IRB TIP: REQUIREMENTS WHEN LLUH IS THE COORDINATING INSTITUTION/LEAD SITE
IRB GUIDANCE FOR IMPLEMENTING FEDERAL AND INSTITUTIONAL IRB POLICIES

In general, the Coordinating Institution or Lead Site has the ultimate responsibility for providing administrative oversight, management of data, and the provision of organizational support in the conduct of a multi-site research project. If an LLUH faculty is designated as the Lead Site PI for the conduct of a multi-site research project, the IRB will require the following information to ensure there is appropriate regulatory oversight and that management of information relevant to the protection of human subjects is adequate. Information reviewed by the IRB will include, but is not limited to, the following:

1. Regulatory Documentation
The Lead Site PI will specify a plan for managing the regulatory documentation (e.g. informed consent document, protocol amendments, site IRB approvals, etc.) from each of the participating sites. The Lead Site PI will also require each participating site to maintain and manage its own regulatory documentation according to their institutional policies and procedures.

2. Participating Site Communication Plan
The Lead Site PI will describe the plan for documented communications between participating sites and LLUH. Communications may include information on changes to the regulatory documentation (research protocol, informed consent document, etc.), interim analysis on the progress of the research project, or safety reporting.

3. Reporting of Serious Adverse Events and Unanticipated Problems
The Lead Site PI is responsible for the development, collection, and maintenance of a plan to review, in a timely fashion, all serious adverse events and unanticipated problems. LLUH is responsible for meeting the reporting timelines to the IRB as described in the research protocol, as well as monitoring the participating sites reporting obligations to their own IRB and LLUH.

4. Data Collection and Analysis
The Lead Site PI is responsible for either the development of case report forms, or other data collection instruments, or delegating the task to another site. The Lead Site PI is also responsible for managing retention of documents according to institutional or sponsor policies and procedures. If the Lead Site PI also has the responsibility of data coordination, then he/she should provide the IRB with a plan for the review of the study data and the submission of any required interim analysis results sent to participating sites.

5. Participating Site Training
The Lead Site PI should confirm that investigators at all participating sites have received appropriate Human Studies training for the conduct of the project and understand the regulatory reporting requirements. In general, the Lead Site PI should ensure that the participating sites are familiar with the research project design and procedures, reporting of serious adverse events and unanticipated problem(s), administration and documentation of study drug or device dispensation, compliance monitoring, and record retention.

6. Additional Responsibilities
The Lead Site PI should determine the plan for delegation of authority within the study team and the participating site(s), for ongoing project management as necessary. The Lead Site PI is responsible for ensuring appropriate IRB approval is obtained by sites prior to initiation of the project at that site.