UC San Diego
INSTITUTIONAL REVIEW BOARD ADMINISTRATION

human research news

August 17, 2022

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NEW: Updated ICF and Assent Templates

After a lengthy period of development, fine tuning, and stakeholder input, OIA is pleased to announce the lauch of our new ICF and assent templates. The new templates can be downloaded from our forms page here. In addition to updating our main ICF template, we've updated our adolescent and child assent templates to match. We've also created an Exempt Information Sheet template to be used with Exempt studies (e.g. surveys, interviews, focus groups, etc.) where there will be interactions with subjects.

Why did OIA make new templates?

There were a number of reasons for issuing new templates. First, the previous templates hadn't been updated since the initial release of the Revised Common Rule back in 2019. Safe to say, we've learned a lot about the workings of the Revised Common Rule, the intent of the regulators, and the consent process since then so it was time for an update to reflect that new knowledge.

Second, there have been changes here at UCSD (the IRB's name change from HRPP to OIA, roll out of the UCSDHP 340.1, increase in use of electronic consent, etc.) that necessitated updates to the language in the documents. Third, we wanted to provide more template text for researchers so that there is less guess work in crafting an ICF and assents that will be acceptable.

So what changed in these new templates?

The child assent template stayed more or less the same; however, the main ICF template and adolescent assent template received the majority of the updates. Probably the most notable change is the formatting of the documents. While we generally kept the same question and answer format, the sections are now all numbered, and the fonts and organization of the document have been updated to provide a better flow when going through the document with a subject.

Another major change is that we've combined the Social/Behavioral and Biomedical ICF templates into one document which can now be used for adult subjects, adult subjects requiring surrogate consent, and parental permission for minor subjects. What used to be four separate templates has been combined into one.

As mentioned earlier, we've also provided a lot more template text for researchers. This is probably most notable in the risks section (Section 9) as we have provided template text for the most common procedures where researchers had struggled to write descriptions in the past. Additionally, in the section on confidentiality (Section 10) we've included new standard language to inform subjects participating in certain biomedical studies about how their participation in a qualifying study will be linked to their medical record, if they have one, and that a medical record will be created for them if they don't have one already in compliance with UCSDHP 340.1.

Is there anything we should pay particular attention to with these new templates?

Please pay special attention to the instructions throughout the documents written in red text. These will tell you exactly what information the IRB is looking for in these sections or when to include template text that has been added. Following the instructions in red will help to reduce the number of times the submission goes back and forth between OIA and the researcher.

As always, the number one issue we see with submissions in OIA is consistency. Please ensure that the information included in the ICF and any assents is consistent with what is described in the study protocol and Kuali application.

Is there a Rady Children's version of this form?

Not yet. We are working with the RCHSD research office to develop a joint UCSD/RCHSD version of the form. We will send another announcement and post the joint form on our website when it is ready.

NEW: 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 webpage here. These templates were designed to complement the Kuali 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 Kuali application) will be required to use the master 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 Kuali transition. Since access to Kuali is controlled through IT systems, some folks (RCHSD researchers, students, etc.) had to obtain business systems accounts to be able to access Kuali. Those accounts are generally good for only a year and need to be renewed. As such, we want to remind everyone about this.

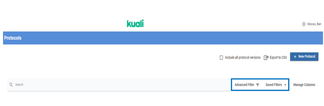
If you are a **user** who has a business systems account that you use to access Kuali, check in with the department who sponsored your account to see if there is anything they need you to do to ensure your account is renewed.

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 Kuali. Furthermore, please be on the lookout for automated emails asking you te renew access for these individuals throughout the course of the year.

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. This will help the OIA team triage and troubleshoot.

University of California San Diego, 9500 Gilman Drive, La Jolla, CA, 92093