UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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NEW: OIA October Office Hours

OIA office hours will be held on October 30, 2024 from 1-2 pm and can be accessed at that time here.

NEW: Kuali IRB Notification Updates

We have heard from many research teams since the implementation of Kuali IRB that the number of notifications coming from the system to everyone on the personnel list

is a lot. Unfortunately, this was largely out of our control and it was either all or nothing...until now.

Thanks to some recent updates from Kuali, we are now able to change how notifications from the system are sent. Starting **November 1, 2024**, notifications will only be sent to individuals with Full Access to the study in Kuali IRB. This includes individuals listed in the personnel list in the Kuali IRB application with Full Access as well as individuals not on the personnel list who are given Full Access on the "Permissions" tab in Kuali IRB.

Please take this coming time to make sure that studies you manage are updated so that those who should be receiving the notifications (e.g. PIs, Regulatory Staff, etc.) are set up with Full Access permissions.

If someone on the personnel list needs to have their permissions updated, please submit an amendment to do so following the instructions here. Such amendments are usually processed within 1-2 business days.

If someone is only listed on the "Permissions" tab, an amendment is not necessary and their permission level can be updated directly on the "Permissions" tab in Kuali IRB.

NOTE: When making these updates, teams must ensure that if an individual is listed as Study Personnel and separately added to the Permissions tab, that individual's permissions are the same in both places. If not, Kuali IRB will default to the lowest level of permissions selected. This will cause problems for individuals needing full access to studies.

Need help figuring our Kuali IRB permissions? Have general questions about using Kuali IRB? Write to us at irb@ucsd.edu anytime and one of our analysts will be happy to help!

NEW: Identifiability of Data

In the Kuali IRB application for a new study, the PI and/or study team may be asked to answer questions about the identifiability of the data they are using. This is particularly true of studies which seek to conduct a secondary analysis of already collected data. Such data may have been previously obtained for research or other processes or may be collected in the future for non-research purposes.

When discussing identifiability there are generally four options to choose from:

- Person-identifiable
- Coded
- De-identified

- HIPAA Limited Dataset

Person-Identifiable

This level of identifiability means that it is possible to "readily determine" the identity of an individual from the data that the research team will have access to. While no full list of data points that meet this standard exists (even from the regulators) and it is largely dependent on the number of variables and the specificity they contain, it includes things like name, MRN, SSN, student ID #, address, email address, etc.

It is also important to keep in mind that while the Biomedical Informatics (BMI) unit within the ACTRI may provide members of a research team with information lacking these identifiers, teams should still select this option for initial collection/receipt when using BMI services.

Coded

This level of identifiability means that it is not possible to "readily determine" the identity of an individual from the data at hand, but a key tying back a "code" within the dataset to person-identifable information does exist. This level of identifiability should be selected when either the research team has direct access to this key and separate identifiable dataset or when these are held by a collaborator who could provide them to the research team.

This option is not appropriate when a key and identifiable dataset exists but they are held by someone outside the research team and there is an agreement (e.g. contract, grant, DUA, etc.) prohibiting the disclosure of these to the research team.

De-identified

Like "coded" as described above; however, in this case no key and no identifiable dataset exists. In a truly de-identified dataset (sometimes also referred to as "anonymized") there is no way to "readily identify" an individual from the information provided. With increased computing power, AI, massive data collections, and additional technological advances, fewer and fewer datasets are truly able to be considered de-identified.

Additionally, it is important to remember that if a researcher collected the original dataset at sometime in the past and destroyed the identifiers, that dataset is permanently considered to be identifiable to that researcher because it was collected by them.

HIPAA Limited Dataset

This is a special class of identifiability which pertains only to Protected Health Information (PHI). Unlike the "readily identifiable" standard that IRBs have to use, HIPAA prescribes that PHI is identifiable if any of the 18 "HIPAA Identifiers" is included in the dataset.

A HIPAA Limited Dataset can contain two of the HIPAA identifiers, 1) addresses consisting of only city, state, and/or zip code **and/or** 2) dates, but not others. In addition, to qualify as a HIPAA Limited Dataset, the data must be accompanied by a DUA that prohibits trying to reidentify the individuals. As such, the UCSD IRB generally considers a HIPAA Limited Dataset to not meet the "readily identifiable" standard of the Common Rule.

Still not sure which option to pick? General IRB questions? Email us at irb@ucsd.edu and we'll be happy to help!

NEW: IRB Expectations on Justice, Equity, Diversity, and Inclusion

As we know, Justice has been a core ethical principle of IRBs since their inception in the late 1970s. This principle, as described in the Belmont Report, demands that in considering who will be selected as participants in a study, we consider whether those who are being asked to bear the burden of research participation are those who will benefit from the knowledge to be gained. This could be thought of on an individual basis or as a class of participants.

Considering the time in which the Belmont Report was written, it is no surprise that this ethical principle was used for many years by IRBs more as a justification to set a high bar for inclusion of vulnerable populations than as a justification to require equal access to research and representative participant populations. This was backed up by guidance from regulators similarly recommending the exclusion of certain vulnerable populations even when precautionary measures were put in place.

However, it was quickly recognized that such overt prohibitions on the inclusion of vulnerable populations in research had a deleterious effect on the knowledge being gained. Many studies were comprised of solely caucasian male participants and the data could not be extrapolated to the broader population. This ultimately led to Congress requiring inclusion policies in federally funded research in the early 1990s. In turn, this led to both the FAD advocating for the inclusion of women and the NIH to require plans for the inclusion of women and minorities in research.

Since then, inclusion/exclusion criteria have become less explicit on excluding various vulnerable populations; however, the IRB does from time to time still see studies which have overly restrictive criteria for study entry. This might take the form of overly complicated or unnecessary contraceptive requirements (e.g. requiring hormonal birth control even after hysterectomy or tubal ligation), only making the study available to English speaking subjects, excluding subjects lacking the cognitive ability to consent, high cost burdens to participation, etc.

To be sure, depending on the study there may be valid scientific justifications for these requirements. When such justifications exist, they should be explicitly spelled out in the study protocol. Overly restrictive study criteria lacking sufficient justification may be returned by the IRB for further explanation and/or removal by the study team.

Study returned for revisions and you want to speak to someone? Have general IRB questions? Contact us at irb@ucsd.edu and one of our analysts will be happy to help!

Reminder: UCSD Part 11 Compliant eSignature Option

With the increasing rise of electronic technologies being employed in research settings, sponsors and researchers continue to look for new ways to reduce the use of paper when conducting studies. One barrier to consenting participants electronically for clinical research regulated by the Food and Drug Administration (FDA) has been the need to comply with the FDA's requirements at 21 CFR 11 (Part 11) for electronic signatures.

For the past couple of years, the ACTRI has been piloting a program through DocuSign to understand if this would be a viable option for UCSD clinical researchers. After a successful pilot, the ACTRI is opening the program to UCSD researchers across the campus who wish to be able to have participants sign consent documents for FDA regulated studies electronically.

While more information is available on the Biomedical Informatics (BMI) webpage, including how to request this service, an important note is that the cost is $7 per "envelope." For those not familiar with DocuSign's terminology, an "envelope" consists of the document(s) to be signed between two (or more) parties. As such, each participant will require their own "envelope."

For questions about this service, please contact the BMI team directly at ctri-support@ucsd.edu.

For IRB questions, including whether your study is approved for eSignatures and whether your study is FDA regulated, contact OIA at irb@ucsd.edu.

Reminder: Need to Submit an Amendment and Continuing Review? Here's What to Do

We've all been in this situation. You've submitted an Amendment to change some aspect of the protocol. While waiting for it to be approved, you get the notice your Continuing Review is due. You don't want to be late on the Continuing Review, but you don't want to throw off the approval of your Amendment either.

Or maybe it happens the other way. You've submitted your Continuing Review at least 30 days in advance, but now you have an Amendment that needs to be submitted. You really don't want to throw off the review of your Continuing Review. What to do?

Fortunately, with the implementation of the Kuali IRB system submitting these two separate types of submissions at the same time is not a problem. Have an Amendment already going through the review process? Go ahead and start and submit that Continuing Review! Already have a Continuing Review going to the IRB? Go ahead and submit an Amendment!

The Kuali IRB system logs each submission type separately in the system so there is no concern about messing up one submission type by submitting a different submission type. It also doesn't matter what order they're submitted in. Even if an Amendment is submitted first and the Continuing Review is submitted second, the IRB can review and approve the Continuing Review in the system before the Amendment is approved without causing an issue. Once both are finally approved, the Kuali IRB system will merge the applications so that the final approved version incorporates the renewal from the Continuing Review and the changes from the Amendment.

Need help with the Kuali IRB system? Write to OIA anytime at IRB@ucsd.edu.

Reminder: Recruitment Prior to Reliance Acceptance

Recently, OIA has received a significant uptick in questions from investigators and research teams regarding starting to recruit participants to studies prior to the reliance being accepted by OIA. To put it simply, this is not allowed.

While OIA acceptance of a reliance is not an "IRB approval" in the sense of the meaning in the regulations, it is also not superfluous. While OIA, when ceding to another IRB, does not perform the typical IRB review as dictated by the regulations, OIA is still required by the regulations, the terms of our reliance agreement, and institutional policy to ensure that the study meets all the local context requirements within OIA's purview. This includes ensuring that required consent information is present, local laws and regulations are adhered to, ensuring investigators have completed their required training, etc.

While reliance acceptance is usually an easy and straightforward process when we've all done everything according to plan, OIA consistently sees studies submitted for reliance acceptance which do not meet the local context requirements and (in some instances) need significant revision before they can be accepted. For these reasons, research teams must wait until OIA reliance acceptance is received to begin recruiting for studies.

Questions on recruiting in a study relying on another IRB? Have general questions about studies under a reliance? Email the reliance team anytime at IRBRely@ucsd.edu.

Don't Forget: 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 and one of our analysts will be happy to assist.

Don't Forget: 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 to renew access for these individuals throughout the course of the year.

Don't Forget: 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 with questions or to report errors/issues. For questions 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.
