**Relying Investigator Guidance and Checklist**

As Principal Investigator at the **Relying** **Institution** for a study that may be overseen by an external IRB, you should be aware of your responsibilities. Once you have agreed to collaborate with an investigator at another institution and intend to use an external IRB for oversight of this study:

Confirm whether:

Ceding IRB oversight to an external IRB is appropriate via:

Reviewing [UAMS IRB Policy 2.3, *Use of Single/Central IRBs*](https://irb.uams.edu/wp-content/uploads/sites/127/2020/05/IRB-Policy-2.3-April-2020-version-FINAL.pdf)

Determining whether the overseeing IRB is AAHRPP accredited by checking at <https://www.aahrpp.org/learn/find-an-accredited-organization>

Contacting the UAMS IRB at [irb@uams.edu](mailto:irb@uams.edu) with any questions about whether we can cede review

Begin the CLARA submission

The new submission form will ask if we are ceding review to another IRB. Check “yes” and provide the requested information.

Obtain:

**A** copy of the approved studywide protocol, template consent and HIPAA document(s), and any other approved study documents.

Relevant forms from the study sponsor or reviewing IRB:

Local context forms, in which the site indicates any local site requirements

Any contracts or other legal agreements – assure these receive appropriate legal review

The reliance agreement (this may be a paper document, or may be done through SMART IRB)

The study’s most recent full approval letter from the overseeing IRB (either original approval or continuing review, whichever is applicable)

Complete the forms you obtained in the steps above.

Local study team completes the local context form, with assistance from the IRB office if necessary.

Review IRB Policy 15.1 for local context consent requirements related to mandated reporting of suspected abuse/harm and/or infectious disease. These must be listed on the local context form.

Local study team completes the study-specific information on the reliance agreement (i.e. entering study title and other local site information) and forwards to IRB office for signature.

Local study team revises any study material, particularly the informed consent, to conform to local requirements, including but not necessarily limited to the below. The IRB:

Mandatory reporting language

Injury language

Language about additional costs

Local study team contact information

Formatting

Complete the CLARA submission

In documents, upload all:

**☐** Centrally approved documents (protocol, consent/HIPAA templates, any other material

Locally adapted versions of consent and HIPAA

A copy of the fully executed reliance agreement, if not done through SMART IRB system

A copy of the most recent xIRB full study approval letter

Promptly respond to questions or requests for information from the Lead Study Team (or their designee), the Reviewing IRB and the UAMS IRB/human research protection program.

Participate, as required, in conference calls regarding a study as requested by the Lead Study Team, Reviewing IRB, or your local IRB/HRPP.

Become familiar with the reportable event policy of the Reviewing IRB to ensure that you appropriately report protocol deviations, noncompliance, significant subject complaints, subject injuries, unanticipated problems, or other events required by the Reviewing IRB to be reported and within the timeframes required.

Ensure that all local reviews and sign offs that, in addition to IRB approval, are in place before a study is activated, such as coverage analysis, department approvals, data use agreements, material transfer agreements, ancillary committee reviews (e.g., radiology, nursing, and pharmacy).

For externally funded studies, provide your sponsored programs office with documentation that IRB oversight for a study has been ceded to and approved by an external IRB.

Notify local IRB administration/HRPP personnel of any staff changes through CLARA so they can confirm their training is current and help ensure any relevant COI management plans are communicated to the Reviewing IRB.

Notify the lead PI of:

* + - Any reportable events that occur locally, according to regulations and the Reviewing IRB’s policy.
    - Any changes (including those related to funding and personnel) in accordance with the Reviewing IRB’s policies and procedures for timing and content of such submissions.
    - Any management plans, including any updates to these plans, as relevant to the study.
    - Any applicable information for continuing review progress reports in accordance with the Reviewing IRB’s policies and procedures for timing and content of such submissions.

Follow all determinations of the Reviewing IRB.

Only implement changes of protocol, including local variations, after the Reviewing IRB has approved them, except in cases where a change is required to avoid an apparent immediate hazard to participants.

Provide, upon request, access to study records for audit by the local institution, the Reviewing IRB’s institution, and other regulatory or monitoring entities.