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NEW: Amendments for Exempt Studies

Exempt studies can be an immense source of confusion for many researchers. Does it need IRB review? Do I have to close it? Do I have to get IRB approval for changes? The answers to these questions are: yes, no, and sometimes (respectively).

Unlike traditional Expedited and Full Board studies where the only changes that can be made without IRB approval are those to eliminate an apparent immediate hazard to a subject (which still have to be reported to the IRB within 5 business days), Exempt studies only need to have changes submitted to the IRB for approval if they would change the exempt determination.

Since a lot goes into making an exempt determination from the procedures, privacy/confidentiality provisions, and subject population, to the nuances and rules of the federal regulations, OIA has developed a [guide](#) with several changes that can be implemented without IRB review.

Don't see your change on the list but think it should be? Email us at irb@ucsd.edu and we can see.

NEW: Action Item Functionality

One of the features of Kualii IRB is the ability for OIA staff to place Action Items in the submission and for researchers to be able to directly reply to each Action Item in Kualii IRB without the need for a point-by-point response letter. For more information about replying to Action Items, see our [KBA on this topic](#).

While this feature is very helpful in allowing OIA analysts to be very specific about the changes that are required and where they should be made, it is important to remember that this is not a real-time chat feature. Entering a reply to an Action Item does not alert the analyst that there may be a question or response and the analyst will only be alerted to re-review the submission once it has been resubmitted.

If you want to discuss an Action Item with the analyst before resubmitting, please contact our general inbox at irb@ucsd.edu or, if you know the analyst you're working with, [contact them directly](#).

NEW: Kualii IRB Application Updates

From time to time OIA makes updates to the Kualii IRB application to add, remove, or improve questions. Here are three recent changes we've made that you might notice on your next submission:

Main Application (Non-English Speaking Individuals Section)

As a part of our commitment to diversity, equity, and inclusion in research, an additional question has been added to this section of the Kualii IRB application. When a study will have direct contact with subjects and has not indicated that it will specifically recruit non-English speaking subjects, the Kualii IRB application will ask "While not targeted for enrollment, will this study include non-English speaking individuals who otherwise qualify for the study?"

Answering this question as "No" (meaning that non-English speakers would be excluded as subjects) opens another question asking for a rationale as to why non-English speakers will be excluded with a few pre-developed reasons as well as an "Other" option.

Answering this question as "Yes" (meaning that non-English speakers would be offered participation in the study) opens the usual questions about how the consent process will be conducted with these individuals.

Main Application (Study Personnel Section)

Studies that indicate they will be performed at RCHSD but not at UCSD will encounter an additional question in the study personnel section asking if there are any study personnel who have joint appointments at both RCHSD and UCSD. Answering this question will not trigger any additional questions in the application and is being asked solely to help us correctly bill RCHSD-only studies. Please help us with the efficiency of our billing process by answering this question accurately.

Renewal Application

Studies completing a renewal application for review by the UCSD IRB will now have an additional Section (Section E) that appears. This section is about funding and starts with the question "Is this study funded in part or in whole by an industry sponsor and administered through a UCSD Sponsored Projects Office (e.g. OCTA, OCGA, etc.)?"

If the answer is "Yes," the user will be prompted to enter three pieces of the study's chart string from Oracle (the project code, task code, and source code) in the renewal application to facilitate accurate and timely billing of IRB fees for industry funded studies. We anticipate that study teams will need to work with their department financial contacts to get this information so we encourage research teams to begin the renewal process when the first renewal reminder is sent from the Kualii IRB system.

NEW: Keep an Eye Out for Expiration Notices

Speaking of renewal applications, OIA has recently noticed a trend of renewal applications being submitted less than 30 days prior to the study's expiration date. OIA requires submission of studies at least 30 days prior to their expiration date to ensure that there is enough time to have the study reviewed and any issues which may arise addressed before the study expires. Researchers who repeatedly submit their renewals late may be issued a determination of continuing non-compliance.

To avoid non-compliance, here are some tips which may help:

- Set a reminder 60 days before the expiration date on your individual work calendar and any team calendars
- Make sure your Outlook isn't sending Kualii notifications to your junk or spam folder
- Update your "Manage Protocols" view in Kualii IRB to include the "Expiration Date" column:
 - In Kualii IRB's Manage Protocols page, click "Manage Protocols" on the right-hand side under the blue "+ New Protocol" button
 - Scroll down and check the box for "Expiration Date"
 - Click the blue "Save" button in the lower right-hand corner

Reminder: Max File Size for Kualii IRB

Many researchers have noticed that sometimes documents that get stamped in Kualii 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 Kualii tries to apply the approval stamp, Kualii 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.

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 occurred 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 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 ***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 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: Kualii KBAs

Knowledge Base Articles (KBAs) are an important part of the transition from the legacy eIRB system to Kualii. These articles help provide additional instruction and guidance about how to use the Kualii system. The research knowledge base containing KBAs for all of UCSD studies 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 Kualii 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 Kualii is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kualii. 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 Kualii, 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 Kualii. 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

[Kualii 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 Kualii 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 Kualii in relation to single IRB/reliance arrangements, contact irb@ucsd.edu.

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

