UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

July 29, 2024

In This Issue

NEW: OIA August Office Hours

The next OIA office hours will be held on August 29, 2024 from 9-10 am and can be accessed at that time here.

NEW: 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

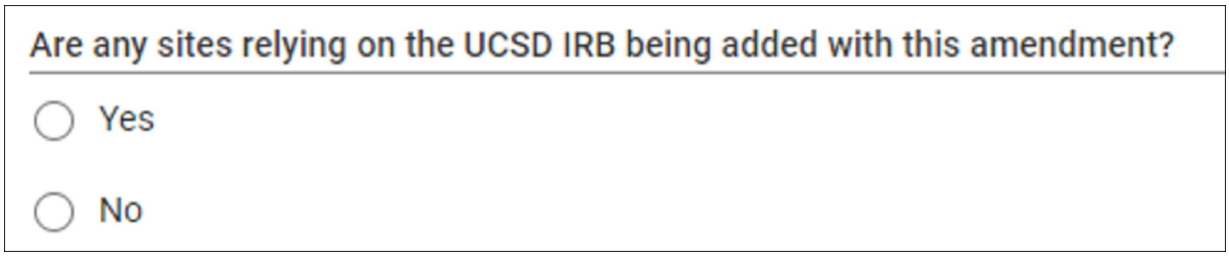
Section B of the amendment application currently asks whether the research is multi-site and, if so, whether there are any sites relying on the UCSD IRB for review of the research. These existing questions allow us to take into account any local context that may be necessary when reviewing the amendment.

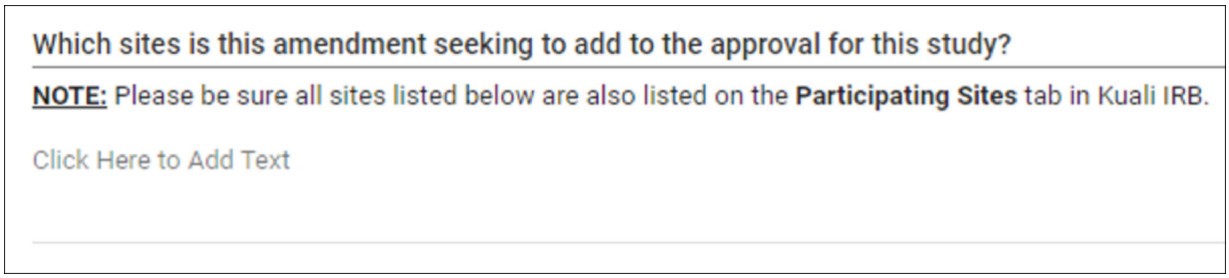
The two new questions only appear when the research is multi-site and there are sites relying on the UCSD IRB for review. In this case, the first new question (shown below) asks "Are any sites relying on the UCSD IRB being added with this amendment?" While this information may be included in other sections 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.

NEW: 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!

NEW: 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!

Reminder: sIRB Attestation Process

If you've ever submitted a study to a commercial IRB (WCG or Advarra), you're likely already familiar with our attestation process that reminds PIs of their responsibilities when another IRB assumes oversight of a study conducted at UCSD/RCHSD. With OIA seeing more and more requests for the UCSD IRB to serve as the sIRB for multiple non-UCSD/RCHSD sites, we've decided to implement a similar attestation process for these studies as well.

Like the current attestation process, the new attestation process will be initiated by our reliance team. The PI will receive an email in their inbox with a link to a powerform in DocuSign and some reference material to review. The PI will need to review the materials and the document. They will then sign the attestation acknowledging their responsibilities when serving as the lead PI. That's all there is to it!

The new process launches July 1st!

What are the responsibilities of individuals serving as the lead PI?

These responsibilities include all the normal PI responsibilities (e.g. adhering to the protocol, seeking IRB approval for any changes, ensuring staff are appropriately trained, promptly reporting certain information, etc.) along with some additional responsibilities like notifying the relying sites of IRB determinations, providing access to study records to the relying institution for audit, submitting one continuing review for the whole study that includes information for all sites, ensuring prompt reporting to the UCSD IRB of reportable events, etc. A full listing of additional responsibilities can be found on our reliance page in the section "Post-Approval/Acceptance Responsibilities."

Have questions about the attestation or just questions about reliances generally? Email us at irbrely@ucsd.edu!

Reminder: Updated Consent Minimums

The UCSD Reliance Consent Minimums document specifies all the required language that needs to be included in the informed consent documents of studies when the UCSD IRB cedes its review to an External IRB. Recently, this document was updated to reflect some common requests we'd seen from Sponsors and provide more context around certain requirements.

This new document has been reviewed and accepted by WCG and Advarra and so they should be incorporating this language into consent documents for study teams. That being said, it's always good for the study teams to double check that the language used is correct.

This new document can be found any time by going to our reliance page and going to the bottom of the "Local Context Requirements" section.

Have questions about consent minimums or just questions about reliances generally? Email us at irbrely@ucsd.edu!

Reminder: Remember to Submit to Ancillary Review Committees

The Kuali IRB system has brought with it a suite of integrations and connectedness that have on the whole improved the administration of human subjects research here at UCSD. One of the nice functionalities of Kuali IRB is that based on researcher responses to various questions, the system can automatically notify ancillary review bodies whether their review is needed or not and they can record their determinations within a "behind the scenes" part of the Kuali IRB system.

Nevertheless, this doesn't necessarily let the researcher off the hook for making submissions to these ancillary review bodies when required. In some cases (i.e. the Stem Cell Research Oversight (SCRO) Committee and OCAA), these ancillary review bodies do not require a separate submission because they use the information in Kuali IRB to make their determinations. In other cases (e.g. COI, HERC, IBC, IACUC, OCTA, OCGA, etc.), a formal submission in their submission portal is required.

Researchers should check with any applicable ancillary review bodies as to what they require to make sure they keep their studies moving along. Additionally, ancillary review bodies may reach out directly if notified through Kuali IRB that a review is necessary.

Not sure what ancillary reviews are required? The IRB Handbook (pages 22-24) contains a listing of some of the most common required ancillary reviews. That being

said, it is by no means an exhaustive list.

Have questions about IRB or SCRO reviews? Contact the Office of IRB Administration anytime at irb@ucsd.edu!

Reminder: Are You Speaking My Language? IRB Requirements for Enrolling non-English Speakers

Ensuring your research is available to as many people as possible is good science and good ethics. A diversity of representation in research studies ensures that we all benefit from the discoveries made. However, sometimes we don't all speak the same language and that can make things complicated.

To help, we wanted to point out a few things about opening studies up to people who speak a language other than English:

1. It is the IRB's expectation that unless there is scientific basis for excluding non-English speakers or it's a small/pilot study, that all studies will be open to non-English speaking individuals who otherwise qualify for enrollment.

2. The IRB has approved and published the Bill of Rights and Short Form consent form in several languages on our Forms & Instructions page. Studies which have been approved to enroll non-English speakers but don't have a translated consent document may use these to enroll subjects who can't read or communicate in English.

3. Sometimes finding an interpreter to facilitate the conversation and assessments can be hard. OIA's current SOP on conducting the informed consent process allows the interpreter to be a professional interpreter, a family member, or a friend of the person consenting to ease the potential burden.

4. For studies where planned enrollment of a non-English speaking population exists, it's important to have all documents for the participants translated into their preferred language. In order to approve the translated versions, the IRB will need to see the translated document. Clinical trials will need to provide a certificate of translation from a professional translator or service for each document. All other studies may provide a certificate of translation or letter of attestation signed by the translator describing their qualifications. When using the letter of attestation method, the PI may determine who is a qualified translator.

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.
