UCLA Research Administration
Human Research Protection Program

Human Research News

March 14, 2024

1) BruinIRB Phase II Update

- BruinIRB Phase II is expected to launch this year in late summer/early fall. Future *Human Research News* will announce the date for accepting new studies in BruinIRB as well as the migration of current studies from webIRB to BruinIRB. Please visit the Electronic Submission Systems page on the OHRPP website for training materials and details on the latest stage of the BruinIRB transition.

- Reminder – At present, BruinIRB is only accepting the following applications. All other applications should be submitted in webIRB until further notice.

    - UCLA relying on another IRB
    - Emergency Use
    - Humanitarian Use Device (HUD)
    - Right to Try
    - Expanded Access (Drug and Biologics and Device)

2) Updates to Educational Materials Supporting the Expansion of IRB Reliance for Industry-Sponsored Clinical Research

- Thank you for your feedback and questions regarding the implementation of the expansion of reliance for industry-sponsored clinical trials. The following items have been updated:

    - 18 new items added to the FAQs for Commercial IRB Review
    - A new workflow diagram, Steps to Serve as the Relying IRB, has been updated to incorporate the process for requests to rely on Advarra or WCG.
    - Updates to Consent Form Checklist for Reliance on External IRBs include:
        - flexibility related to the use of Sponsor's template describing costs related to participation
        - an additional template injury section language to be used for research subject to Section 111 of the Medicare, Medicaid, and S_CHIP Extension Act (MMSEA 111.)

- clarification that the template statements regarding the separately required UCLA HIPAA authorization form and the distribution of the Subject's Bill of Rights as required under California law should be included (as applicable)

- Please continue to direct any additional questions or feedback to irbreliance@research.ucla.edu to help us maintain the usefulness of IRB reliance educational resources.

3) Completing the Migration Process for Reliance Studies

- OHRPP previously migrated reliance studies from webIRB to BruinIRB

- As part of the migration process, investigators were instructed to submit an amendment to complete items new to the BruinIRB system

- Reminders will be sent through BruinIRB to investigators who have not yet submitted the needed amendment to complete their reliance application

4) Reliance Studies that have been migrated to BruinIRB and use of the *Edit Study Details* Activity

- As previously announced, the *optional* Update Study Details activity, was added to BruinIRB to allow study teams to upload revised protocol versions and consent forms approved by an external IRB but that do not require submission and review by UCLA OHRPP (to allow for the revised documents to be passed through to the study file in OnCore).

- To see and use this feature, reliance submissions *migrated from webIRB* must **FIRST** submit an amendment to address new and required questions in BruinIRB.

5) Advarra and WCG Presentational Materials Available for Review

- The following OHRPP Learn at Lunch video presentations have been posted to the new OHRPP Educational Library on YouTube:
  - Preparing a Request to Rely on a Commercial IRB (Presenter: Rebecca Flores Stella)
  - Preparing Submissions to Advarra Presenter: Andrew Saunders)
  - Preparing Submissions to WCG (Presenter: Andy Parkhurst)

- The slides from the Advarra and WCG training sessions have been posted to the OHRPP commercial IRB reliance webpage.

6) OHRPP's "Learn at Lunch" – *upcoming presentation*

"***The meaning and limits of IRB approval"***

Presented by Moore Rhys, OHRPP QIU

This session will cover what it means (and doesn't mean) to receive IRB approval. Topics include review of policy 991 which authorizes the IRB to conduct human subjects review and other university policies and practices that may limit the conduct of research, regardless of IRB approval.

Date: **Wednesday March 20, 2024**
Time: **Noon-1pm**
Location: **Zoom** (Register for this meeting)

7) OHRPP's Office Hours

Register once to join any session:

Upcoming Office Hours:

- March 14, 2024, at 2pm
- March 28, 2024, at 2pm

8) Additional Training Opportunities

- OHRP's Participant-Centered Informed Consent Training Program (on-demand)
  - This interactive online program consists of 6 modules and delivers a comprehensive training for creating, designing, and reviewing consent forms or templates for the purposes of ***ensuring that prospective research participants understand the content and appreciate how it relates to them***.
- The MRCT at Brigham and Women's Hospital presents their new clinical research glossary: New Words, New Opportunities (9-10am PT, 4/2/2024)
  - This plain-language global standard has been developed at the MRCT in collaboration with CDISC for research participants ***and anyone interested in developing easy-to-understand research materials***.