

October 27, 2023

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## NEW: OIA November Office Hours

The next OIA office hours will be held on November 17, 2023 from 9-10 am and can be accessed at that time [here](#).

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## NEW: OIA Holiday Closure

Like much of UCSD, the Office of IRB Administration (OIA) will be closed from Saturday December 23rd, 2023 through Tuesday January 2nd, 2024. OIA staff will be back to the office on Wednesday January 3rd, 2024.

If you have a study which will expire before January 20th, 2024, please submit your renewal at least 30 days in advance or by December 1, 2023, whichever is sooner. This will allow our office time to review your study to ensure it doesn't expire.

Happy Holidays!

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## NEW: OIA FAQ Webpage

The Office of IRB Administration (OIA) has recently launched a new [FAQ webpage](#). The questions on the webpage are drawn from thousands of tickets, emails, and phone calls we've received to answer some of the UCSD and RCHSD research community's most common questions. It covers everything from general questions like "Do I need to submit to the IRB?" to more specific questions like "How do I find my approval letter?" We encourage you to check out our new page the next time you have a question.

Not finding an answer you're looking for? OIA is always standing by to help. Write to us anytime at [irb@ucsd.edu](mailto:irb@ucsd.edu) and we'll be happy to help.

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## NEW: Thank You to Our Stakeholders

Last month we sent draft SOPs to our researcher stakeholder group for review. Between two Zoom meetings and countless comments, edits, and suggestions we're thrilled to have had so much engagement from the research community in developing our new SOPs.

To that end, we want to extend a huge thank you to those amongst the research community at UCSD and RCHSD who took time to read the SOPs and provide feedback. Your contributions help our office to work as better partners with the research community

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THANK YOU!

OIA is currently reviewing all of the feedback and will be sending the SOPs to leadership for approval. When the SOPs have been approved, we'll send another announcement to the research community. Watch your inboxes!

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## **NEW: Use of Gender Neutral Language**

Those of you who have been submitting to OIA for the last couple of years may have noticed more of a push to incorporate gender neutral language into consent forms. While we haven't talked about it so much publicly, this push is part of a larger effort within OIA and IRBs nationally to make research more inclusive to people from all walks of life in deference to the responsibility of all IRBs to uphold the Belmont principles of Justice and Respect for Persons. One way we can do that is by ensuring the language we use in our consent forms less off putting to people who align with various gender identities.

The most common place that IRBs tend to see gendered language in consent forms is when clinical studies require additional safeguards against pregnancy. There are often phrases like "Women of childbearing potential..." or "You shouldn't father a child..." which can be off putting to people who may not identify within the gender binary or may be transgender. Additionally, while we have seen some consent forms try to replace these phrases with things like "subjects who have a uterus and ovaries," "subjects who menstruate," and "subjects who produce sperm" these phrases can be equally problematic for people who are transgender or experience body dysmorphia.

Instead, OIA prefers to describe people "who can become pregnant" and people "who can cause a pregnancy" as needing to take extra protections. We have incorporated this gender neutral language into our current consent template and consent minimums document for when we rely on external IRBs. We encourage the research community to work this language into their normal process of talking with subjects to foster a sense of inclusivity.

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## **NEW: Compliance Awareness Week**

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[Subscribe](#) to our email list.

The Office of Compliance and Privacy (OCP) invites you to participate in UC San Diego Health's Compliance Awareness Week, taking place Monday, October 30, through Friday, November 3, with the theme of "Celebrating Our Health Care Heroes."

The week will begin with a brief webinar focused on compliance awareness, featuring OCP's Chief Compliance and Privacy Officer Ron Skillens and Vice Chancellor Dr. John Carethers. More fun events are planned, including a Halloween mini carnival!

Please be sure to tune in on Monday, 10/30, celebrate with OCP on Tuesday, 10/31, and be on the lookout for OCP's information tables and department staff rounding. See [OCP's Pulse page](#) for more information. If you are unable to tune into the webinar, a recording will be posted to Pulse after.

For questions, please email [hscomply@health.ucsd.edu](mailto:hscomply@health.ucsd.edu).

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## Reminder: UC Reliance Registry Ending

The University of California Office of the President (UCOP) has informed campuses that it will be sun-setting the UC Reliance Registry as of June 2024. Given this information, the utility of the UC Reliance Registry only accepting reliances between UC campuses, and the fact that the majority of our studies that don't use a commercial IRB go through the SMART IRB reliance mechanism, we have ended the use of the UC Reliance Registry for new studies as of **September 30th, 2023**.

To ensure the least amount of administrative burden possible, as of **October 1st, 2023** all new reliance requests are being administered through SMART IRB or individual agreements, as needed. This will save OIA staff and research teams the hassle of getting everything ironed out, just to have to do it all over again in a few months.

When we have more information about the plan for the deprecation of the UC Reliance Registry, we will advise on what studies currently using the registry for management of their reliances should do. Stay tuned!

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## Reminder: Submitting a Funding Proposal?

[Subscribe](#) to our email list.

# 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: KualI KBAs

Knowledge Base Articles (KBAs) are an important part of the transition from the legacy eIRB system to KualI. These articles help provide additional instruction and guidance about how to use the KualI system. The research knowledge base containing KBAs for all of UCSD research can be found [here](#).

### Administrative Determinations

The OIA generally has 5 types of administrative determinations it can make:

- A study is not human subjects research
- UCSD/RCHSD is not engaged in the human subjects research
- The research qualifies for an exempt determination

- The research involves indefinite plans or delayed onset

The [KBA on this topic](#) walks users through how to submit each of the 5 types of determination applications above.

### **Amendments**

The [KBA on this topic](#) walks users through the process of submitting an amendment and some particular nuances of how to use the Kuali IRB system.

### **Renewals**

The [KBA on this topic](#) walks users through the process of submitting a renewal application.

### **Reportable Events**

The [KBA on this topic](#) walks users through the process of submitting a reportable event application.

### **Closures**

The [KBA on this topic](#) walks users through the process of submitting a closure application.

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## **Reminder: 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.

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## 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.

Install and enable the [WalkMe](#) extension in your browser to get contextual help as you navigate Kuali IRB. This includes tips about using the system as well as key regulatory background. The extension is approved for Campus and Health Sciences computers.

Contact OIA by email at [irb@ucsd.edu](mailto:irb@ucsd.edu) with questions or to report errors/issues. For questions about Kuali 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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