

Clinical Research Center
INVESTIGATOR RESPONSIBILITIES

The purpose of the Clinical Research Center (CRC) is to promote and support patient-oriented research. CRC personnel are prepared to facilitate and document the collection of accurate and timely data to complete the research protocol and to administer the research grant appropriately. Since the CRC provides services to many new investigators, it has proven useful to clarify the CRC's expectations of the Principal Investigator (PI).

Principal Investigator (PI) is responsible for:

1. Informed Consent of each subject.

Beyond the initial pre-screening qualification of potential subjects, informed consent must be obtained before any study procedures or further investigation can be done. The PI is responsible for the consent discussion with the subject. If PI delegates this responsibility to study personnel, the PI ensures that such individuals are fully qualified and knowledgeable enough to explain the study, answer questions and evaluate the subject's understanding of the study before having them sign the form. In addition, the PI needs to ensure that the signature section of the consent form is consistent with the practice (e.g., if Investigator signature is required, a named investigator performs the consent process with the participant and signs the consent form at that time). The consent form must be formatted to allow for signature of "Person obtaining Consent" if CRC staff or other personnel are delegated by PI to perform this responsibility; qualification of the person obtaining consent is the responsibility of the PI.

2. Recruitment/enrollment of subjects.

Identification of pools of potential subjects and development of advertising methods is the responsibility of the Investigator; this may include obtaining permission of other physicians to contact their patients. CRC personnel may be able to help with initial telephone screening by utilizing an intake questionnaire developed by the Investigator. CRC staff coordinating the study may be involved in further screening of individuals found appropriate for consideration during initial pre-screening. Selection of subjects for inclusion in the study is ultimately the Investigator's responsibility.

3. Medication orders.

Physician orders for investigational drugs, study medications and infusions must be written for each participant and, in certain studies, prescriptions must be written for dispensing by the Pharmacy. The Principal Investigator or a Co-investigator must be available in the building during infusions and at any other time required for special procedures (e.g., during observation following investigative vaccinations).

4. Recording of research data in the subject's research record.

In most cases, the research record serves as the primary source document for all data reporting. The Investigator and study staff (e.g., nurse or Clinical Research Assistant) must agree on their respective responsibilities for collecting and recording data for each study and must develop a system to facilitate that process. Assigned CRC staff will review data (e.g., laboratory reports, etc.) for safety and completeness and consult with the Investigator as required. The Investigator is ultimately responsible for the accuracy of reported data.

5. Providing current IRB approval and approved materials to CRC.

CRC requires evidence of current IRB approval for use of CRC resources. PI must ensure the CRC RSA (Ms. Kristen Tremblay) is listed in the electronic IRB submission system as a Contact so CRC receives all IRB correspondence. CRC RSA will obtain copies of IRB submissions/approvals directly from the system. PI is responsible for providing CRC staff assigned to work on the project with updated/current IRB documents, as required for the conduct of the study.

6. Providing agendas and minutes of meetings and other proceedings, as described in the study's Data and Safety Monitoring Plan (DSMP), to the CRC RSA.

This material is used to monitor the safety of research participants and the integrity of study data. Information is to be submitted in a timely manner, generally the month following meetings.

7. Data management and analysis.

The Investigator may choose to manage their own data or seek support of the CRC Data Management group. Investigators approved to use CRC Data Management services are expected to work closely with data management staff to design the study's Case Report Forms (CRFs) and data collection/entry method (i.e., Double-Data entry by CRC staff for paper-based CRFs or Web-based entry by the patient and/or Study Coordinator using REDCap). Investigators must discuss methods of data storage with the CRC data group, to ensure consistency with IRB approval. Investigators are also expected to meet with the CRC data group regularly throughout the study to assess the progress of data collection. At the conclusion of the study, the data management group will clean the data to prepare it for analysis by the PI. After data are clean, the PI is solely responsible for analysis of their data.

CRC Informatics also offers a secure file-share ("G drive") for use by PIs and/or their designated staff. CRC Informatics personnel maintain security and backups of data housed on CRC systems, with input from the PI as applicable. Investigators may seek CRC staff assistance with training and troubleshooting use of CRC computer systems.

8. Study billing.

If a study has ancillary charges (e.g., JDH or UMG services) requiring a budget workbook through the Office of Clinical and Translational Research (OCTR), then prior to enrollment of the first subject, OCTR will set up a Budget Initiation Meeting to include the PI, OCTR personnel, and the PI's grant administrator; that meeting includes review of how ancillary bills will be handled. PI is expected to attend the meeting. If a study does not have ancillary charges but will incur CRC/ DCRC charges for staff time, CRC management will review the billing process with the Investigator during the CRC Project Initiation meeting.

9. Communication with CRC personnel working on the protocol.

Regular meetings of the study team are strongly recommended to maintain timely and complete communication and to monitor study progress. The Investigator is responsible for being available or for communicating who is providing medical coverage in his/her absence; the Investigator is responsible for study-related instruction of covering physician(s).

10. Timely and complete responses to CRC requests for information.

CRC has certain reporting requirements. To fulfill those obligations, CRC, in turn, has certain reporting requirements for all CRC PIs. As a CRC PI you are expected to provide timely and complete responses to our requests for information from you. These include the following:

- Reporting subject visits each month
- Providing projected enrollment and resource utilization volumes each year, which CRC uses in preparing a budget for the next fiscal year
- Verifying periodically the number of subjects who have signed Informed Consent Forms (ICFs) for your study and reconciling data quality items
- Providing a progress report or project close-out report, upon request
- **To acknowledge the CRC in publications and presentations (state the following: *We acknowledge the support of The Lowell P. Weicker, Jr. Clinical Research Center, University of Connecticut Health Center.*)**