UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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NEW: OIA November Office Hours

OIA office hours will be held on November 15, 2024 from 9-10 am and can be accessed at that time here.

NEW: OIA Holiday Closure

As noted in the recent communication from Campus HR, the AVC for Health Sciences, and the AVC for Academic Personnel, the UCSD campus will be closed starting Tuesday, December 24th through Wednesday, January 1st. OIA also

participates in this closure and will be closed for these same dates. Additionally, it is expected that many staff will take Monday, December 23rd, Thursday, January 2nd, and Friday, January 3rd off as well to spend time with their families and loved ones during the winter holiday period.

With this in mind, if you have a study which will expire before January 20, 2025, please be sure to submit it 30 days in advance or by December 1, 2024, whichever is sooner. This will allow our office time to review your study to ensure it doesn't expire.

Happy Holidays!

NEW: Pregnant Partner Consent

During the course of research, particularly research which involves a drug, biologic, or medical device, Sponsors or researchers may wish to follow-up with partners of study participants who become pregnant while their partner is participating in the study. To that end, Sponsors may provide research teams with pregnant partner consent documents to be provided to the IRB for review and approval. How research teams should handle these will depend on whether a UCSD IRB or an External IRB is the IRB overseeing the research

Research Overseen by a UCSD IRB

The UCSD IRBs have long held that pregnant partners do not meet the definition of a "human subject" as provided in either the FDA regulations or the Common Rule. This stems from the fact that pregnant partners do not receive the test article (i.e. drug, biologic, or device) nor do they serve as controls, thus not meeting the FDA definition. Similarly, a sexual partner of a participant becoming pregnant during the course of a study is generally a rare event. So rare in fact that it is believed that the information to be gained from following a pregnancy, while useful, does not "develop or contribute to generalizable knowledge." Thus, these individuals would also not meet the Common Rule criteria.

As such, if a study team receives a pregnant partner consent from a sponsor, they can provide the information about the UCSD IRBs' position to the sponsor and these documents do not need to be provided to the UCSD IRB in the Kuali submission. Of course, that doesn't mean that's the end of the story. If the research team still needs to follow the pregnancy and report any outcomes data, please talk to the Office of Compliance and Privacy (OCP) about requirements related to protecting HIPAA rights of these individuals. OCP can be contacted at hscomply@health.ucsd.edu.

Research Overseen by an External IRB

While the above is the position of the UCSD IRBs, this is not the position that all IRBs take. As this is a matter of some interpretation of the regulations, reasonable

folks can disagree on their application. What is important to remember is that when a research team relies on an External IRB, that External IRB's policies (not those of OIA and the UCSD IRBs) is what must be followed. That means that if the External IRB considers that consent must be obtained for pregnant partners, a consent document must be developed.

In such a case, this document needs to be treated like any other consent form when relying on an external IRB. The document can't contain any HIPAA language about authorizing release of medical records except to say that they will be provided with the separate HIPAA authorization document to read and sign. In addition, all the other information which is applicable to the study from OIA's consent minimums document must be incorporated into the pregnant partner consent form. Need help navigating a reliance on an External IRB? Contact the reliance team at irbrely@ucsd.edu anytime!

NEW: AI, Machine Learning, and Medical Devices

While decision trees, algorithms, and early forms of AI have been around for decades, the promise of new predictive and generative AI tools built on large language models and deep neural networks has seemingly made its way into every aspect of our lives. AI can order us a soda, write a research paper on plate tectonics, regulate our A/C to be more efficient, and troubleshoot our computer problems faster than ever. The promise of AI is astounding and it's no surprise it's made its way into the world of human subjects research.

Human subjects research studies using AI range from using AI to control ventilators and infusion pumps to understanding if AI translators can bridge language gaps. Still some of the more common research projects using AI in the human subjects research space seek to utilize AI's predictive potential to uncover patterns that us humans can't see for ourselves. Sometimes this is behavioral in nature (which students are likely to drop out after their first semester?) and sometimes this is biomedical in nature (can an AI diagnose a patient's condition faster than a physician?).

Recently, OIA authored an article in our May 2024 newsletter which had a companion piece in the RCI June 2024 newsletter (see page 6). These articles shine a spotlight on how easy it is for AI algorithms in the biomedical space to veer into the realm of FDA regulation as a medical device. However, while this means OIA and the UCSD IRBs have a few more things to consider when this happens, it generally involves no additional burden or regulatory submissions for investigators. Rest assured, while it may be jarring to suddenly be told a study involves a medical device, OIA is here to help our research navigate what this means and make sure that all human subjects research is safeguarded from regulatory pitfalls.

Have questions about when AI is a medical device? Have general human subjects questions? Right to OIA anytime at irb@ucsd.edu.

Reminder: 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!

Reminder: 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!

Reminder: 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!

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.