UC San Diego

INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

September 28, 2023

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NEW: OIA October Office Hours

The next OIA office hours will be held on October 25, 2023 from 9-10 am and can be accessed at that time [here](#).

NEW: OIA Website & SOP Updates

The Office of IRB Administration (OIA) has been working for the last many months to do an office-wide overhaul as a natural progression from the recent changes our office has undergone from the implementation of Kuali IRB to our new leadership and

staff. One aspect of this overhaul is to continually update our website with additional information so that the website continues to serve as a resource to our researchers.

To this end, our guidance page was recently updated. Old guidance documents which are out of date have been removed and we've left only pertinent guidance documents on the page. Additionally, the old HRPP SOPPs have been removed. These old SOPPs were relegated to guidance with the update to UCSD PPM 100-5 back in March 2021. The old SOPPs can still be found on our website here if needed by research teams.

The SOPs currently posted on our guidance page are primarily related to OIA day-to-day operations (e.g. review of studies, conducting IRB meetings, reliance processes, etc.). The next set of SOPs we are working on are for investigators. These will include specific SOPs on the consent and assesnt processes, recruitment, and a general Investigator's Manual of responsibilities. We're quickly approaching the stakeholder review portion of our process of getting these investigator SOPs developed and are looking for those interested in providing us with feedback. For more information, see the article about needed stakeholders below.

NEW: Micro Trainings for Research Compliance

This article comes from the Office of Compliance and Privacy (OCP):

The UCSDHS Office of Compliance and Privacy (OCP) is happy to announce an addition to our educational offerings: Micro Training for Research Compliance.

Adherence to regulations and ethical standards is paramount for researchers and institutions alike, and we are committed to providing you with a dynamic, efficient, and accessible solution. With our new Micro Training modules, research compliance training has never been more convenient or accessible. Most modules are less than 10 minutes long and you can find them on our Research Compliance Training and Education webpage at this link:

https://pulse.ucsd.edu/departments/compliance/education-training/research-compliance-training/Pages/default.aspx

Check back often as we are adding more modules soon!

Please contact OCP with any questions at hscomply@health.ucsd.edu

NEW: UC Reliance Registry Ending

The University of California Office of the President (UCOP) has informed campuses that it will be sunsetting the UC Reliance Registry as of June 2024. Given this new 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 will be ending the use of the UC Reliance Registry for new studies on **September 30th, 2023**.

To ensure the least amount of administrative burden possible, starting October 1, 2023 all new reliance requests will be 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!

NEW: Energy Research Symposium Opportunity

Refine your skills and learn best practices in ethical human subject research at DOE/NNSA's inaugural Human Subjects in Energy Technology and Policy Research Symposium. Engage with experts, participate in interactive sessions, and network with fellow professionals to stay updated and inspire new approaches in your field. Register now to secure your spot in this free, virtual opportunity on October 17th and 19th, 2023, to shape the future of responsible research.

To learn more and to register for the event, visit the [Symposium's webpage](#).

Reminder: Stakeholders Needed for OIA SOP Review

OIA is in the process of a wholesale revamp of our SOPs. While many of our SOPs focus on how staff in OIA do their jobs (e.g. review submissions, conduct meetings, determine the level of review, etc.), some of our SOPs instruct investigators and their teams on how to conduct their research (e.g. conduct informed consent, what needs IRB review before being implemented, who can serve as a legally authorized representative, etc.).

In recognition of this, we want to make sure the SOPs we eventually publish are both understandable and reasonable. For that, we need your help. We need folks who do this every day to review our proposed SOPs and meet with us to provide feedback. If you're interested in getting a sneak peek and providing your thoughts on our new SOPs, sign up to be a part of our stakeholder team [here](#) before the end of September to be included.

Whether or not you are able be a part of our stakeholder team, watch out for newsletters in the coming months announcing our SOP changes.

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 and one of our analysts will be happy to assist.

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 will rely on a non-UCSD IRB for review
- 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.

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 te renew access for these individuals throughout the course of the year.

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 with questions or to report errors/issues. For questions about Kuali 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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