

While it's important that the list be updated regularly and include all the individuals we mentioned in February'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 "Smith, Jane" 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!

# 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.

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