**Lead Site/Coordinating Center Investigator Responsibilities
Addendum to IRB Application**

The terms ‘Lead Site” and ‘Coordinating Center’ (CC) cover a number of very different research-related activities that range from a data center focused on the aggregation, management, and analysis of data from multiple sites, to a study-wide center responsible for overseeing all aspects of a multi-site study. Because the nature of these activities may vary from study to study, depending in part on the design of the study and the type of funding, it is critically important that investigators accurately describe to the IRB exactly what their responsibilities are – as detailed in the grant application or contract.

*For each of the activities listed below, if you are assuming responsibility, provide a response or respond ‘N/A’ if not within your scope of work. If you are responsible for overseeing all aspects of a multi-site study, you must provide a response to all questions.*

1. Describe your plan for selecting appropriately qualified study sites.
2. Describe your plan for ensuring that all collaborating institutions hold an OHRP-approved Federalwide Assurance (FWA).
3. Describe your plan for providing study-specific training for personnel at all sites.
4. Describe your plan for collecting and maintaining essential documents, e.g., resumes/CVs, medical licenses, certifications of training, laboratory certifications, laboratory norms, etc.
5. Describe your plan for reviewing and submitting each site's site-specific documents (e.g. consent documents, recruitment materials) to the IRB for review.
6. Describe your plan for assuring that each site receives the current version of the protocol, and when applicable, protocol amendments and other study-related communications.
7. Describe your plan for assuring that informed consent is obtained and documented from each participant in compliance with federal regulations and local IRB requirements.
8. Describe your plan for tracking enrollment, and when applicable, randomization to treatment.
9. Describe your plan for tracking, reporting and maintaining documentation of all unanticipated problems involving risks to subjects and disseminating related information (e.g. revised protocols, consent documents, and for sites relying on the UNC-Chapel Hill IRB, IRB determinations) to all sites.
10. Describe your plan for auditing and monitoring on a periodic basis, to assess compliance and progress.
11. Describe your plan for securing compliance at external sites that are not adhering to the current approved protocol and/or good clinical research practices.
12. Describe your plan for designing data forms and providing instructions for the use of the forms.
13. Describe your plan for the collection and management of data across all sites/locations participating in the research.
14. Describe your plan for managing data and statistical analysis.
15. Describe your plan for overseeing secure data transmission and storage.