UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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NEW: OIA January Office Hours

OIA office hours will be held on January 15, 2025 from 9-10 am and can be accessed at that time here.

NEW: OIA Website Updates

Two new updates to the OIA website have been made this month that we wanted to bring your attention to:

First, OIA has received numerous requests for extra guidance on performing a root cause analysis and developing a corrective and preventative action (CAPA) plan for certain types of reportable events. We're happy to announce that we have published a guidance document and template on our Guidance page. The document can be accessed directly here.

Second, the Consent Minimums document for use when relying on an external IRB has been updated. The changes include updating the file name on our website to remove the date as this was causing confusion and adding in information about mandated reporting and pregnant minors to comply with California law. This new document has already been circulated to WCG and Advarra so your new consent documents should reflect this information if using one of them as your IRB of record.

Have suggestions for our website? Questions on where to find something? Email us at IRB@ucsd.edu and we'll be happy to help!

NEW: Kuali Tips - Selecting the Right Study Personnel

Kuali IRB uses the permissions assigned to folks in the Study Personnel table in the application the Permissions tab to make sure the right people get notified about important things happening with a study. This could be an impending expiration date, comments from reviewers, or resolution of a reportable event. For these reasons, it's important to make sure the right people are listed in these sections.

One common issue is that someone with the same or similar name will be selected instead of someone else. To help avoid this issue, use the person's email address to look them up in Kuali IRB instead of their name. For example, if you're trying to find Jane Doe in Kuali IRB, don't search "doe, jane." Instead, use Jane's email address: j1doe@ucsd.edu. Just search "j1doe" and the right Jane Doe should come up.

Another issue we see is that someone who was a student has now become a UCSD employee. Sometimes this also means a new email address. Because the Kuali IRB system uses email addresses (which come straight from UC PATH) to make each person's identity in the system, if a student becomes an employee all the studies they had access to will not be available under their new address. If they were listed as Study Personnel in the application, then a simple amendment to remove the old account and add the new one is all that is needed. If they just had permissions on the Permissions tab, that tab can be edited at any time without an amendment.

The last common issue we see is people accidentally removing their own access. Usually this happens when they're altering their own role on the study in the Study Personnel section. When someone's role is changed, Kuali IRB automatically sets

their permissions to the default for that role. So if someone is changed to be the new PI of the study, they'll get full access; however, if someone was PI but is now a Key Person their default will be read-only access. To avoid removing your own permissions, make sure the permissions in the pop-up window are correct before clicking the "Done" button.

Still having troubles with accounts or permissions in Kuali IRB? Have a different Kuali IRB question? Contact us at IRB@ucsd.edu and we'll be happy to help!

NEW: OIA Becomes CARE-Q Certified

Earlier this year, OIA applied for certification of our program through the Consortium for Applied Research Ethics Quality (CARE-Q). CARE-Q is a program put together by the University of California and Stanford to review IRBs and their administrative offices to ensure they are following the laws, regulations, and policies required to protect human subjects. To learn more about CARE-Q, visit their webpage.

Following review of our application, SOPs, guidance documents, and approved studies in conjunction with an observation of IRB meetings and interviews with staff, leadership, PIs, IRB chairs, and IRB members, OIA received certification. As a marker of this, CARE-Q supplies us with their logo which you may have already seen in your approval letters. The logo is also reproduced below. If sponsors have any questions about this certification, please direct them to the webpage above.

Certification is not a one and done idea, but rather is only the beginning. As a CARE-Q certified program, OIA will participate in assessment visits of other IRB programs and regular engagement webinars and meetings with other IRBs in CARE-Q. This will ensure that OIA continues to grow and evolve to keep in line with ethical best practices in the IRB space. We want to take this time to thank everyone here at UC San Diego who made this possible.

Reminder: OIA Holiday Closure

As noted in the communication from Campus HR, the AVC for Health Sciences, and the AVC for Academic Personnel, the UCSD campus will be closed starting Tuesday, December 24th through Wednesday, January 1st. OIA also participates in this closure and will be closed for these same dates.

Additionally, it is expected that many staff will take Monday, December 23rd, Thursday, January 2nd, and Friday, January 3rd off as well to spend time with their families and loved ones during the winter holiday period.

Happy Holidays!

Reminder: Institutional Sign Off for Studies Relying on Commercial IRBs

When UCSD researchers rely on a commercial IRB (i.e. WCG or Advarra) for the review of their studies, these IRBs consult with OIA in a process known as Institutional Sign Off or ISO. ISO would typically occur between the commercial IRB's review of the study and the dissemination of the approved documents. During this review, the OIA reliance team looks at the consent documents to ensure that the UCSD consent minimums have been appropriately incorporated into the consent document.

Starting with submissions made to WCG and Advarra on December 1, 2024, the ISO process is being phased out. While this is being done for specific reasons, we want to make sure our research community is aware of this change and what to look for.

So what does this mean for you, our researchers? Here are a few things you should know:

- This **doesn't** change the submission process to OIA or the commercial IRBs at all.
- This **doesn't** change the requirement to make sure all consent minimums, as appropriate, are in the consent document.
- This **does** mean there will no longer be a hold placed on studies after commercial IRB approval. The commercial IRBs will proceed straight from their IRB's determination to their process for releasing documents.
- This **doesn't** change the requirement for getting OIA acceptance of the reliance on the commercial IRB's approval (or any other ancillary reviews [e.g. COI, OCAA, contracting, etc.]) before proceeding with the study.

But **most importantly**, this means that researchers will need to pay special attention to the consent customization process of the commercial IRB. WCG will provide the

research team with an emailed "Site Pre-Review" of the consent document(s). Advarra will provide researchers with an "ICF Review" via their CIRBI system after their IRB has reviewed to confirm the consent document(s) are acceptable as approved. Whether it is a "Site Pre-Review" or "ICF Review," this step will be the researcher's one and only opportunity to make sure all the study documents are correct before they're approved or finalized by the commercial IRB.

If consent forms are approved by the commercial IRB with missing or incorrect consent minimums language, OIA will be unable to accept the reliance and the researcher will need to submit an amendment to the commercial IRB to have the document(s) fixed.

Have questions about this change? Have questions about the reliance process in general? Our OIA reliance team is here to help! Email them anytime at irbrely@ucsd.edu!

Reminder: Sharing Research Data for Secondary Research

It is common practice to share research data with collaborators to keep from reinventing the wheel. Not only can this practice save time and effort, it can often be protective because new participants can be spared the risk of data collection and other risks associated with human research. That being said, there are some important caveats that go along with data sharing.

First, it's important to remember that each study is unique and so it needs its own Kuali application. While it can seem like the easiest path is to simply add a UCSD collaborator on to your current study so they can perform a secondary analysis of the already collected data, that often subjects them to higher administrative burden and regulation than if they simply submitted their own study in the first place. The proper pathway when a researcher wants to use data to perform a secondary analysis, and that works constitutes human subjects research, is to submit a new application to OIA via Kuali.

Second, it is important to adhere to any privacy and confidentiality provisions that were provided to the research participants. If the participants were told that their data weren't going to be shared, then use of that data for secondary research isn't allowed. Similarly, if the participants were told that their data would only be used for certain types of research or only after being de-identified, that similarly has to be respected. OIA makes this determination on a case-by-case basis by reviewing what subjects were initially told and highlights the importance of ensuring appropriate review of these secondary use studies.

Lastly, if data will be shared with collaborators or other entities outside UCSD, it is important that non-IRB procedures for sharing are adhered to as well. Namely, there must be a data use agreement in place to govern how that data will and won't be used. The UCSD Sponsored Projects Office (SPO) facilitates these agreements. Additionally, if health data will be shared, the Health Data Oversight Committee (HDOC) will need to review the proposed sharing to see if it can proceed.

Have questions about sharing your data from an IRB perspective, contact OIA anytime at irb@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.

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

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