SIRB FOR INDUSTRY-SPONSORED CLINICAL TRIALS

UCLA Research Administration
COMMERCIAL IRB RELIANCE: ORDER OF REVIEW

This is a basic framework for WCG and Advarra. For other IRBs, there may be a slightly adjusted process.

SUBMIT TO REVIEWING IRB
Obtain overall approval from the Reviewing IRB. Application is usually submitted by the Sponsor.

SUBMIT TO ANCILLARY COMMITTEES
Obtain review/approval from ancillary committees (as applicable) before OHRPP can issue an “external review accepted” letter. This includes MRSC, CIRC, hPSCRO, and IBC.

PREPARE THE LOCAL UCLA CONSENT(S)
Take the reviewing IRB’s approved consent template(s) and make local context changes per the reliance consent checklist.

SUBMIT TO OTHER UCLA OFFICES
Consult with Sponsor to determine who submits this. AM. Receive approval from the reviewing IRB to begin at UCLA site.

SUBMIT TO OHRPP
In the BruinIRB application, provide the overall IRB approval and any ancillary approvals obtained in the BruinIRB application. Provide the UCLA-specific consent(s). Request HIPAA waivers for screening (if applicable). Obtain “External Review Accepted” (ERA) letter.

READY* TO START ENROLLMENT AT UCLA
*Pending other UCLA and external approvals (such as finalizing the contract, setting up accounts and regulatory binder, Sponsor’s site initiation visit, etc...)

SUBMIT LOCAL SITE CONSENT & ERA LETTER TO REVIEWING IRB VIA AMENDMENT
Obtain review/approval from ancillary committees (as applicable) before OHRPP can issue an “external review accepted” letter. This includes MRSC, CIRC, hPSCRO, and IBC.

SUBMIT TO OHRPP
In the BruinIRB application, provide the overall IRB approval and any ancillary approvals obtained in the BruinIRB application. Provide the UCLA-specific consent(s). Request HIPAA waivers for screening (if applicable). Obtain “External Review Accepted” (ERA) letter.
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view after SSO login (in the "Dashboard"):

First, click "create"

Then, click "create new study"
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s “basic study information” page:

Item #1 is the same as “full title” in webirb. This is the protocol title that will be on “external review accepted” letters.

Item #2 is the same as “working or lay title”

For item #4, it’s important that you check “multi-site” for sIRB studies.
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s "basic study information" page:

Item #5 should have “yes”

Item #7 is only required when the PI does not qualify under UCLA Policy 900 and they do not have an exception letter

Item #8: the protocol should be the multi-site protocol approved by the reviewing IRB

Item #9 is included to help the system forward the reliance application to the correct staff team inside OHRPP. The application will not be reviewed by the IRB.
For most studies, this response will be “all”
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application's “external IRB” page:

Item #1: Click the “…” for a pop-up window of all entities with which we have reliance agreements. Type the first few letters of the company being used and hit “go”. Note: WCG is listed under “Western Copernicus Group (WCG) IRB”

Item #2: This is the study code created by the reviewing IRB (similar to how UCLA uses IRB-YY-XXXX)

Item #3: For industry-sponsored clinical trials, you can just indicate “UCLA policy”
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s “study funding sources” page:

Item #1: click “add” and the pop-up window on the right will appear.
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s “additional local funding sources” page:
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s “local study team members” page:

Item #2 is auto-populated from the account of the PI indicated in “basic study information” section.
Item #3: select “none of the above” for reliance studies
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s "study scope" page:

7. * Federal regulations (45 CFR 46.111) require scientific review before an IRB approves a study. For the majority of studies being reviewed and approved by the UCLA IRB, the IRB performs this review. Has the study received scientific review external to UCLA?
   - [ ] Yes
   - [ ] No
   - [ ] Clear

8. * Is this study cancer relevant? A study is cancer relevant if it meets any of the following criteria:
   - Intends to treat, prevent, or diagnose cancer
   - Improves comfort for or quality of life of cancer patients
   - Assesses cancer risk, outcomes or therapy response, including epidemiologic/observational/lab-based studies
   - Focuses on cancer
   - Recruits a participant population primarily made up of cancer patients, cancer survivors or those at risk of developing cancer
   - Collects cancer human biological samples, specimens or data
   - [ ] Yes
   - [ ] No
   - [ ] Clear

9. Does this study involve human gene transfer/recombinant DNA?
   - [ ] Yes
   - [ ] No
   - [ ] Clear

10. Does this study require review with the UCLA Institutional Biosafety Committee (IBC)?
    - [ ] Yes
    - [ ] No
    - [ ] Clear
For item #1, we mean locations under the UCLA local PI responsibilities, not collaborating sites.
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s “drugs” page:
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s “devices” page:

Item #2: Be sure to select the device status consistent with the determinations made by the reviewing IRB.
Item #1: The consent(s) should be the template consent(s) approved by the reviewing IRB modified to include UCLA-site-specific language.

Item #3: This is where the reviewing IRB’s approval should be uploaded. The approval(s) uploaded should include all of the reviewing IRB’s current determinations.
RELIANCE SUBMISSION THROUGH BRUIINIRB

Investigator/staff view of newly created application’s “HIPAA (site)” page:

Item #1 is where you would request a waiver for screening & recruitment and indicate that you will obtain HIPAA authorization before collecting information from or providing study information to UCLA medical records.

Item 2: if you are requesting a HIPAA waiver to identify potential subjects, ensure that all boxes are checked.
RELIANCE SUBMISSION THROUGH BRUINIRB

Investigator/staff view of newly created application’s “clinical research form (site)” page:

All items: this is information that SRC and CRMS requested OHRPP collect. **OHRPP does not review this content.** However, it may be used for downstream purposes in UCLA Health and may also affect the study information in OnCore.
RESOURCES FOR BRUINIRB & SINGLE IRB

- BruinIRB training guides can be found at the bottom of [this OHRPP page](https://example.com) [reliance applications may only be submitted through BruinIRB]
- Information on UCLA relying on another IRB can be found on [this OHRPP page](https://example.com) (including what should and shouldn’t be submitted to OHRPP as amendments, annual assurances for continuing the research at UCLA – instead of CRs)
- The [Consent form checklist for reliance on external IRBs](https://example.com) is an essential tool for making only the permitted, local changes to consent documents (from the IRB-approved template)
- Only very limited types of PARs should be submitted to OHRPP when UCLA is relying on another IRB. Please review pages 13-16 of the [PAR guidance](https://example.com) for details
- SMARTIRB (NIH-funded project) has lot of resources for Investigators on sIRB including:
  - [Relying on an External IRB: FAQ for research teams](https://example.com)
  - [Relying Investigator Guidance and Checklist](https://example.com)
  - [Considerations for a single IRB Model](https://example.com) (video from the University of Utah)
  - Single IRB from the perspective of Research Teams ([video](https://example.com) and [slide deck](https://example.com) from SMARTIRB)
- OHRPP [Guidance and Procedure: Reliance](https://example.com)