UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

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About This Message

You are receiving this as a Principal Investigator and/or a Study Contact for research reviewed in the final 3 years of the legacy e-IRB system (through mid-June 2021).

This is a one-time broadcast with important instructions about the ongoing transition to the Kuali IRB system and a reminder about the retirement of the legacy system coming up at the end of July.

To receive future updates about Office of IRB Administration (OIA) processes, policies and training schedules, **please opt in to our mailing list.** Click the blue button below and complete the brief form.

To those of you who've already opted in, thank you (and apologies if you received this message twice)!

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Halfway There!

Please Note: 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.

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).

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 reading for new guidance on studies not previously covered by the original matrix previously published and 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!

A Peek Behind the Curtain...

In the first six months of Kuali IRB, the UC San Diego research community used the system to submit **900 new studies and 800 renewals of existing studies** for review.

Kuali IRB solidifies the strides made by the OIA team and the IRBs over the past 4 years. These include shifting to a more risk proportionate process, better applying regulations (and the flexibility built into those regulations), and eliminating unnecessary work.

As a result, of those 900 new studies **75% have been eligible for minimal risk reviews or for administrative determinations** (such as the research is not regulated, the research is exempt from IRB review, or that UC San Diego would rely on an external IRB's review).

That 75% figure is roughly the inverse of where the program stood in 2018 and now puts UC San Diego in line with peer institutions.

New Guidance: Orphan Studies

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

This new guidance addresses how to handle each of these situations so that the study is appropriately rolled into Kuali.

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

Studies With 3-Year Approvals, Expiration Dates After July 2022, or No Expiration Date

Since the legacy e-IRB Services system will be retired at the end of July 2022 as a part of the transition plan, it is important that these studies be transitioned to Kuali prior to that time. Because these studies would not expire prior to July 2022, the previous matrix did not address how or when these studies should be transitioned to Kuali. However, it is imperative that these studies be transitioned into Kuali prior to July 2022 so that there is not a lapse in IRB oversight.

As such, we are asking that researchers submit a rollover amendment by following **only** steps 1-7 of the transfer process (See Transferring an Existing Study to Kuali IRB).

Additional Action May Be Required: If the study has an expiration date which is within 60 days of the transfer submission, a continuing review submission is also required. If the study shows as expired in the Kuali system, you will need to first submit a Renewal in the Kuali system without a transfer amendment. Once the renewal is approved, a transfer amendment must be immediately submitted to be able to obtain stamped documents.

We ask researchers to submit these amendments in Kuali as soon as possible so as to allow our office time to process the 1200+ submissions we expect. We ask that researchers complete this process ***no later than*** June 3, 2022 to allow the office sufficient time to process these amendments.

Please Note: The IRB cannot guarantee that it will be able to review studies not submitted by the June 3, 2022 deadline before the legacy e-IRB Services system is retired. If that occurs, the studies may expire and may have to be temporarily halted by the study team until the IRB can catch up.

Studies Determined to be Exempt

A transfer to Kuali for Exempt studies is not required prior to July 2022. The determination from the legacy e-IRB Services system continues to be valid so long as the study remains unchanged.

Amendments for exempt studies are only required in certain circumstances when there is something that the IRB needs to be aware of (e.g. a change in the study PI) or when there is a change to the study that would alter the IRB's determination that the study is exempt (e.g., new funding, new sensitive questions, new populations of subjects, new procedures, etc.). For more information about what changes **do not** require amendments, see our guidance here.

If a change requiring an amendment should occur from March 1, 2022 forward, please initiate a transfer amendment by following **only** steps 1-7 of the transfer process (See Transferring an Existing Study to Kuali IRB). After that is approved, you will be able to submit a separate amendment describing the change that prompted the transfer into Kuali.

Studies Relying on an External IRB

The UCSD IRB is not the IRB of record for these studies. As such, a submission in Kuali is only required at the following times:

- Continuing Review;
- When the PI or UCSD Key Personnel of the study changes;
- When a new or changed Conflict of Interest (COI) occurs;
- When a new HIPAA determination or a change in the HIPAA determination needs to be made by the UCSD IRB;
- When new funding is received or there is a change in study funding;
- When a new ancillary review becomes required (e.g. study previously didn't involve radiation and now it does so HERC review is required);
- When there are changes to UCSD required consent language (e.g. injury language, subjects bill of rights, etc.); or
- When the IRB of Record (external IRB) makes a determination of Serious Non-Compliance, Continuing Non-Compliance, or Unanticipated Problem Involving Risk to Subjects or Others (UPIRSO/UPIR).

Because the UCSD IRB is not the IRB of Record for these studies, it is not imperative that these studies be transferred into Kuali prior to July 2022. As such, whenever the first of any of the events listed above occurs, please initiate a transfer amendment by following **only** steps 1-7 of the transfer process (See Transferring an Existing Study to Kuali IRB) unless the reason for transfer is continuing review and then all steps should be followed.

Studies Reviewed by SCRO Only

As the OIA administers both the UCSD IRB and the Stem Cell Research Oversight (SCRO) committee, researchers may have studies in the legacy e-IRB Service system which do not involve IRB review and thus would not be applicable to the previously released matrix. The easiest way to tell if a study was reviewed by SCRO and the IRB or SCRO alone is to look at the approval letter. Studies approved by SCRO and the IRB will contain the IRB Director's signature, while those approved by SCRO alone (with no IRB review) will not contain the IRB Director's signature.

If a study was reviewed by SCRO and the IRB, follow either the originally provided matrix or the new guidance provided above in this announcement. If a study was reviewed by SCRO only, please know that OIA is aware that many studies were submitted to SCRO which did not need to be because they did not involve covered stem cell lines. California law defines covered stem cell lines as:

> A culture-derived, human pluripotent (i.e. capable of differentiation into mesoderm, ectoderm, and endoderm) stem cell population derived from an embryo or product of somatic cell nuclear transfer (SCNT) that is capable of (1) sustained propagation in culture; **and** (2) self-renewal to produce daughter cells with equivalent developmental potential.

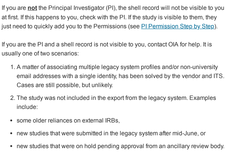
If your study was previously reviewed by SCRO only and **does not** involve covered stem cell lines, future submission to OIA is not required. If your study was reviewed by SCRO only and **does** involve covered stem cell lines, make sure to review your current approval letter and note the expiration date. Submit a transfer amendment and continuing review (See Transferring an Existing Study to Kuali IRB) at least 45 days prior to the expiration date.

Please Note: Parts of Sections B and D of the Kuali application for renewal/continuing review may not be applicable to studies reviewed by SCRO only. If the study does not involve the enrollment of human subjects, please input "0" for all numeric fields in Section B and answer the one "yes/no" question as "no". In Section D, when reading the questions please mentally substitute "SCRO" for mentions of "IRB".

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 relances 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 ebrely@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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