UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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NEW: OIA December Office Hours

OIA office hours will be held on December 12, 2024 from 11 am - noon and can be accessed at that time here.

NEW: 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!

NEW: 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!

NEW: IPPS Hosting Training on Gift Cards for Research Participants

One of the easiest ways to provide compensation for those who participate in research studies is through gift cards. They are easy to obtain, easy to use, and can

even be reloaded remotely. There are many different options when it comes to how researchers obtain these gift cards and can vary by study sponsor and personal preference.

UCSD's Integrated Procure-to-Pay Solutions (IPPS) manages one way for researchers at UCSD to provide research participants with gift cards. They even have digital gift cards for when your studies don't involve an on-campus visit. On Wednesday, December 4th IPPS will be hosting a training about their digital gift card program at 11 am. Those interested in attending can register here.

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.

With this in mind, if you have a study which will expire before January 20, 2025, please be sure to submit it 30 days in advance or by December 1, 2024, whichever is sooner. This will allow our office time to review your study to ensure it doesn't expire.

Happy Holidays!

Reminder: Pregnant Partner Consent

During the course of research, particularly research which involves a drug, biologic, or medical device, Sponsors or researchers may wish to follow-up with partners of study participants who become pregnant while their partner is participating in the study. To that end, Sponsors may provide research teams with pregnant partner consent documents to be provided to the IRB for review and approval. How research teams should handle these will depend on whether a UCSD IRB or an External IRB is the IRB overseeing the research

Research Overseen by a UCSD IRB

The UCSD IRBs have long held that pregnant partners do not meet the definition of a "human subject" as provided in either the FDA regulations or the Common Rule. This stems from the fact that pregnant partners do not receive the test article (i.e. drug,

biologic, or device) nor do they serve as controls, thus not meeting the FDA definition. Similarly, a sexual partner of a participant becoming pregnant during the course of a study is generally a rare event. So rare in fact that it is believed that the information to be gained from following a pregnancy, while useful, does not "develop or contribute to generalizable knowledge." Thus, these individuals would also not meet the Common Rule criteria.

As such, if a study team receives a pregnant partner consent from a sponsor, they can provide the information about the UCSD IRBs' position to the sponsor and these documents do not need to be provided to the UCSD IRB in the Kuali submission. Of course, that doesn't mean that's the end of the story. If the research team still needs to follow the pregnancy and report any outcomes data, please talk to the Office of Compliance and Privacy (OCP) about requirements related to protecting HIPAA rights of these individuals. OCP can be contacted at hscomply@health.ucsd.edu.

Research Overseen by an External IRB

While the above is the position of the UCSD IRBs, this is not the position that all IRBs take. As this is a matter of some interpretation of the regulations, reasonable folks can disagree on their application. What is important to remember is that when a research team relies on an External IRB, that External IRB's policies (not those of OIA and the UCSD IRBs) is what must be followed. That means that if the External IRB considers that consent must be obtained for pregnant partners, a consent document must be developed.

In such a case, this document needs to be treated like any other consent form when relying on an external IRB. The document can't contain any HIPAA language about authorizing release of medical records except to say that they will be provided with the separate HIPAA authorization document to read and sign. In addition, all the other information which is applicable to the study from OIA's consent minimums document must be incorporated into the pregnant partner consent form. Need help navigating a reliance on an External IRB? Contact the reliance team at irbrely@ucsd.edu anytime!

Reminder: AI, Machine Learning, and Medical Devices

While decision trees, algorithms, and early forms of AI have been around for decades, the promise of new predictive and generative AI tools built on large language models and deep neural networks has seemingly made its way into every aspect of our lives. AI can order us a soda, write a research paper on plate tectonics, regulate our A/C to be more efficient, and troubleshoot our computer problems faster than ever. The promise of AI is astounding and it's no surprise it's made its way into the world of human subjects research.

Human subjects research studies using AI range from using AI to control ventilators and infusion pumps to understanding if AI translators can bridge language gaps. Still some of the more common research projects using AI in the human subjects research space seek to utilize AI's predictive potential to uncover patterns that us humans can't see for ourselves. Sometimes this is behavioral in nature (which students are likely to drop out after their first semester?) and sometimes this is biomedical in nature (can an AI diagnose a patient's condition faster than a physician?).

Recently, OIA authored an article in our May 2024 newsletter which had a companion piece in the RCI June 2024 newsletter (see page 6). These articles shine a spotlight on how easy it is for AI algorithms in the biomedical space to veer into the realm of FDA regulation as a medical device. However, while this means OIA and the UCSD IRBs have a few more things to consider when this happens, it generally involves no additional burden or regulatory submissions for investigators. Rest assured, while it may be jarring to suddenly be told a study involves a medical device, OIA is here to help our research navigate what this means and make sure that all human subjects research is safeguarded from regulatory pitfalls.

Have questions about when AI is a medical device? Have general human subjects questions? Right to 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.
