UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

August 28, 2024

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NEW: OIA September Office Hours

OIA office hours will be held on September 11, 2024 from 9:30-10:30 am and can be accessed at that time here.

NEW: UCSD Part 11 Compliant eSignature Option

With the increasing rise of electronic technologies being employed in research settings, sponsors and researchers continue to look for new ways to reduce the use of paper when conducting studies. One barrier to consenting participants electronically for clinical research regulated by the Food and Drug Administration (FDA) has been the need to comply with the FDA's requirements at 21 CFR 11 (Part 11) for electronic signatures.

For the past couple of years, the ACTRI has been piloting a program through DocuSign to understand if this would be a viable option for UCSD clinical researchers. After a successful pilot, the ACTRI is opening the program to UCSD researchers across the campus who wish to be able to have participants sign consent documents for FDA regulated studies electronically.

While more information is available on the Biomedical Informatics (BMI) webpage, including how to request this service, an important note is that the cost is $7 per "envelope." For those not familiar with DocuSign's terminology, an "envelope" consists of the document(s) to be signed between two (or more) parties. As such, each participant will require their own "envelope."

For questions about this service, please contact the BMI team directly at ctri-support@ucsd.edu.

For IRB questions, including whether your study is approved for eSignatures and whether your study is FDA regulated, contact OIA at irb@ucsd.edu.

NEW: Need to Submit an Amendment and Continuing Review? Here's What to Do

We've all been in this situation. You've submitted an Amendment to change some aspect of the protocol. While waiting for it to be approved, you get the notice your Continuing Review is due. You don't want to be late on the Continuing Review, but you don't want to throw off the approval of your Amendment either.

Or maybe it happens the other way. You've submitted your Continuing Review at least 30 days in advance, but now you have an Amendment that needs to be submitted. You really don't want to throw off the review of your Continuing Review. What to do?

Fortunately, with the implementation of the Kuali IRB system submitting these two separate types of submissions at the same time is not a problem. Have an Amendment already going through the review process? Go ahead and start and submit that Continuing Review! Already have a Continuing Review going to the IRB? Go ahead and submit an Amendment!

The Kuali IRB system logs each submission type separately in the system so there is no concern about messing up one submission type by submitting a different submission type. It also doesn't matter what order they're submitted in. Even if an Amendment is submitted first and the Continuing Review is submitted second, the IRB can review and approve the Continuing Review in the system before the Amendment is approved without causing an issue. Once both are finally approved, the Kuali IRB system will merge the applications so that the final approved version incorporates the renewal from the Continuing Review and the changes from the Amendment.

Need help with the Kuali IRB system? Write to OIA anytime at IRB@ucsd.edu.

NEW: Recruitment Prior to Reliance Acceptance

Recently, OIA has received a significant uptick in questions from investigators and research teams regarding starting to recruit participants to studies prior to the reliance being accepted by OIA. To put it simply, this is not allowed.

While OIA acceptance of a reliance is not an "IRB approval" in the sense of the meaning in the regulations, it is also not superfluous. While OIA, when ceding to another IRB, does not perform the typical IRB review as dictated by the regulations, OIA is still required by the regulations, the terms of our reliance agreement, and institutional policy to ensure that the study meets all the local context requirements within OIA's purview. This includes ensuring that required consent information is present, local laws and regulations are adhered to, ensuring investigators have completed their required training, etc.

While reliance acceptance is usually an easy and straightforward process when we've all done everything according to plan, OIA consistently sees studies submitted for reliance acceptance which do not meet the local context requirements and (in some instances) need significant revision before they can be accepted. For these reasons, research teams must wait until OIA reliance acceptance is received to begin recruiting for studies.

Questions on recruiting in a study relying on another IRB? Have general questions about studies under a reliance? Email the reliance team anytime at IRBRely@ucsd.edu.

Reminder: Kuali IRB Application Updates

Recently OIA has made some changes to the Kuali IRB application for new studies that we want to make you aware of:

HIPAA Section Changes

This section of the application lets researchers who will use or access PHI as a part of their research tell OIA how they will comply with HIPAA regulations that protect patient privacy. Commonly, this is the section where researchers may ask for a full waiver (e.g. for a chart review study) or partial waiver (e.g. to recruit for a study) and indicate whether they will have subjects sign a HIPAA authorization document.

We have made two changes to this section:

1. This section now appears when requesting that the UCSD IRB rely on an external IRB. This is necessary because sometimes external IRBs still want OIA to issue a HIPAA waiver and so we need to collect the required information to be able to do that. There are new lead in questions when this is the case so researchers don't have to answer any unecessary questions.
2. We have added an additional question for anyone requesting a HIPAA waiver from OIA about when identifiers collected under the HIPAA waiver will be destroyed. Previously this was something OIA analysts had to inquire about separately and so we've added it to the application to streamline the review process and minimize the number of follow-up questions we need to ask.

New Amendment Questions for Multi-Site Research

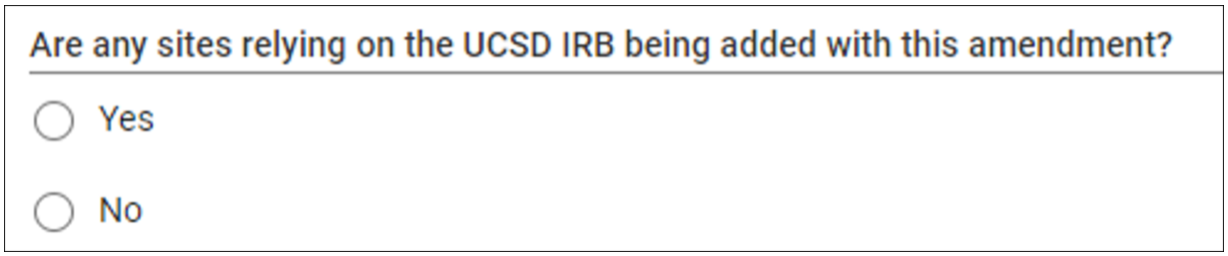
Section B of the amendment application currently asks whether the research is multi-site and, if so, whether there are any sites relying on the UCSD IRB for review of the research. These existing questions allow us to take into account any local context that may be necessary when reviewing the amendment.

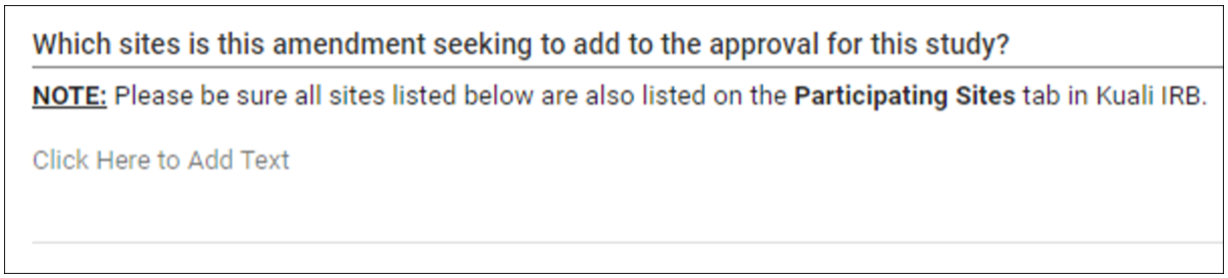
The two new questions only appear when the research is multi-site and there are sites relying on the UCSD IRB for review. In this case, the first new question (shown below) asks "Are any sites relying on the UCSD IRB being added with this amendment?" While this information may be included in other sections of the amendment, it is not explicitly asked anywhere and so a question was needed to help streamline the review process.

This question should be answered "yes" when, as a part of the submitted amendment, the research team is asking the UCSD IRB to approve one or more additional external sites (i.e. not UCSD or RCHSD) to conduct the research. Because OIA's process is to first approve the study and just UCSD/RCHSD as study sites, any multi-site research needs to submit an amendment to add any other external sites after initial approval. For more information on this process, see our sIRB page.

If the question is answered "yes," the second new question (shown below) will appear asking which site(s) are being added. This is a free text field so researchers

can add as many sites as are needed. Researchers should also make sure that all required information has been added on the Participating Sites tab in Kuali.





Questions? Email our general inbox at irb@ucsd.edu. Questions for our reliance team? Email them directly at irbrely@ucsd.edu.

Reminder: Starting an Amendment in Kuali IRB - That First Question is a Doozy

Starting an amendment in the Kuali IRB system involves first getting into the study, clicking the "Amend" button on the right-hand side of the screen, and then selecting what parts of the application need to be changed. These steps, outlined in our step-by-step guide, help the Kuali IRB system understand how to initally generate the amendment application.

Following this process, the amendment application always starts with a singular question shown below which asks "Is this an amendment where review of the study is conducted by an external IRB and the changes do not meet the criteria for OIA submission and are being submitted only to trigger OCAA review?"

This question should only be answered as "yes" when all of the following are true:

- The study is ceded to an external IRB like WCG, Advarra, another academic IRB, etc.
- There are changes being made to the study which require OCAA review or re-review to ensure the coverage analysis document remains correct.
- The changes being made don't require OIA review.

If all of the above are true, then "yes" is the appropriate answer. This is most likely the case when the changes are limited to a new Investigator's Brochure (IB), a new protocol, or a new consent form that doesn't change any of the language shown on OIA's consent minimums document. This allows researchers to save on the burden of completing a whole amendment application when they don't need to and ensures their study isn't waiting on an OIA review that isn't needed.

Times when a "no" answer is correct include when a UCSD IRB has reviewed and approved the study, when study personnel are changing, when there is new or changed funding, when there are wholly new consent documents, and/or when there are changes to a consent form which alter any of the language shown on OIA's consent minimums document.

Still not sure how to answer this question? Contact us at irb@ucsd.edu!

Reminder: Updated Short Forms and Bill of Rights Documents

With the changes in the IRBs' administrative office name from HRPP to OIA, changes in the Common Rule, and the increasing diversity of our research participant population here at UCSD and RCHSD, it was time for a much needed update to our short form documents and bill of rights documents available to researchers on our current forms page.

The changes to the stand alone bill of rights document are fairly minor, just updating our office name and adding our email address. The short forms received more extensive updates like having spaces to insert more study information (e.g. title, study number, sponsor, 24-hour number, etc.), including more elements of consent, and including a place to print the name of both the participant and the witness. All of this has been done to ensure subjects/LARs are provided as much information as possible in the language they are most comfortable with so that they can be fully informed before participating in research. It also ensures that researchers fully comply with the regulatory requirements for consent.

Additionally, through an amazing collaboration with the Moores Cancer Center Clinical Trials Office we are pleased to be offering both the short form and bill of

rights in 22 languages! All of the previous languages are present along with several new ones like French, Japanese, Tagalog, Ukranian, Vietnamese, and more.

The process for using these documents and the required approvals has not changed.

Questions about conducting informed consent using a short form? Don't know if your study qualifies? Email us at irb@ucsd.edu and one of our analysts will 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.

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