UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

April 26, 2023

## In This Issue



## NEW: Come Visit OIA at SURF

The Office of Research Compliance and Integrity (RCI) is hosting it's second Symposium for University Research Fundamentals (SURF) on Wednesday May 24, 2023 at the Price Center from 8:30 am to 3 pm. Representatives from OIA will be in attendance providing a booth where you can talk to OIA staff and giving fundamental and intermediate level presentations.

For more information about RCI's SURF and to register, visit the SURF page.

## NEW: 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 their study. 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 **4.6 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.

## NEW: Tips to Submit for NHSR and Exempt Determinations

The two most common administrative determinations that OIA makes are that a study is Not Human Subjects Research (NHSR) or that a study is Exempt human subjects research. These terms (NHSR and Exempt) are often used interchangably when speaking colloquially but they have some important distinctions:

**NHSR**

A determination that a project is NHSR means that it either 1) doesn't qualify as "research" according to the Federal definitions in the Common Rule or FDA regulations or 2) doesn't involve "human subjects" according to the Federal definitions in the Common Rule or FDA regulations. Projects that are NHSR are not required to be reviewed by the IRB before beginning and researchers can use OIA's self-determination tool in Kuali to better assess whether their project is human subjects research or NHSR. If needed, these projects can be submitted to OIA for formal determination. In addition, clinical projects which are NHSR can receive such determination from ACQUIRE (Pulse link) at UCSD Health or E-QUAL at RCHSD.

**Exempt**

Unlike an NHSR determination, a study which is determined to be Exempt is human subjects research. The determination of Exempt means that the study activities all fall into one or more of the categories of exempt research found in the Common Rule at 45 CFR 46.104. While Exempt research doesn't have to comply with all the provisions of the Common Rule (hence the term "Exempt"), Exempt research is still required to be reviewed by the IRB at UCSD per policy 100-5.

**Tips**

When submitting studies for these determinations, there are some common tips that are useful for researchers to remember:

- Exempt studies still require an informed consent process if there is an opportunity to obtain subjects. The consent process for Exempt studies is very abbreviated and we supply a special Exempt Information Sheet template on our forms page for use with these studies.
- If a project is NHSR and an official determination is needed, please submit to our office for determination before the project is begun. Please be sure to check with any funders, publishers, etc. to see if formal IRB determination is required.
- When submitting for these determinations to our office, please be sure to follow the instructions in the KBA on Administrative Determinations to be sure the application is completed correctly. This will save the study team and OIA significant time in creating and reviewing these submissions.

## UPDATE: 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 recent 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 fee schedule.

***NEW!** 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 have increased. Second, as pointed out on the QCOA 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% 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 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, 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 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: Standardized Institutional Forms Need not be Submitted

Historically, the OIA accepted and reviewed many standardized institutional documents including audio/video recording consents and HIPAA authorization documents. As a part of our switch to Kuali and new office vision, OIA is no longer reviewing these standardized institutional documents. The reason that OIA and the UCSD IRB will not review these documents is because either they are used for non-research purposes (and thus fall out of our purview) or they are locked by the institution/legal and thus cannot be altered. This means that HIPAA authorizations, audio/video consents for non-research purposes, surgical consents, etc. do not need to be submitted for review in Kuali.

*My study involves audio/video recording, what should I do?*

If the audio/video recording will be used for research purposes, information about the recording, how it will be used, and how privacy and confidentiality will be maintained should be included in the study's consent form. If the audio/video recording will be used for non-research purposes (e.g. recruitment, training, etc.), contact the institution's PR department to obtain the standardized form for use in non-research settings.

For UCSD Campus, if the request for such recordings is not incorporated into the research informed consent as described above, there is a Model Release Form available on the University Communications Blink page.

For UCSD Health, UCSDHP 340.2 (Pulse page) requires consent be obtained for recordings. If the request for such recordings is not incorporated into the research informed consent as described above, either form D798 (English Pulse page) or form D798S (Spanish Pulse page) is to be used.

For RCHSD, if the request for such recordings is not incorporated into the research informed consent as described above, the RCHSD Authorization for Use, Disclosure or Publication of Photographs form should be used. Please note the above link will only work on the RCHSD network.

## 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 renewal application.

**Closures**

The KBA on this topic walks users through the process of submitting a renewal 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, please 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 the 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 sbirb@ucsd.edu.

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