Before assuming the overall Principal Investigator/ Lead Study Team roles for a multisite study where the DUHS IRB may serve as a single IRB for all or most sites, you should be aware of your additional responsibilities in assuming that role.

Have adequate resources and qualified study team members (i.e. study coordinators, regulatory coordinators and research staff) to conduct and manage the study.

Determine and document specific roles and responsibilities for communicating and coordinating key information to relying institutions; this includes developing a plan for communicating with collaborators across the lifetime of the study (i.e. regular conference calls, site initiation procedures and training materials).

Promptly respond to questions or requests for information from study teams and IRB personnel at institutions who are relying on the DUHS IRB.

Obtain all required documentation to add on relying sites (e.g., reliance agreements, local context, etc.)

Provide the relying sites with the applicable DUHS IRB policies. This includes, but is not limited to, policies for reporting unanticipated problems, noncompliance, and subject complaints.

Provide participating relying sites with the IRB-approved versions of all study documents (e.g., consent and authorization forms, protocol, recruitment materials).

Prepare and submit IRB applications on behalf of all relying sites, including initial reviews, local amendments, local reportable events, and studywide information for continuing review.

As part of preparing the IRB application, the DUHS lead study team must

* + - Obtain and collate information from relying site, regarding local variations in study conduct, such as recruitment materials and process, consent process and language, and subject identification processes.
    - Ensure consent documents follow the DUHS IRB’s template form and include applicable site-specific required language from each relying site.

Notify the relying site PI/study team of all study-wide DUHS IRB determinations and communications, including those for initial review, continuing review, amendments, and reportable events.

When agreed upon in coordination with the DUHS IRB, promptly report to the relying site PI/study team any unanticipated problems involving risks to subjects or others research-related subject injuries, or significant subject complaints that are related to or may affect subjects participating in the research at the relying institution.

If a relying site study team does not provide the lead study team (or designee) with the required information before the continuing review application is submitted to the reviewing IRB, reports the absence of this information as part of the continuing review and notifying affected relying site study team of lapse in approval for their site and any applicable corrective action plans.

Providing access, upon request, to study records for audit by the relying institution, the reviewing IRB, and other regulatory or monitoring entities.

Follow all requirements of the relying institution with regard to ceded review, such as ensuring administrative requirements for documenting ceded review have been met before study activation occurs at a relying institution.