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## NEW: OIA January Office Hours

The next OIA office hours will be held on January 17, 2024 from 9-10 am and can be accessed at that time [here](#).

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## NEW: NHR Closures in Quali IRB

Researchers conducting activities which are not human subjects research (NHSR) may find themselves in need of official IRB determination that a project is NHSR for a variety of reasons. Maybe there is another UCSD office that requires an official determination, maybe a funding agency requires it, maybe a journal requires it. Whatever the reason, OIA is happy to review NHSR applications in the Kuali IRB system and make NHSR determinations.

**Note:** Historically, NHSR projects may have been referred to colloquially as "Exempt" given that they do not require IRB review both by regulation and policy. This use of the term "Exempt" can become confusing as the IRB also makes formal Exemption determinations which means that a project is human subjects research but falls into one of the eight federally defined exempt categories found in the Common Rule at [45 CFR 46.104](#).

Because NHSR projects are not regulated like studies that receive IRB approval, they are not required to be closed out in the Kuali system. NHSR projects may carry on indefinitely, a few months, or only a day without further IRB review so long as they do not incorporate human subjects research activities.

While the Kuali system offers the ability to "Request Close" within the system for projects which have been determined to be NHSR, this is not necessary and only serves to bog down OIA's review teams. As such, we kindly request that researchers do not submit closure applications for their NHSR projects.

Not sure if your project is NHSR? Questioning whether you need to close your project/study? The OIA team is here to help! Please email us at [irb@ucsd.edu](mailto:irb@ucsd.edu) with your study number and questions and we'll be happy to help.

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## **NEW: HSR Training Requirements**

OIA has long required that all study personnel working on human subjects research (HSR) receive training in the basics of working with human subjects through the CITI training modules designed for biomedical and social/behavioral researchers. In addition, all study personnel must also be specifically trained on the study protocol and the procedures to be followed.

OIA will review PI training at Initial and Continuing Review to ensure that the PI has completed the required CITI training. It is the PI's responsibility, as spelled out in our [OIA-103 IRB Handbook](#), to ensure that all other study personnel have completed the required CITI and protocol training.

Failure to ensure that staff are appropriately trained may result in findings of serious and/or continuing non-compliance on the part of the PI which are reportable to funding agencies, the FDA, and UCSD officials.

If there are questions about the PI's responsibility for study personnel training or other PI responsibilities, please contact OIA at [irb@ucsd.edu](mailto:irb@ucsd.edu).

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## Reminder: OIA Holiday Closure

Like much of UCSD, the Office of IRB Administration (OIA) will be closed from Saturday December 23rd, 2023 through Tuesday January 2nd, 2024. OIA staff will be back to the office on Wednesday January 3rd, 2024.

# Happy Holidays!

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## Reminder: "Is IRB Review Required?" Web Page

As OIA continues to improve [our web page](#) to serve as a resource for researchers and their teams, we have added new sections. The newest section we've added is named after the question we get most often.

This new section, called "[Is IRB Review Required?](#)", discusses how researchers and their teams can determine if IRB review is required for their project, the levels/types of review that OIA can provide, and guidance on specific types of projects (e.g. case studies, QA/QI, Evidence Based Practice, and student research).

We invite you to check out our new page. Not finding the answer to your question here? Try our [FAQs page](#) or email us at [irb@ucsd.edu](mailto:irb@ucsd.edu).

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## Reminder: Updated Consent Minimums

OIA constantly strives to make sure that what we ask for in our reliance processes reflect what we ask of researchers when the UCSD IRBs review a study. To that end, it is necessary from time to time for us to update our consent minimums document to reflect any changes that may have occurred.

Recently, we published a new [consent minimums document](#) on our [reliance page](#). These most recent updates reflect the following:

- Added new instructions to the beginning of the document to provide clarity for researchers and research teams.
- Updated radiation risks to be consistent with language requirements from HERC.
- Added Genetic Testing language to be used to align with the CalGINA requirements (more restrictive than federal GINA legislation).
- Clarified that the language about participant injury only applies to studies which are greater than minimal risk.
- Corrections of minor typos and formatting issues throughout.

Advarra and WCG IRB both have this new language on file and should be incorporating the language as appropriate into the consent forms they develop for UCSD/RCHSD sites. If research teams use another IRB as their IRB of record, they will need to incorporate this language into the consent form and submit the UCSD/RCHSD-specific consent template for review as a part of their reliance clearance submission.

Need more information about how to rely on an external IRB? Visit our [reliance page](#), view our [KBAs](#), or email us at [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu).

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## Reminder: UCSD IDS Rate Change for 2024

Please be aware that the Investigational Drug Services (IDS) has a [new fee structure](#) (pulse link) for 2024 which will become effective on January 1, 2024. The new structure includes a scheduled 5% increase in every category.

The new fees are based on current salaries, benefits and actual time required to perform given functions, and have been benchmarked against our peer institutions, to assure that they remain competitive.

Studies that are already in progress, or for which we have already provided a budget estimate, will continue to be charged the old fees.

For more detail, please refer to the new [IDS 2024 Fee Structure](#) or [contact IDS](#) directly.

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## Reminder: Submitting a Funding Proposal? Don't Wait to Submit to OIA

UCSD researchers collectively bring in an extraordinary amount of funding from outside sources to help support their research, but these funders need to see certain things before they hand over any money. This includes IRB approvals or determinations when there are human subjects involved.

In OIA, we strive to be partners with our researchers and not stand in the way of getting research started. OIA often receives requests for rush approvals and reviews when Just In Time (JIT) notices come out. While we are happy to accommodate, these tend to bog down our review process for other researchers. In addition, there may be unforeseen complications with how research is proposed which means it cannot be easily approved even if it is moved to the front of the line.

As such, we ask that after researchers submit their proposals for funding, if the research will involve human subjects, go ahead and submit an application for review to OIA. That way, if something unforeseen arises there is time to deal with it without putting research funding in jeopardy.

Please keep in mind that the normal OIA review process can take from 6-8 weeks from the time of submission, so be sure to get those studies submitted with plenty of time for review. Our office (and your fellow researchers) thank you!

Need help with a submission? Contact us at [irb@ucsd.edu](mailto:irb@ucsd.edu) and one of our analysts will be happy to assist.

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## Reminder: Renewal of Business Systems Accounts

Since access to Kualu is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kualu. 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 Kualu, 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 Kualu. 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.

Our [OIA FAQ page](#) answers the top questions our office receives from the research community. It covers everything from "Do I need to submit to the IRB?" to "How do I find my approval letter?"

Can't find what you're looking for? Contact OIA by email at [irb@ucsd.edu](mailto:irb@ucsd.edu) with questions or to report errors/issues. For questions in relation to single IRB/reliance arrangements, contact [irbrely@ucsd.edu](mailto:irbrely@ucsd.edu).

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

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