

## Are you prepared to be the Lead/Coordinating Site for a Multi-Site Study using a Single IRB?

Do you have the staff, knowledge, resources, and systems in place to handle each of the following...

1. Handling of any **proposal preparation** and award setup (and if NIH-funded, speaking with your NIH Program Officer regarding whether the study falls under the NIH Single IRB Mandate and speaking with your IRB regarding the Single IRB Plan)
2. **Drafting of the initial protocol** and initial consent and authorization documents and recruitment materials (and any updates of these)
3. Providing of administrative, clinical, and technical **expertise and leadership in the design** and coordination of the research to Lead and Relying Study Team members
4. Navigation of **the reliance request process** with the Reviewing IRB
5. Assurance that the Relying Study Team undergoes their local IRB reliance request process (providing them with all of the information, documents, and support necessary for the to undergo the process)
6. Assurance that any non-institutional individual investigator without a designated IRB signs an **Individual Investigator Agreement** and undergoes conflict of interest disclosures and is added to the Lead Study Team at the time of initial submission or amendment submission
7. Application of any **waivers of consent or HIPAA authorization** studywide
8. Assurance of **data use agreements** being established with the relying sites
9. Creation of a **Data Management Plan** which includes the relying sites
10. **Data management responsibilities** (creating and managing case report forms, handling data quality control, data collection, editing data, preparing administrative and management reports, and taking care of data analysis)
11. Studywide **management and security when storing** the data or specimens
12. Studywide management of **statistical reporting and analysis** (developing the Statistical Analysis Plan and the presentation of data in listings and tables for the DSMB)
13. Studywide **Data Safety Monitoring Board (DSMB)** management
14. Tracking of the **Points of Contact** (IRB and Relying Study Team) at the relying sites
15. Notification to the relying sites about any **key information** they need across the lifetime of the study (i.e. holding regular conference calls, guiding them through site initiation procedures, developing and providing training materials)
16. **Prompt responses** to questions or requests for information from the Relying Study Teams, Relying IRB staff, or Reviewing IRB staff
17. Notification to Relying Study Teams of **updates to the Reviewing IRB's policies** and procedures

18. Providing to Relying Study Teams all **IRB-approved versions** of all study documents (e.g. consent and authorization forms, protocol, recruitment materials) throughout the life of the study
19. Preparation and submission of **the initial IRB submission**
20. Collection of **site-specific information and documents** (including Local Context Worksheets, fully-executed reliance agreements, site-specific consent and authorization documents, and other reliance-specific forms) from Relying Study Teams
21. Submission of amendments to the Reviewing IRB to **onboard each relying site**
22. Preparation and submission of **studywide amendments** to the study
23. Collection of site-specific information and documents from Relying Study Teams and submission of **site-specific amendments** to the Reviewing IRB on behalf of each relying site any time a site-specific change is needed at any one site
24. Collection of studywide information, lead site information, and relying site-specific information in order to submit **continuing review progress reports**
25. Notification to Relying Study Team of **lapse** in IRB approval for a particular Relying Site or studywide
26. Notification to the Relying Study Team any applicable **CAPA plans**
27. Collection of studywide information, lead site information, and relying site-specific information needed in order to **close out** the study
28. Closing out of study (studywide or for any one relying site) with the IRB and providing of the IRB's **close-out documentation** to the Relying Study Team
29. When agreed upon in coordination with the Reviewing IRB: Prompt report to the Relying Study Teams of 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 (i.e., the specific study or studies ceded to the Reviewing IRB) at the relying site
30. Report to Reviewing IRB of the **absence** of the information as part of the continuing review if a Relying Study Team doesn't provide the Lead Study Team with information for continuing review submission
31. Management of **regulatory documentation** for the lead site and relying sites
32. Creation of a **Manual of Operations binder** containing all information required by each relying site to complete the study and providing of the Manual to each Relying Study Team
33. Assurance that the **Relying Study Team understands** the regulatory and institutional reporting requirements
34. Management and responsibility of the plan for **delegation of authority**
35. Maintenance of up-to-date **study team staff listings** for the Lead Study Team and Relying Study Team
36. Notification to the Reviewing IRB of **study team members to be added or removed** from the submission studywide (ensuring that each added member has adequate training and has submitted conflict of interest disclosures)
37. Assurance that there is **studywide compliance** with FDA or other regulations (if applicable)