

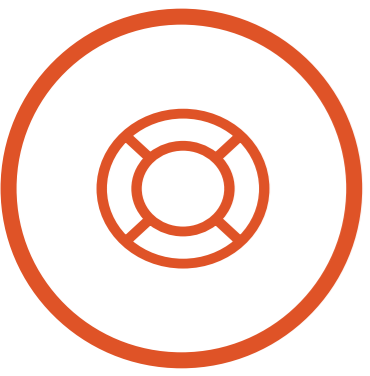


OHRPP WebIRB Updates & Announcements

July 14, 2022

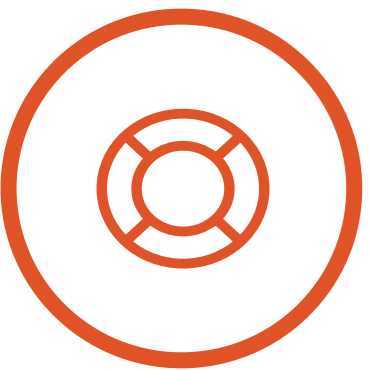
OHRPP Updates





webIRB Update

- ***In support of new UCLA Policies 916 & 917***, ORIS has updated a few functions in webIRB.
- The policies are effective as of 6/30/2022, and we anticipate a BruinPost from Vice Chancellor for Research and Creative Activities announcing these policies soon.
- These new functions **will go live in webIRB on July 22, 2022**
- webIRB will be down for a few hours in the late afternoon on July 21, 2022 in order for ORIS to update the system. A reminder about the downtime will be posted in webIRB.



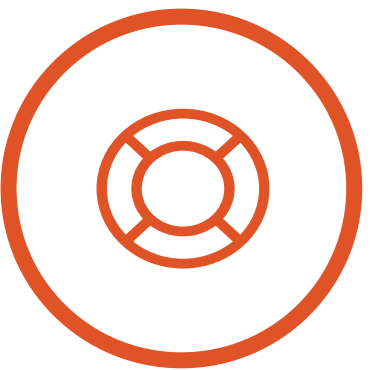
webIRB Update – SRC (Policy 916)

- ***Summary of the Policy:***
 - Establishes a new process for *required review of clinical trial protocols** by an internal, independent scientific review committee
 - Excludes studies that have received external scientific review
 - Excludes studies that are reviewed by ISPRC For complete review criteria and workflow, please see [this chart](#)
 - Review will be ***sequential***. When applicable, SRC review will come first then IRB review.

* Protocols that meet the [NIH definition of a clinical trial](#)

webIRB Update – SRC (Policy 916)

- ***Operationalizing of the Policy:***
 - When a new application (that meets the requirement for CTSI SRC review) is submitted to the IRB through webIRB, it will be re-routed in the webIRB system for review by the SRC.
 - Once the SRC process is completed, the SRC signs off on the protocol and it moves along to IRB review



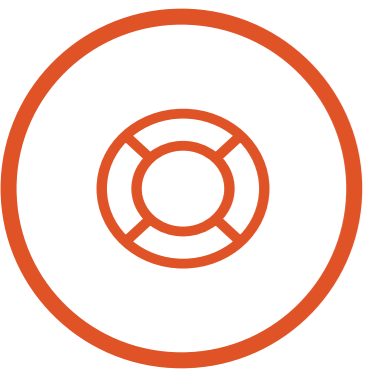
webIRB Update – GCP (Policy 917)

- **Summary of the Policy:**
 - Establishes a new training requirement for key personnel conducting research that meets the NIH definition of a clinical trial
 - *This expands the previous requirement for GCP training for key personnel on NIH-funded clinical trials to key personnel conducting clinical trials, **regardless of funding source***



webIRB Update – GCP (Policy 917)

- ***Operationalizing of the Policy:***
- The webIRB system will conduct an ***automatic check*** to ensure GCP training has been completed by key personnel when:
 - An initial application is submitted
 - When an amendment is submitted
 - When the “edit study personnel” function is used
- This automatic check will follow the same process as the check for human subjects training already in place.



webIRB Update – GCP (Policy 917)

As a reminder:

- GCP training is completed through [CITI](#)
- ***GCP training can meet both the GCP requirement AND the human subjects training requirement.***
- ***For this reason, we recommend that key personnel conducting clinical trials consider using GCP training to meet their minimum requirements for human subjects training***
- For more details on GCP training, please review [this page](#)



Learn at Lunch

“Operationalizing UCLA Policies 916 & 917”

July 28, 2022 at noon

joint presentation by CTSI SRC and OHRPP

[Register for the zoom link](#)

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Reminder – BruinIRB Phase 1b launched 7/1/2022

- All new abbreviated applications (HUD, RTT, Emergency Use, Expanded access) *as well as all reliance applications* should now be submitted via [BruinIRB](#)
- Please bookmark OHRPP's [Electronic Submission Systems webpage](#) for the current status of the BruinIRB roll-out

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OHRPP Office Hours

- OHRPP Quality Improvement Unit staff are hosting *half-hour open Q/A sessions every other week* to answer your questions
- *Upcoming sessions*
 - Tuesday, July 19, 2022 8:30am
 - Tuesday, August 2, 2022 8:30am

Register once and you can join any session.



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Contact

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