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Have You Transferred Your Study into Kualii?

While the deadline for submitting transfers of most IRB studies into Kualii was **Friday, June 3, 2022**, we encourage anyone who has not yet completed the transfer process to do so ASAP.

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 Kualii 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!

Changes Coming to the Kualii Amendment Form

To be better partners with our colleagues in the Office of Coverage Analysis Administration (OCAA), we will be updating the Kualii IRB amendment application on July 1, 2022 with one additional question at the start of all amendment applications. The new question will look like this:

SECTION A: Study Classification

OCAA Review
Is this an amendment where review of the study is conducted by an external IRB and the changes do not meet the criteria for OIA submission and are being submitted only to trigger OCAA review?

Yes

No

The text of the question reads "Is this an amendment where review of the study is conducted by an external IRB and the changes do not meet the criteria for OIA submission and are being submitted only to trigger OCAA review?"

The purpose of this question is to provide clinical studies that are reviewed by an external IRB (e.g. WIRB/WCG IRB, Advarra, etc.) a way to easily provide updated documents to OCAA to see if the coverage analysis needs to be changed even when an IRB amendment wouldn't normally be necessary.

Answering "Yes" will mean no other questions populate in the application and the user should upload any revised documents (e.g. protocol) for OCAA review.

Answering "No" will populate the rest of the questions normally seen on the amendment application in Kualii.

Q: Who should answer "Yes"?

A: Only studies which are reviewed by an external IRB that are submitting an amendment that doesn't meet UCSD IRB submission requirements so that OCAA is aware of the changes.

Q: What amendments for external IRB studies need to be submitted to UCSD IRB?

A: Changes to the UCSD/RCHSD PI of key personnel, new or changed COI, new or changed HIPAA determinations to be made by UCSD IRB, new or changed study funding, new ancillary review is required (e.g. HERC, IBC, etc.), changes to UCSD/RCHSD required consent language (e.g. bill of rights, injury language, etc.).

Q: What amendments for external IRB studies does OCAA want to see?

A: OCAA wants to see a submission when there are changes that result in the addition/removal of any visits and/or items/services that occur within the study (e.g. drugs, labs, imaging, or tests performed at a UCSDH facility). Failure to submit these may result in improper billing.

Q: Will this hold up my study with the IRB?

A: No. The UCSD IRB has worked out an internal process so that this should not add a significant delay to any study which is submitting purely for OCAA review.

Reminder: Renewal of Business Systems Accounts

As we approach July 2022 we are coming up on the one year anniversary of the beginning of the Kualii transition. Since access to Kualii is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kualii. 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 Kualii, 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 Kualii. Furthermore, please be on the lookout for automated emails asking you to renew access for these individuals throughout the course of the year.

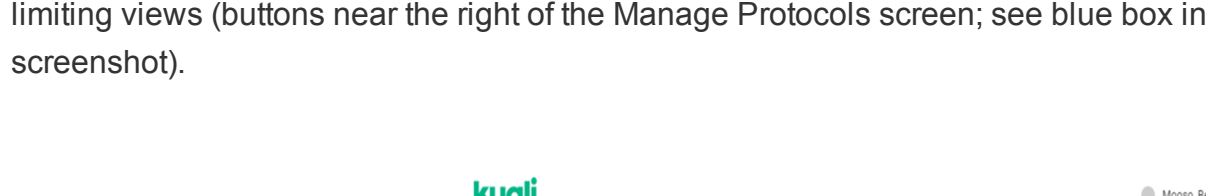
Reminder: e-IRB Being Retired

Any documents contained within the legacy e-IRB Services system will not be readily accessible after July 2022. As researchers remain responsible for maintaining their own complete study records, 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 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; 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

[Kualii 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 Kualii 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 Kualii 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 "Kualii IRB"). This will help the OIA team triage and troubleshoot.

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