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In This Issue

NEW: Reliance Team Update

Reminder: Office of Compliance and Privacy HIPAA Training Requirements for Researchers

Reminder: Deadline to Begin Using New ICF, Assent, and Protocol Templates

Reminder: Renewal of Business Systems Accounts

Reminder: Getting Help

NEW: Reliance Team Update

Greetings from the Reliance Team!

We would like to thank you for your patience while we process a large influx of transfer amendment applications. During our review of transfer amendments for studies where the UCSD IRB relies on an external IRB, we have noticed some recurring issues listed below that are requiring revisions to projects and are causing additional delays and resubmissions in the review process.

Incorrect Submission Type

Submissions that have submission type as "Automatic conversion from eIRB" are incorrect. The correct submission type should be "Admin Determination or Registration" followed by selecting "Request to Rely on a non-UCSD IRB". Once the submission type is corrected, additional sections that need to be added and completed are: Local Context, Reviewing IRB, and Characteristics. These can be "unlocked" for editing by clicking "Add/Remove Section" from the right-hand menu within the amendment and then clicking the checkboxes for each corresponding section.

Newer Documents in the Supporting Information Section

The initial shell created in Kualu automatically (if a shell was created), did not include any study documents. As such, we've requested that transfer amendments include only the most recent IRB-approved documents that were accepted/acknowledged by OIA in the eIRB system along with a brief update of the status of the research, update to Study Personnel and funding, as applicable. Documents required for an external reliance review transfer are research plan/protocol, clean version of consents/assents and recruitment materials.

When newer documents are submitted, those applications are being returned with action items for every document that does not align with eIRB and creating additional processing time. Newer documents can be submitted after the transfer amendment is complete, if they either meet our [criteria](#) for amendment submissions or require ancillary review such as OCAA review.

Unnecessary Documents

Applications to request that the UCSD IRB rely on an external IRB do not require the submission of subject facing materials, data collection tools, external IRB rosters or translated materials.

If you have a transfer amendment for an external reliance in queue to be processed, please consider reviewing the application(s) to ensure that your application(s) do not have any of the common errors listed above. Your assistance in ensuring your transfer amendment did not include these errors will improve our review times and we can get through the applications quicker.

Reminder: Office of Compliance and Privacy HIPAA Training Requirements for Researchers

HIPAA Research Privacy training is offered by the CITI Program and is now available to UCSD faculty and staff. This training will replace the legacy HIPAA training offered on OIA's old webpage which will be retired by August 2023.

For researchers who potentially use Protected Health Information (PHI) or related data, completion of the following modules in CITI's Research Privacy curriculum is recommended:

Health Privacy Issues for Researchers

This module discusses data protection requirements for human subjects research that creates, obtains, uses, or discloses health data, principally the protections that derive from the Health Insurance Portability and Accountability Act (HIPAA).

Basics of Health Privacy

This module discusses the basic privacy protections for health information provided by HIPAA, and other legal-regulatory and non-government sources. It identifies the duties and responsibilities of persons with access to protected health information (PHI) in order to fulfill privacy protections.

For additional information on available CITI training and instructions for accessing the training modules, please see the Office of Compliance and Privacy's pulse page: [Collaborative Institutional Training Initiative \(CITI\) Program](#)

For technical questions about CITI training please see the CITI Support Center: <https://support.citi-program.org>

For questions about the Office of Compliance and Privacy's HIPAA training requirements for researchers, please email hscomply@health.ucsd.edu.

For questions about UCSD OIA training requirements, please see the published guidance [here](#).

Reminder: Deadline to Begin Using New ICF, Assent, and Protocol Templates

Back in December 2021, OIA quietly rolled out three new protocol templates and made them available on our forms webpage [here](#). These templates were designed to complement the Kualu application and not require duplicative information.

With the new rollout of the updated ICF and assent templates, we're ready to make both sets of templates official. As such, starting September 1st, all new studies (except for secondary use studies which only require the Kualu application) will be required to use the new protocol if one exists (e.g. from an industry sponsor, cooperative group, etc.). Otherwise, you must use one of the three new protocol templates.

Additionally, all new UCSD studies requiring an informed consent or assent document will be required to use the new ICF and assent templates starting September 1st.

Reminder: Renewal of Business Systems Accounts

As we approach the end of 2022 we are now past the one year anniversary of the beginning of the Kualu transition. Since access to Kualu is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kualu. 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 Kualu, 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 department policies on renewing (or not) accounts in a timely fashion so that researchers do not lose access to Kualu. Furthermore, please be on the lookout for automated emails asking you to renew access for these individuals throughout the course of the year.

Reminder: Getting Help

[Kualu 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 Kualu 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 with questions or to report errors/issues. For questions about Kualu 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.

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