UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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In This Issue

NEW: 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.

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.

NEW: Negotiating Sponsor Consents

Working with industry sponsors on research studies can be a great partnership. These collaborations helped get emergency use authorizations for the COVID vaccines, have advanced the treatment of previously untreatable cancers, and help support the overall research enterprise here at UCSD. However, getting a study up and running with an industry sponsor often involves many negotiations when it comes to the budget, the contract, and even IRB approval.

OIA has recently seen an uptick in unapprovable language being included in consent forms whether the study is being reviewed by our IRB or an external IRB. As such, we wanted to provide a few reminders about the requirements as well as resources for researchers in navigating through the consent negotiation with sponsors.

HIPAA Language

The number one issue that OIA catches in our review of studies going to external IRBs is the inclusion of HIPAA language in the ICF. Though it is primarily an issue for studies reviewed by an External IRB, it is also important that such language be removed for studies which are being reviewed by the UCSD IRB as well. Because of the various California Laws and UC policies surrounding the implementation of HIPAA and CMIA, UC requires researchers to use a stand alone HIPAA authorization document. In addition, RCHSD policy similarly requires the use of a stand alone HIPAA authorization. So as to avoid conflicting information or terms, this means all authorization language needs to be removed from consent documents and replaced with our standard HIPAA language which is available in our consent minimums document.

Recognizing HIPAA authorization language can be tricky so we recommend looking for phrases like "I authorize release of my medical information" or "I allow the study doctor to review my medical information" or sections that ask "how long will my authorization last?" or "what does this authorization cover?"

If sponsors claim that HIPAA authorization language must remain in the consent document, researchers can provide them the Sponsor Letter from OIA that discusses this topic at the top of page 2.

Injury Language

The next most common issue that OIA finds is the use of non-standard injury language in the consent form. This language has been approved by both UC and RCHSD at the highest levels and the UCSD IRB does not have the power to make changes to this language outside of the options listed on our consent minimums document and in our consent templates.

Researchers should remove any sponsor template language about how subjects will be compensated for research related injuries and replace it with the approved language. OIA's Sponsor Letter also describes this requirement starting in the middle of page 2 and researchers should provide this letter to sponsors if they pushback on this requirement. It is important to remember that the consent document is not a contract and contractual terms (e.g. liability, fault, etc.) should not be included.

Additionally, as a reminder, the Common Rule (both the Revised and Old versions) only requires that injury language be included for studies which are greater than minimal risk. As such, OIA will generally not require injury language for studies determined to be minimal risk.

NEW: 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, 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.

NEW: 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 insitution/legal and 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 D796 (English Pulse page) or form D796S (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.

NEW: Remembering the UCSD IRB "Enrollment" Definition

The human subjects research world is littered with words that have both a colloquial and formal definition. Words like "Exempt," "Expedited," and "Clinical Trial" have long plagued research administrators and researchers alike. Recently, the question of when a person is considered "enrolled" has been gaining prominence in the applications for renewal that OIA has received. As such, we would like to remind the research community at UCSD and RCHSD that the UCSD IRB considers a person to be "enrolled" in research when they sign the consent form.

We realize that many sponsors, studies, and other groups have different points (e.g. upon passing screening, upon randomization, etc.) at which someone is considered "enrolled" in a study. We ask that researchers keep in mind when submitting applications to OIA the UCSD IRB's definition of "enrolled."

What if my study doesn't have a consent process?

If a study does not require consent (e.g. chart review studies) then the number "enrolled" is equal to the number of charts or records you've reviewed regardless of whether the data in those charts or records will actually be used in the final analysis of the study. These studies are also generally not required to go through continuing reveiw under the Revised Common Rule.

What if my study doesn't require documented informed consent?

Studies that have an oral consent process where a signature is not required should consider any person who has provided oral or implied consent to be "enrolled" in their study regardless of whether or not they complete the study activities. These studies are also generally not required to go through continuing reveiw under the Revised Common Rule.

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: Office of Compliance and Privacy HIPAA Training Requirements for Researchers

HIPAA Research Privacy training is offered by the CITI Program and is now available to UCSD faculty and staff. **This training will replace the legacy HIPAA training offered on OIA's old webpage which will be retired by August 2023.**

For researchers who potentially use Protected Health Information (PHI) or related data, completion of the following modules in CITI's Research Privacy curriculum is recommended:

Health Privacy Issues for Researchers

This module discusses data protection requirements for human subjects research that creates, obtains, uses, or discloses health data, principally the protections that derive from the Health Insurance Portability and Accountability Act (HIPAA).

Basics of Health Privacy

This module discusses the basic privacy protections for health information provided by HIPAA, and other legal-regulatory and non-government sources. It identifies the duties and responsibilities of persons with access to protected health information (PHI) in order to fulfill privacy protections.

For additional information on available CITI training and instructions for accessing the training modules, please see the Office of Compliance and Privacy's pulse page: Collaborative Institutional Training Initiative (CITI) Program

For technical questions about CITI training please see the CITI Support Center: https://support.citiprogram.org

For questions about the Office of Compliance and Privacy's HIPAA training requirements for researchers, please email hscomply@health.ucsd.edu.

For questions about UCSD OIA training requirements, please see the published guidance here.

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.