

October 20, 2021: Kualii IRB Updates

The implementation phase of the Kualii IRB project is coming to a close. Ongoing Kualii IRB support and communications are transitioning to the Office of IRB Administration (OIA) and the mailing lists for Kualii IRB updates and OIA's Human Research News have been merged.

Through the July 2022 completion of the transition period and beyond, Human Research News will be your source for regular updates about Kualii IRB and other human subjects research policies, procedures and news.

The project team and OIA appreciate the patience and contributions of the UC San Diego research community during the implementation. Kualii IRB is not just a long-overdue system replacement, but is also essential to other long-overdue updates and improvements to our approach to human research protections.

While many of you have already benefitted from the new system and other improvements, we recognize that these changes involve some extra learning and work for everyone and that aspects of the rollout have been challenging, especially when you're adapting to changes to a number of other systems too.

See below for reminders about upcoming training opportunities and how to find help and information, more about common issues experienced by study teams (apologies in advance for the detailed discussion), and a sneak peek at other information coming soon through Human Research News.

Upcoming Training

The OIA team is continuing its schedule of regular training sessions. Recordings of prior sessions (covering a number of topics) are still available on the [ESR Kualii IRB Training](#) page and will soon be added to the new [OIA Training](#) page.

Zoom links for the following sessions are posted on the new [OIA Training](#) page. No registration is required, but the sessions are intended only for research teams from UC San Diego and Rady Children's Hospital. The Waiting Room feature will be turned on, so please log in to Zoom using your work account to avoid any delays in joining the session.

[Kualii IRB: Continuing Review & Rolling Over/Transferring](#)

- Thursday, October 21st between 9:30 - 11:00am
- Monday, November 15th between 10:30am - 12:00pm
- Monday, December 6th between 10:30am - 12:00pm

[Collaborating Sites Relying on UCSD IRB Review: What to Do now that Kualii IRB is Live](#)

- Tuesday, November 2nd between 9:00 - 10:00am

Additional Information and Support

[Kualii IRB Knowledge Base Articles](#) 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 the system. 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@health.ucsd.edu or by voicemail at 858.246.4777 with questions or to report errors/issues. Please be sure to include the protocol number (if available) and a reference to the system you are using ("e-IRB" or "Kualii IRB"). This will help the OIA team triage and troubleshoot. For questions about Kualii in relation to single IRB/reliance arrangements, contact irbely@health.ucsd.edu.

Kualii IRB Common Issues

Visibility of Transferred Studies

OIA exported limited information from the legacy e-IRB Services system to create shell records for studies in Kualii. 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).
- If you are not the Principal Investigator (PI), the shell record will not be visible to you at first. This is because we could only export the PI information. 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. The first, 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. The second scenario is that 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.

Conversion of Transferred Studies

Converting an existing study when it comes up for renewal has been the biggest challenge for first-time users. Preparing both an amendment application and a renewal application is more involved than what everyone is used to, but the extra work now is designed to make things much simpler in the long run.

First, consult our [Study Transition Matrix](#) to know which system to use and when. When it's time to convert a study, your next stop should be our [Quick Sheet](#) on the topic. Finally, if you need more help or want to see someone walk through and discuss the steps, check out a live or recorded webinar (see above for details).

Access to Kualii IRB

For UC San Diego faculty and staff, getting started with Kualii IRB is simply a matter of logging in with Single Sign-On credentials.

Student Single Sign-On credentials do not provide the same access to university Business Systems such as Kualii IRB. Students who are not employed by the university should leave extra time to [arrange access through their departments](#).

Accounts for non-UC San Diego personnel are generally unnecessary, but [can be arranged](#) for situations such as volunteers or consultants working at UC San Diego and some individuals from Rady Children's, from member organizations of the Sanford Consortium for Regenerative Medicine, or from institutions offering Joint Degree Programs with UC San Diego.

Accounts should not be arranged for collaborators who are under the jurisdiction of their home institution's IRB or whose home institutions have agreed to rely on the UC San Diego IRB review.

Protocol/Research Plan

The traditional Research Plan is no longer required. If the study has a protocol, that protocol should be submitted as an attachment to the IRB application.

OIA will release protocol templates appropriate to different types of research. In the meantime, for studies that do not have protocols the IRB will need a description of the background, aims, population and procedures/schedule involved. You may complete and upload the Research Plan (the forms are being added back to our website) or use some other document that covers similar information.

If you plan to prepare the Research Plan or other document, please be careful to avoid duplicating or contradicting information that you provide in the smartform in Kualii IRB.

Notifications

Questions and comments about Kualii IRB notification messages stem from two issues. First is how widely distributed notifications are. We appreciate that this adds more to already noisy inboxes. We do have an open request with the vendor to develop more granular controls over notifications, but this will likely be a long-term fix. We will continue to re-evaluate the risks and benefits of these notifications and look for opportunities to reduce noise.

The second issue is with limited synchronization of information between the legacy system and Kualii IRB. Some people have received notifications from one or the other system that reflects outdated information. This primarily happened in the July-September timeframe before renewals were completed in Kualii.

While these outdated or contradictory messages can be momentarily disconcerting, they should not be cause for concern and they are already occurring less and less as the transition progresses.

Before an existing study completes a renewal in Kualii, the legacy system remains the system of record and all actions should continue to be taken in that system. Any notifications from Kualii can be safely ignored.

After an existing study completes a renewal in Kualii IRB, the legacy system is no longer the system of record and all actions will be taken in Kualii IRB. Any notifications from the legacy system from that point can be safely ignored.

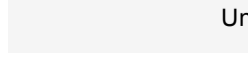
To learn more, please see our [Expiration Notifications](#) article.

Coming Soon in Human Research News!

- The return of Zoom office hours.
- More details about the renaming of the office, deployment of a new website and the updated campus policy underlying all our changes: [PPM 100-5](#).
- Kualii IRB conversion instructions for existing studies that didn't fit neatly into the conversion matrix, such as studies that were not exported from the legacy system, studies with no expiration or studies expiring after July 2022.
- Consent updates, including new informed consent templates and updates to guidance about surrogate consent and about short form consent.
- Simplified procedures for relying on the reviews of external IRBs.
- And more...

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