Roles and Responsibilities of the Clinical Research Team

Kathleen O’Malley RN, BSN, CCRP
Manager of Education and Training
Jefferson Clinical Research Institute
Kathleen.omalley@jefferson.edu
Learning Objectives:

• Name the required and possible members of the research team
• List two resources that outline the responsibilities of a Principal Investigator
• Describe three areas of expertise that clinical research coordinator may need in order to successfully manage a clinical research study
• Identify what TJU document describes the roles and responsibilities of research personnel
The Research Team

Need sufficient study staff to perform clinical research efficiently and effectively:

• Appropriate skill set and training
• GCP (Good Clinical Practice) standards
• Follow protocol requirements
Who makes up the research team?

- Principal Investigator (PI)
- Sub Investigator (Sub I)
- Clinical Research Nurse Coordinator (CRNC)
- Clinical Research Coordinator (CRC)
- Regulatory Coordinator
- Key Personnel
Principal Investigator:
An individual who conducts a clinical investigation or, in the event of an investigation conducted by a team of individuals, is the responsible leader of the team.
21 CFR 312.60: An Investigator is responsible for ensuring that an investigation is conducted according to the signed investigator statement, the investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of the subjects under the investigator’s care; and for the control of the drugs under investigation.

- Protocol compliance
- Informed consent prior to study procedures
- Record keeping and retention
- Control of investigational drug
- IRB review & approval
- Adverse event reporting
- Integrity of data/inspection of records
Principal Investigator:

Responsibilities of investigators can be found in the following sections of the regulations:

- IND trials: 21 CFR 312 subpart D
- IDE trials: 21 CFR 812 subpart E and subpart G
- 21 CFR 50 (informed consent requirements)
- 21 CFR 56 (IRB requirements)

The investigator must also be aware of any local rules or regulations in addition to those outlined in the CFR.
Investigator Statement: Form FDA 1572

A **contract** between the Sponsor and the investigator in which the investigator agrees to comply with the protocol and all regulations pertaining to clinical research

- Signed before a clinical trial involving an investigational drug or biologic can begin
- Not a regulatory requirement, but used frequently in **IND (investigational New Drug)** studies

Investigators participating in **IDE (Investigational Device Exemption)** studies do not complete a Form FDA 1572, but similar information is collected by the Sponsor

- sometimes called an **Investigator Agreement**
Principal Investigator Responsibilities

- Investigators must understand and adhere to federal regulations...it’s the law!
- The regulations are in place to protect the RIGHTS, SAFETY and WELFARE of study subjects.
Clinical Research Coordinator: manages and conducts the day-to-day study activities in accordance with the protocol, applicable regulations and GCP requirements.

- Vital to the success of a trial
- Come from a variety of backgrounds
The responsibilities of the CRC have expanded to beyond the clinical management of subjects to much more sophisticated expertise in compliance, research administration, marketing, fiscal and legal activities.

### Expansion of the CRC Role over the years

<table>
<thead>
<tr>
<th>Core CRC Responsibilities</th>
<th>Additional CRC Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Adherence to an IRB approved protocol</td>
<td></td>
</tr>
<tr>
<td>- Participation in the proper consenting of study subjects</td>
<td></td>
</tr>
<tr>
<td>- Support of the safety of clinical research subjects</td>
<td></td>
</tr>
<tr>
<td>- Coordination of clinical treatment, study visits, and follow-up care</td>
<td></td>
</tr>
<tr>
<td>- Subject screening, recruitment, and enrollment</td>
<td></td>
</tr>
<tr>
<td>- Maintenance of study source documents</td>
<td></td>
</tr>
<tr>
<td>- Proper reporting of adverse events</td>
<td></td>
</tr>
<tr>
<td>- Submissions to regulatory authorities (e.g. IRB, FDA, etc.)</td>
<td></td>
</tr>
<tr>
<td>- Regulatory documentation development and management</td>
<td></td>
</tr>
<tr>
<td>- Completion of case report forms (paper &amp; electronic data capture)</td>
<td></td>
</tr>
<tr>
<td>- Coordination of pre study, initiation visit, monitoring visits</td>
<td></td>
</tr>
<tr>
<td>- Collection, processing, shipping of laboratory specimens</td>
<td></td>
</tr>
<tr>
<td>- Maintenance of drug accountability documentation</td>
<td></td>
</tr>
<tr>
<td>- Study budget preparation</td>
<td></td>
</tr>
<tr>
<td>- Management of study finances including resolving study subject billing issues</td>
<td></td>
</tr>
<tr>
<td>- Acting as liaison for research subject, investigator, IRB, sponsor, healthcare professionals</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from the CTSA Research Coordinator Taskforce Critical Needs for CRC Training Support and Career Development slides January 11-12, 2011
FIGURE 1. Competency Domains for the Clinical Research Professional

1. Ethical and Participant Safety Considerations
   - Encompasses care of patients, aspects of human subject protection, and safety in the conduct of a clinical trial.

2. Medicines Development and Regulation
   - Encompasses knowledge of how drugs, devices, and biologicals are developed and regulated.

3. Clinical Trials Operations (GCPs)
   - Encompasses study management and GCP compliance, safety management (adverse event identification and reporting, postmarket surveillance, and pharmacovigilance), and handling of investigational product.

4. Study and Site Management
   - Encompasses content required at the site level to run a study (financial and personnel aspects). Includes site and study operations (not encompassing regulatory/GCPs).

5. Data Management and Informatics
   - Encompasses how data are acquired and managed during a clinical trial, including source data, data entry, queries, quality control, and correction and the concept of a locked database.

6. Leadership and Professionalism
   - Encompasses the principles and practice of leadership and professionalism in clinical research.

7. Communication and Teamwork
   - Encompasses all elements of communication within the site and between the site and sponsor, CRO, and regulators. Understanding of teamwork skills necessary for conducting a clinical trial.

8. Scientific Concepts and Research Design
   - Encompasses knowledge of scientific concepts related to the design and analysis of clinical trials.
What makes a successful CRC?

- Attention to Detail
- Excellent communication skills
- Flexibility
- Ability to work independently
- Organizational skills
- Grit / Can-do attitude
**Additional Research Personnel:**

- **Sub-investigator:** A member of the research team designated and supervised by the PI to perform critical study-related procedures and/or to make important study-related decisions
  - The FDA regards sub-investigators as those individuals authorized to make medical judgments and decisions regarding study subjects

- **CRNC:** Clinical Research *Nurse* Coordinator
  - Certain protocol-related activities may require a license or certificate of training (ex. administration of medications or Glasgow Coma Scale)
Additional Research Personnel:

- **Regulatory Coordinator/Specialist:**
  - Prepares and maintains IRB submissions and Regulatory documents
  - Tracks study progress in Clinical Trial Management systems (Portal and JeffTrial)

- **Key Personnel:**
  - Personnel considered to be of primary importance to the successful conduct of a research project
  - IRB Policy G 601

Learning Objectives:

• Name the required and possible members of the research team
• List two resources that outline the responsibilities of a Principal Investigator
• Describe three areas of expertise that clinical research coordinator may need in order to successfully manage a clinical research study
• Identify what TJU document describes the roles and responsibilities of research personnel
Questions?