UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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COVID Guidance for IRB Studies

With the continual change in guidelines, on campus processes, and preventative measures, the IRB is changing its guidance for how investiagtors must keep their subjects safe from COVID. Going forward, the IRB will require that researchers follow the UCSD Health Sciences guidance on COVID for studies taking place in person. To access the latest guidance, please click here.

In addition, this change in our guidance has been posted at the top of our Guidance page here so that Sponsors, CROs, funders, and anyone else who needs to be referred can find it.

New Process for Certificates of Confidentiality from the NIH

Several years ago, the NIH revamped their process for requesting a Certificate of Confidentiality (CoC) from one of their institutes. This change made the request and processing of such requests much faster and easier. However, this also put all the pressure on researchers to fill out the request correctly. The IRB has recently noticed that researchers were completing this process inconsistently and so we wanted to provide a more streamlined approach. As such, we have developed a guidance document with instructions which is available on our webpage here for researchers who are applying for a CoC from the NIH.

Please Note: Studies funded by the NIH are automatically granted a CoC upon award of the grant and do not separately need to apply for a CoC.

Announcement: Returning Unused Scrip Checks

Last week, the folks at Budget and Finance issued a final call for the return of unused scrip checks that were previously issued for use as subject compensation. Here is what they had to say:

All Scrip checks were stale dated as of June 19, 2021, and are no longer negotiable. If you have any outstanding items left and wish to receive funds back, all items must be received no later than May 31, 2022.

To return unused Scrip, write VOID on the face of the checks and mail them to Disbursements, MC 0955. Please include the following information:

- The original MyPayments request number
- The full COA in which you'd like the funds to be returned to

Two and a Half Months Left!

July 2021 was the start of a yearlong transition period from the legacy eIRB Services system to the new Kuali IRB system. The OIA team deeply appreciates your patience and tenacity both as you learn the new system and as we navigate significant structural and policy changes in our office (and as everyone continues to adapt to the pandemic and new normal).

The extra work of this transition is already more than half over and we need your help to make it to the finish line of this important project. Please continue to follow our original matrix and additional guidance for studies that do not fall into the matrix. Also see below for important reminders when a study from the legacy e-IRB Services system is not easily located in Kuali or help from OIA is needed.

Together we can finish this transition period strong and continue the groundbreaking research that makes us proud to be Tritons!

Reminder: Orphan Studies and June 3rd Deadline

In early July 2021, OIA released a matrix for how investigators should continue to use the legacy e-IRB Services system during the period of transition to Kuali. While this matrix included many common scenarios we expected, it did not address what OIA is referring to as "Orphan Studies":

- Studies with 3-year approvals
- Studies with expiration dates after July 2022
- Studies without expiration dates
- Studies determined to be Exempt
- Studies relying on an external IRB
- Studies that involved only Stem Cell Research Oversight (SCRO) review without IRB review

In February 2022, OIA released additional guidance for how these Orphan Studies should be handled.

Please Note: Studies with 3-year approvals, expiration dates after July 2022, and without an expiration date must be submitted for transition to Kuali by **June 3, 2022**.

Not sure what kind of study you have? View our guide here to help.

Tips and Tricks for Common Kuali IRB Transfer Mistakes

1) Include only the currently approved documents in the "Supporting Information" section when preparing a transfer amendment. The IRB doesn't need to see every previous version of each document, just the current **clean** version of the documents that are in use.

2) Consent forms need to be submitted in **clean PDF format and without any stamps.** In order for Kuali iRB to be able to stamp documents they have to be in PDF format without any stamps already on them. The same goes for assent and recruitment documents as well.

3) Don't forget to hit submit. The OIA won't know that a submission is ready for our review until the "Submit" button has been clicked in Kuali IRB.

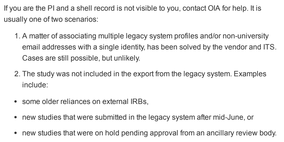
Reminder: e-IRB Being Retired

Any documents contained within the legacy e-IRB Services system will not be readily accessible after July 2022. As such, researchers are encouraged to download any documents they will need after July 2022 now.

Reminder: Troubleshooting Missing Studies

OIA exported limited information from the legacy e-IRB Services system to create shell records for studies in Kuali. Although the export went smoothly, some users don't see all the studies they expect. Here's why (and what to do if it happens to you):

The first step for any user is to make sure no Advanced Filter or Saved Filters are limiting views (buttons near the right of the Manage Protocols screen; see blue box in screenshot).



If you are **not** the Principal Investigator (PI), the shell record will not be visible to you at first. If this happens to you, check with the PI. If the study is visible to them, they just need to quickly add you to the Permissions (see PI Permission Step by Step).

If you are the PI and a shell record is not visible to you, contact OIA for help. It is usually one of two scenarios:

1. A matter of associating multiple legacy system profiles and/or non-university email addresses with a single identity, has been solved by the vendor and ITS. Cases are still possible, but unlikely.
2. The study was not included in the export from the legacy system. Examples include:

- some older reliances on external IRBs,
- new studies that were submitted in the legacy system after mid-June, or
- new studies that were on hold pending approval from an ancillary review body.

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 or by voicemail at 858.246.4777 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) and a reference to the system you are using ("e-IRB" or "Kuali IRB"). This will help the OIA team triage and troubleshoot.

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