UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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In This Issue

NEW: OIA July Office Hours

OIA held its first office hours in quite a while on June 22, 2023 and it was a great success. Thank you to all of those who came, asked questions, and participated!

Given the positive response, OIA will be continuing to offer office hours in July. July office hours will be held on July 19, 2023 from 9-10 am and can be accessed at the time here.

NEW: Using the Replace Feature in Kuali IRB

Throughout the life of a study, there are times when changes need to be made. Sometimes these changes involve wholly new documents, but more often changes involve updating currently approved documents. For some studies, there may be 10 or more iterations of a protocol, consent, or other documents by the time the study closes.

To help keep the "Supporting Information" section of Kuali IRB submissions from becoming unwieldy, Kuali has a "Replace" feature for researchers with delegation in an amendment. Detailed instructions for how to use this feature of Kuali IRB can be found in Step 8 of our KBA on Submitting Amendments.

Please remember to use this important feature of Kuali IRB when submitting amendments and revisions. IRB will needs both a clean and tracked changes version of any documents that are being revised.

Need help? Please send us an email at irb@ucsd.edu. Please include as much detail as possible about the issue being experienced so we can provide the best advice and assistance. Including screenshots is also a good idea.

NEW: Using OIA's Protocol Templates

The protocol is a key document in any research study. It tells the study team exactly how the study will be conducted and allows the IRB to understand the nitty gritty details. When a study is sponsored by an industry partner, a cooperative group, or has an IND or IDE from the FDA, there may already be a master protocol available for submission to OIA. We in OIA not only welcome these master protocols, we prefer them.

But what if there isn't a master protocol? OIA currently offers three protocol templates on our Forms and Instructions page which researchers should use when there isn't a master protocol. Each section of these templates describes exactly what OIA is looking for in that section. While we in OIA understand it can be tempting to copy/paste information from other sources (e.g. grant proposals, investigator brochures, device instructions, consent documents, etc.), these documents rarely provide the level of detail needed for OIA reviewers to assess the approvability of a study. As such, please carefully review the instructions for each section of the template and ensure that the information provided addresses all the areas of information for each section.

Not sure what information OIA is asking for in a particular section or sections? Write to us at irb@ucsd.edu.

NEW: UCSD/RCHSD Exempt Information Sheet Now Available

You spoke and we listened. Several of the researchers who work with pediatric subjects noted a need for an Exempt Information Sheet for studies jointly carried out at UCSD and RCHSD. We're happy to announce that after review by RCHSD, the new information sheet is now available. The information sheet is posted on our Forms and Instructions page.

The new information sheet can be used for studies which meet Exempt determination criteria and are carried out jointly by UCSD and RCHSD.

Have an Exempt study that is being carried out by UCSD? We also have an information sheet for UCSD-only studies available on our Forms and Instructions page.

NEW: Submitting for Reliance Acceptance KBA

The process for OIA to accept a reliance on an external IRB involves two steps: clearance and acceptance. For a detailed visualization of this process, please view our flowchart. Submitting for the first step (clearance) in Kuali IRB is currently covered in our Administrative Determinations Submission KBA.

Following clearance, researchers can submit to the external IRB for approval of UCSD's involvement in the human subjects research. After the external IRB grants approval for UCSD, researchers need to complete the second step (acceptance) by submitting approval documentation in Kuali IRB. Our new Submitting for Reliance Acceptance KBA walks researchers through this process step-by-step.

Running into issues with relying on an external IRB? Email us at rbrely@ucsd.edu.

Reminder: Max File Size for Kuali IRB

Many researchers have noticed that sometimes documents that get stamped in Kuali IRB (i.e. consent forms, assent forms, and recruitment materials) won't load properly after the IRB has approved them. Clearly a more recent reason for this happening has been that files have been too large. When a file is too big and Kuali tries to apply the approval stamp, Kuali can't load the final document. To avoid this happening, please keep all file sizes for documents to be stamped less than **4.8 MB**.

As always, please remember that documents that get stamped should be provided in PDF format, completely "clean" of any track changes or comments, and should be "unlocked" for editing.

Reminder: Updated IRB Fees for UCSD Investigators

OIA currently charges three fees to UCSD investigators as described on our IRB Review Fees page. In light of the fact that these fees have not been evaluated in over three years and the significant changes that have occured in OIA during that time period, OIA was asked to re-evaluate the fee charges.

As a result of that re-evaluation, the following fee changes will apply to submissions made starting July 1, 2023:

- The fee for initial review of industry funded studies **will not** increase and will remain at $2700 + 30% FAA for a total of $3510
- The fee for annual/continuing review of industry funded studies **will** increase by $1200 to $1200 + 30% FAA for a total of $1560
- The one-time fee for using a commercial external IRB (e.g. WCG/WIRB and Advarra) has been clarified to only pertain to studies which are funded in part or in whole by industry sponsors and **will** increase by $200 to $1200 + 30% FAA for a total of $1560

What if my study is unfunded?

Unfunded studies of UCSD investigators will continue to be reviewed by the UCSD IRB without charge. None of the above fees apply to unfunded studies.

What if my study only has federal/non-industry funding?

Studies with only federal and/or non-industry funding will remain exempt from the IRB fees listed above.

Will already approved industry-funded studies be grandfathered in to the old fee schedule?

No, previously approved studies will not be grandfathered in to the old fee schedule. All submissions eligible for billing submitted to OIA on or after July 1, 2023 will be billed at the new rate.

Why are the fees increasing?

There are a variety of reasons for the two fee increases above. First, due to inflation, periodic mandatory salary and benefits increases, and necessary increases in OIA staffing, the cost of performing these reviews has increased. Second, as pointed out on the OCGA website, UC policy requires that industry sponsors must cover the costs of the project. As the stewards of the taxpayer money that is used to fund our institution, we cannot subsidize research for industry sponsors and so the rates have to periodically increase.

Reminder: New IRB Fee for UCSD Investigators

Starting July 1, 2023 a **new** one-time fee will be implemented for funded studies **regardless of funding source** where the UCSD IRB serves as the IRB of Record for external sites. This fee will cover UCSD IRB's review of the outside investigator at the external site and the local context information (e.g. site specific policies, regulations, laws, etc.) as well as any local documents. The new fee will be $615 + 30% FAA for a total of $800 **per site** for which the UCSD IRB will provide review.

What if my study is unfunded?

Unfunded studies of UCSD investigators will continue to be reviewed by the UCSD IRB without charge. The new fee will not apply to unfunded studies.

What if my study is funded by someone other than an industry sponsor?

For studies with any kind of funding **"including federal funding"** where the UCSD IRB will be the IRB of Record for external sites, these studies will be subject to the new one-time fee of $800 per site. This fee should be incorporated into the budgets for studies with a proposal due on or after July 1, 2023. For studies where a proposal is not required, new awards or contracts executed on or after July 1, 2023 should have this fee included in their budgets.

What counts as an external site?

RCHSD and SIO do not count as external sites for the purposes of the new one-time fee being implemented. Any other site/institution would be considered an external site. This includes community clinics, other academic institutions, and other organizations for which the UCSD IRB is asked to provide IRB review and oversight.

Why is this new fee being created?

In the wake of the NIH's single IRB mandate and the Revised Common Rule's single IRB requirement, the work associated with multi-center studies for OIA has increased. When the UCSD IRB/es serve as the single IRB for multi-center studies, OIA staff have to negotiate and execute reliance agreements, review and interpret local laws and policies at the external sites, and evaluate investigators we aren't familiar with. All of this comes at an additional cost which is not otherwise covered by OIA's current funding streams.

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 to 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 rbrely@ucsd.edu.

Please be sure to include the protocol number, if available. This will help the OIA team triage and troubleshoot.