**“UAMS as reviewing IRB” investigator checklist**

This checklist is intended for use when a **UAMS investigator is involved in a multisite research project for which the UAMS IRB will be the IRB of record.**

Once you have determined that your multisite study will use the UAMS IRB as the IRB of record for multiple sites:

Review UAMS IRB Policy 2.3, *Use of Single/Central IRBs*. [See link under “Resources” here.](https://irb.uams.edu/resources/single-central-irb-review/)

Email the IRB office at [irb@uams.edu](mailto:irb@uams.edu) to let them know we will be the IRB of record for a multisite study. Neitrisha Harris is the IRB office’s xIRB coordinator.

Helpful, but not required: Determine whether each participating site has its own Federalwide Assurance (FWA). [You can look them up here](https://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc). The collaborating site contacts can help with this, as can the IRB office.

Helpful, but not required: Determine whether the participating sites participate in the SMART IRB system. [You can look that up here](https://smartirb.org/participating-institutions/). Again, the collaborating sites and the IRB office can help with this.

Begin the CLARA submission

The new submission form will ask if the UAMS IRB will be the IRB of record for a multisite study. Check “yes.”

In the form’s “sites” section, list the sites that will rely on the UAMS IRB for IRB oversight.

Two things to note here.

This list can be amended through modification forms as site participation changes through the study.

**This list is not sufficient to formally add a site to the study. A second step, the site addition modification form, will be required later.**

Continue with the new submission process, including submitting documents.

Protocol

TEMPLATE informed consent form, if applicable. Each site will later customize the form to their specific site requirements.

HIPAA authorization form template, if applicable, assuming all sites will use the same HIPAA authorization form.

UAMS-specific Informed consent and HIPAA authorization forms, based on the template. (Note: you may wish to submit these only after the templates are approved.)

Any other study documents. Note that if there are other documents the participating sites will adapt for their local use, e.g. recruitment materials, submit templates of these items with the original submission.

The study will undergo the usual prereview and IRB review processes. While that’s happening, the IRB office will help you with the following:

Getting any necessary local context forms from the relying sites, as applicable. [(See link under “Resources” here.)](https://irb.uams.edu/resources/single-central-irb-review/)

Completing the reliance agreements.

After the IRB has approved the overall study:

Submit a site addition form to officially add each site to the study.

Include with the form the signed reliance agreement and any site-specific forms, such as the consent and HIPAA authorization form, recruitment materials, etc.

Any site specific document changes are to be submitted to the UAMS IRB by modifying each site’s site addition form (the only CLARA form that can be modified after initial approval).

Note: If you need to modify a template document, such as the informed consent, get that overall modification approved first. You will then submit a separate site addition modification form for each site that will adapt the revised template document to their own site.

**The IRB office is available to help you with this process. Contact us at** [**irb@uams.edu**](mailto:irb@uams.edu)**. Neitrisha Harris is our xIRB coordinator.**