TEAM MEMBERS

Principal Investigator

The principal investigator is the responsible leader of the team. This is usually a physician, but in rare instances may be a nonphysician. An example would be a nurse or a pharmacist for certain studies.

The general responsibilities of a principal investigator are:

- To ensure that the investigation is conducted according to the signed investigator statement (1572 form), the protocol, and applicable regulations.
- To protect the rights, safety, and welfare of study participants.
- To control the test article under investigation.
- To maintain adequate records of the disposition of the test article and provide for proper disposition.
- Prepare and maintain adequate and accurate case histories.
- To retain records in accordance with applicable regulatory requirements.
- To obtain the informed consent of each human subject to whom the drug is administered.
- To ensure than an IRB in compliance with federal regulations will be responsible for the initial and continuing review and approval of the clinical investigation.

The principal investigator is ultimately responsible for the overall conduct of the study, but many of the responsibilities are delegated to the study coordinator or other members of the research team.

Subinvestigators

Other members of the research team who assist the principal investigator in the conduct of the study. This is most often other physicians, but can also include nurses, pharmacists, or coordinators. These subinvestigators must be listed on the 1572 form.

Clinical Research Coordinator

The Clinical Research Coordinator is critical to the success of a research program. Study coordinators assist principal investigators to implement research protocols at the sites. The role of the coordinator may vary from study to study, but generally the coordinator organizes the study program, conducts study required tests and procedures, completes required paperwork, and acts as a liaison between the site and the sponsor.

Clinical Research Coordinator Assistant

Assist the clinical research coordinator in the day today operation of running a study. This may include, but is not limited to, completing case report forms, handling lab specimens and shipping, scheduling patients and assists the CRC with all aspects of patient visit requirements.