UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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NEW: OIA August Office Hours

The next OIA office hours will be held on August 9, 2023 from 9-10 am and can be accessed at that time here.

NEW: Updated Consent Minimums for External Reliances

When relying on an External IRB for oversight of a study, the role of the UCSD IRB is limited to ensuring that local context information is adequately reflected in the work that the External IRB does on behalf of UCSD/RCHSD. This includes making sure State laws, institutional policies, and required consent language are all taken into account. The UCSD IRB reviews for local context during both the clearance and acceptance process.

While both Advarra and WCG IRB have our local context on file and will automatically incorporate consent language, such an arrangement doesn't exist with other IRBs. To help the clearance process go faster when using an External IRB that isn't Advarra or WCG IRB, we ask that researchers incorporate the consent minimums language during the consent negotiation with the sponsor before submitting for clearance.

We've recently updated our consent minimums document which can be found on our reliance webpage. For those who use Advarra or WCG IRB, the updated document has already been communicated to those IRBs. As always, if there are any questions about the reliance process, please feel free to email us at irbrely@ucsd.edu.

NEW: IRB Review of Medical Devices

At UCSD we are fortunate to have many faculty and students interested in developing new biomedical devices as a part of our amazing campus. These interests, ties to local and national device manufacturers, as well as UCSD's own "home-grown" devices have brought about many new indispensible tools which have no doubt improved the lives of many. The IRB wants to help researchers on their journey to test these new commercial and "home-grown" devices and demonstrate their safety and efficacy. To that end, we wanted to provide some tips and tricks for a smooth IRB review:

- Unless a device is exempt from the requirement for an IDE, it will need review by the Full Board. Please plan submissions accordingly to allow for enough time.
- A device that has already received FDA approval/clearance is only exempt from the IDE requirements if it is being used in accordance with its approved/cleared indication or otherwise meets the criteria for an IDE exemption. "Off-label" uses of devices will generally still need an IDE.
- Even though a device may not be exempt from needing an IDE, that doesn't mean an FDA submission will always be necessary. If the device is not a significant risk (SR) device, the IRB can issue an abbreviated IDE to the investigator. If you believe your device is a non-significant risk (NSR), please

be sure to provide appropriate justification in your Kuali application and/or protocol.

- If available, a master protocol provided by the device manufacturer must be submitted in the Supporting Information section in Kuali IRB. Assuming that studies of "home-grown" devices won't have a master protocol, please be sure to use the IRB's interventional protocol template.
- When filling out the Research Characterics section of Kuali IRB for studies of medical devices, please be sure to check the box for "Investigational Use of a Medical Device" to populate the relevant sections in Kuali IRB.

NEW: When to Close a Study with the IRB

A perennial question researchers face is when to close out a study. There are many stages to the overall research lifecycle and the IRB is only involved in oversight of the stages that involve human subjects research. In much the same way that writing a protocol and a grant proposal don't require IRB review, there are stages at the end of the lifecycle of a research project where IRB oversight is no longer necessary.

The best general advice is to close the study with the IRB when there is no longer a need to access identifiable private information. This could be for the purposes of follow-up, data analysis, or even writing a paper. For multi-site sponsored studies, this is usually easy as the sponsor will tell you when to close the study with the IRB. For an Investigator Initiated Trial or even a simple chart review, this can be more complex. The best rule of thumb is to wait until the paper on the study has been published as editors and reviewers may require additional information an analyses requiring access to identifiable information. Of course, if it is known that further access to private identifiable information will be needed, the study should remain open.

Please note that when determining when to close a study with the IRB, an investigator needn't take into account possible audits from regulatory agencies.

NEW: Incomplete Submissions

OIA reguarly receives incomplete submissions from investigators hoping to get IRB review and approval for submission to funding agencies. While OIA can issue an Indefinite Plans/Delayed Onset determination in accordance with Section 118 of the

Common Rule (formerly Approval in Principle), such letters are often unacceptable to Program Officers.

As such, OIA asks that all necessary documents be included in the initial submission so that we can perform our reviews as quickly as possible. The Supporting Information section in Kuali will describe the documents that should be submitted. Generally this will include:

- A protocol (unless the study is limited to a secondary analysis of existing data)
- An informed consent document or information sheet (unless requesting a waiver of consent)
- Any surveys, questionnaires, focus group/interview questions
- Any recruitment materials (e.g. flyers, email scripts, cold call phone scripts, etc.)
- Anything meant to be seen or heard by subjects (e.g. educational materials being investigated, videos to be watched by subjects, etc.)

Reminder: 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 when submitting 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 remember OIA still 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.

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 our fees.

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% F&A for a total of $3510
- The fee for annual/continuing review of industry funded studies **will** increase by $200 to $1200 + 30% F&A 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% F&A 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 instituion, 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% F&A 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 requirment, the work associated with multi-center studies for OIA has increased. When the UCSD IRBs 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 te 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 irbrely@ucsd.edu.

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