# Lead/Data Coordinating Center Protocol Template

**Background:** In a multicenter study, an individual or several individuals are generally responsible for the coordination of all phases of the collaborative research study. This may be limited to the review and oversight of adverse events or data; or may encompass all aspects of administrative, clinical and technical expertise and leadership in the design and coordination of the multi-site collaborative study. The following information is being offered as guidance for developing a protocol to address the investigator's role and responsibility as the overseer of a data-coordinating center.

**Definition of Data Coordinating Center:** A data-coordinating center is defined as a site that is responsible for the collection, verification and storage of data collected from all sites involved in a multi-site trial.

**Instructions:** Provide a full description of the study and outline how the principal investigator will assume responsibility for collection, storage, verification, management, and (if applicable) analysis of data collected on subjects from all sites involved in a multi-site trial. The protocol should include the elements outlined below.

1. **Protocol Title:**

2. **Version Date:**

3. **Principal Investigator's Name and Address:**

4. **Lead site and PI:**

5. **Study Description:** A description of the overall study including background, aims and significance.

6. **Site Information:**
    a. A listing of all sites that CW will receive data from.
    b. If the CW PI is responsible for ensuring that each site has obtained IRB approval, provide the name of the local IRB or other human subject protections entity responsible for the review and approval of research conducted for each non-local site. A copy of the IRB approval letter from each site should be submitted to the CW IRB once obtained.

7. **Inclusion/Exclusion Criteria:** Description of subject recruitment outlining the inclusion and exclusion criteria.

8. **Data Collection Instruments:** Copies of all data collection instruments/forms to be used by investigators at all sites. Provide detailed instructions for completing each item on each form (if needed), any variables that might be encountered, the frequency of collecting the data and how often data are to be sent to the data coordinating center.

9. **Training:** A description of the responsibilities of the data coordinating center principal investigator with regard to training of staff to ensure accurate, consistent instrument training and data management across all sites. Include specific details of any special equipment needed (e.g., scanners, computers, software) for data transfer.

10. **Data Safety Monitoring Plan (DSMP):** The plan must describe steps taken to ensure the integrity of the data from the point of collection and the measures put in place to protect the data during transfer to the coordinating center and storage of the data at the coordinating center.

    a. **Data Transmission:** Provide a description of the data to be sent to the data coordinating center, how it will be sent (paper, electronic, or both), or on what electronic platform (RedCap) and if it will be coded, or sent with identifiers. If coded, clarify who retains the link between the code and subject identifiers. If identifiers are sent, provide justification for doing so. Indicate the specific department/office that will receive the data. Indicate that the investigators at the data coordinating center will review all data for completeness and indicate who is responsible for obtain missing data or correcting errors and how this will be managed.

    b. **Data Storage:** Clarify how long the data will be stored, where it will be stored, who has overall control of the storage area, whether or not the data will be shared with other investigators not listed on the current study, and what will happen to the data should the subject withdraw from the study.

11. **Data Analysis:** If the data coordinating center is also responsible for data analysis, include details of the analysis to be conducted and who will be doing the analysis.