UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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NEW: OIA July Office Hours

The next OIA office hours will be held on July 12, 2024 from 9-10 am and can be accessed at that time here.

NEW: 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!

NEW: 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!

NEW: 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!

NEW: 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.

Reminder: My Study Uses a Medical Device - Now What?

This article is a companion piece to the article "Unexpected Medical Devices in Human Subjects Research" published in RCI's June 2024 newsletter.

It can be a jarring experience. You've been patiently awaiting IRB review of your recent study and you finally get that Kuali IRB notification that there are revisions needed. You open up the study in Kuali IRB and see that OIA has determined your study involves a medical device. Your mind suddenly flashes with images of huge binders, stacks of paper, and endless hours of reading through documents to compile an IDE application. You might even think to yourself, "It's just an AI! How could that possibly be a medical device?" Fear not, for not all medical devices are created

equal or require an IDE submission to the FDA.

Some medical devices can be determined to be "IDE exempt." This means that while they are indeed medical devices, an IDE submission isn't necessary. The most common of these exemptions come in two forms:

1. Currently approved or cleared medical devices being used in accordance with their FDA approved or cleared labelling. **NOTE:** Unlike drugs, many devices used "off label" will not be IDE exempt unless they meet #2 below.
2. Diagnostic devices which are unapproved or used for an unapproved indication when:

1. The testing is noninvasive; and
2. The testing doesn't use an invasive sampling procedure that presents significant risk; and
3. The testing does not introduce energy into a subject by design or intention; and
4. The testing will not be used without confirmation by another medically established product or procedure; and
5. The sponsor will comply with the requirements for labelling at 21 CFR 809.10(c)

In practice, this means that a fair number of the studies using medical devices that get submitted to OIA can be determined to be IDE exempt. However, as a research institution that is consistently coming up with new devices and new ways to use existing devices we also see plenty of studies that use medical devices which **are not** IDE exempt. So do all of these studies need to submit to the FDA for an IDE?

Not necessarily, just because a medical device isn't IDE exempt doesn't mean an FDA submission is required. IRBs are empowered to issue what are called "abbreviated IDEs" for studies which use medical devices which are determined to be a "non-significant risk." Unfortunately, the FDA doesn't define what makes a medical device non-significant risk, so IRBs have to instead look at the definition of a "significant risk device" and determine that these criteria **are not** met.

A significant risk device is any device that presents a potential for serious risk to the health, safety, or welfare of subject. In addition, that device may be:

- Intended as an implant (e.g. a pacemaker)
- Purported or represented to be for a use in sustaining human life (e.g. a ventilator)
- For a use of substantial importance in diagnosing, curing, mitigating, or treating disease or otherwise preventing impairment of human health (e.g. intracranial

pressure monitor)

If the IRB determines that the medical device is a non-significant risk device (or “NSR device”) no submission to FDA is necessary. On the other hand, if the medical device is determined to be a significant risk device (or “SR device”) an IDE application will need to be filed with the FDA.

Have an SR device and don’t know what to do next? The ACTRI’s Clinical Trial Support Services (CTSS) group is available to help with your IDE submission. A request for services can be submitted here.

Not sure why something was determined to be a medical device in the first place? Read our companion piece in RCI’s June 2024 newsletter.

Have questions and want to talk to someone at OIA? Email us 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.