The Clinical Research Team: Roles and Responsibilities

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Agenda

1. Investigator
2. Sub-investigators
3. Study Coordinator
4. Clinical Data Manager
5. Participant
6. Resources
   - Websites
   - Professional Organizations
Clinical Research Team
Roles/Members

- Investigator(s)
  - Principal
  - Sub
  - Multi-site protocols
    - Study
    - Site
- Study Coordinator
  - Nurse
  - Non-nurse
- Clinical Data Manager

❖ Participant
The Clinical Research Team: General Responsibilities

- All members of the research team must understand and adhere to federal regulations …it’s the law
- Need sufficient study staff to perform clinical research efficiently and effectively:
  - Appropriate skill set and training
  - GCP (Good Clinical Practice) standards
  - Follow protocol requirements
What Makes Research Team/Team Members Successful?

- Attention to Detail
- Excellent communication skills
- Flexibility
- Organizational skills
- Ability to work independently
- Can-do attitude
PI Responsibilities

- Office of Human Research Protection (OHRP)
- Food and Drug Administration (FDA)
- Good Clinical Practice (GCP) Guidelines
- Local/HRPP SOP
OHRP’s Use of “Investigator”...

- Any individual who is involved in conducting human subjects research studies including:
  - obtaining information about living individuals by intervening or interacting with them for research purposes;
  - obtaining identifiable private information about living individuals for research purposes;
  - obtaining the voluntary informed consent of individuals to be subjects in research; and
  - studying, interpreting, or analyzing identifiable private information or data for research purposes.
...OHRP’s Use of “Investigator”

- Investigators can include physicians, scientists, nurses, administrative staff, teachers, students
- Multiple investigators, 1 investigator is designated the “principal investigator” with overall responsibilities for the study
- Learn more: OHRP’s Investigator Responsibility Frequently Asked Questions
FDA and the Role of the Investigator

- Clinical Investigator = PI
  - Overall responsibility for the conduct of the clinical trial
- Other Investigators are referred to as Sub-investigators
- Refer to 21 CFR Parts 11, 50, 54, 56, 312, and 812 for a more comprehensive listing of FDA's requirements
Role of the Investigator: Drugs or Biologics...

- Investigator’s responsibilities in conducting clinical investigations of **drugs** or **biologics** are provided in 21 CFR Part 312
- Many of these responsibilities are included in the required investigator’s signed statement, Form FDA-1572
...Role of the Investigator: Drugs or Biologics

- Page 2, Section 9 lists the commitments of the Investigator
  - Conduct study according to current protocol
  - Personally conduct or supervise the described investigation(s).
  - Ensure that all team members assisting in the conduct of the study are informed about their obligations
Form 1572

- Form 1572 is updated as needed
- All copies of the Form 1572 are to be maintained in the regulatory binder
- One Form 1572 per protocol per site
  - Note: For NCI studies, one Form 1572 per investigator
- FDA’s 2010 Information Sheet: Guidance for Sponsors, Clinical Investigators, and IRBs: Frequently Asked Questions—Statement of Investigator (Form FDA 1572)
Role of the Investigator: Devices

- Investigator’s responsibilities in conducting clinical investigations of a *medical device* are provided in 21 CFR Part 812, including the requirement that there be a signed agreement between the investigator and sponsor.
- Device regulations do not require the use of a specific form for an investigator’s statement.
FDA Guidance…

- FDA 2009 guidance document provides overview of Investigator responsibilities in drug, biological product, or medical device studies
- Protecting the rights, safety, and welfare of study subjects
  - Reasonable medical care necessitated by participation in a clinical trial
  - Reasonable access to medical care
  - Protocol violations that present unreasonable risk
FDA Guidance

- Supervisory activities associated with the conduct of a clinical trial including:
  - Appropriate delegation of study-related tasks
  - Adequate training
  - Adequate supervision of the conduct of ongoing clinical trial
  - Investigator's responsibilities for oversight of other parties involved in the conduct of a clinical trial
ICH GCP and the Investigator

- Investigator qualifications & agreements
- Adequate resources
- Medical care of trial subjects
- Communication with the IRB
- Compliance with protocol
- Investigational product
- Randomization procedures and unblinding
- Informed consent
- Record and reports
- Safety reporting
- Premature termination of trial
- Final report
Delegation & Supervision

- Individuals who are delegated tasks:
  - Are qualified/licensed to perform the tasks
    - Credentialed per CC
  - Receive adequate training on the delegated tasks
  - Understand the study
- Supervision by PI
  - Documentation that PI is involved in the ongoing conduct of the study
  - Documentation of PI supervision or oversight individual not in PI’s employ
## Delegated Research Activities

<table>
<thead>
<tr>
<th>Delegated Activity</th>
<th>Responsibility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obtain informed consent</td>
<td>Study drug storage and temperature monitoring</td>
</tr>
<tr>
<td>Subject selection/recruitment</td>
<td>Sample collection</td>
</tr>
<tr>
<td>Confirm eligibility (review inclusion/exclusion criteria)</td>
<td>Sample processing and/or shipment</td>
</tr>
<tr>
<td>Obtain medical history (source documents)</td>
<td>Evaluate study-related test results</td>
</tr>
<tr>
<td>Perform physical exam</td>
<td>Use of Registration system</td>
</tr>
<tr>
<td>Conduct study visit procedure as outlined in the protocol</td>
<td>Make entries/Corrections on (e)CRFs</td>
</tr>
<tr>
<td>Make study-related medical decisions</td>
<td>Sign- off on (e)CRFs</td>
</tr>
<tr>
<td>Assess AEs/SAEs including attribution</td>
<td>Maintain essential documents</td>
</tr>
<tr>
<td>Dispense study drug</td>
<td>Perform study-related assessments as per protocol</td>
</tr>
<tr>
<td>Perform drug accountability</td>
<td>Regulatory submissions</td>
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</tbody>
</table>
Delegation of Tasks Log

- Log that allows PI to note delegation of research related tasks
- Delegation based on education, training, and experience, and state licensure, when relevant
- Meet the expectation of the FDA guidance
- Fulfill FDA regulations 21 CFR 312.53
- Fulfill the requirements stated in ICH GCP E6 Guideline Section 4.1.5
- Address the requirement in Section 8 of ICH GCP 8.3.24 “signature sheet”
Delegation Log Initiation and Maintenance

- What is your team process?
- How does PI know who to delegate what to in terms of training and licensure?
- What do you do if you don’t feel comfortable with a task that has been delegated to you?
- Does the log include who will cover for the PI?

Reminder: Update the log in a timely manner as new personnel are added or removed and/or study roles and responsibilities change.
PI Additional Responsibilities

- Communication
  - Team
  - Outside of team
  - Coverage for PI
- Eligibility determination
- Documentation
- Data/Data Safety Monitoring Plan
- Reportable event
- Monitoring/auditing
- Developing a Corrective and Preventive Action (CAPA) plan
Sub-Investigator

- "Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows)."
- Include in block #6 of the FDA Form 1572
- Note for NCI studies:
  - Each investigator will need to have a Form 1572 which is accessed online
  - Use Registration and Credential Repository
Study 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
- AKA:
  - Clinical Research Coordinator (CRC)
Study Coordinator Responsibilities...

- Recruitment
- Screen and schedule
- Secure informed consent
- Maintain integrity of protocol
  - Ensuring study procedures done as per the protocol
- Coordinate lab pick-ups & supplies
- Maintain essential documents/regulatory files
...Study Coordinator Responsibilities...

- Assist PI in preparing protocol & consent for IRB submissions
  - Timely submissions
  - Meets the regulatory requirements
- Identify and report events (e.g., adverse events, unanticipated problems, non-compliance, protocol deviations) to IRB and/or sponsor
  - Timely, complete
- Maintain participant records & documentation
...Study Coordinator Responsibilities...

- Data management & QA
- Teach participants/reinforce the informed consent process
- Teach staff/research team members
- Stay informed (with PI) of new information regarding investigational agent
  - Investigators Brochure, Articles, IND Safety Reports
- Prepare & facilitate monitoring of trials
  - Resolve discrepancies, common goals/time lines
…Study Coordinator

- Anticipate the deadlines & data needed
  - IRB
  - FDA
  - Professional meeting abstracts
  - Audit/monitoring visits
- Abstract, analyze & publish findings with PI
- Orient/precept others
Nurses in Clinical Research

- Direct care nurses (AKA: Staff Nurse)
  - Spends the majority of their time delivering direct care to research participants and their families
- Research Nurse (AKA: Clinical Trial Nurse, Clinical Research Nurse, Research Nurse Coordinator, Study Coordinator)
  - Spends the majority of their time in the managing the study, coordinating within the multidisciplinary team, communicating with referring physicians and providing for protection of human subjects
- Licensure responsibilities
- Clinical care, drug prep & administration
Clinical Data Manager (CDM)

- Individual responsible for some or all activities related to Clinical Data Management:
  - Data acquisition/collection
  - Data abstraction/extraction
  - Data processing/coding
  - Data analysis
  - Data storage
  - Data privacy/confidentiality
  - Data QA
Research Participant…

- Respect research staff and other participants
- Read the consent form and other documents
  - Ask questions if they do not understand something about the study, their rights and responsibilities
  - Carefully weigh the risks and benefits when deciding whether to participate in the study
  - Refrain from signing the consent document until they understand its content and feel comfortable with decision to participate
... Research Participant ...

- Know when the study begins and ends
  - Particularly important for studies with a follow-up period after the intervention
- Follow directions for all protocol related procedure
- Show up at scheduled appointments on time, and inform the staff within a reasonable time if they need to reschedule
- Provide truthful answers to questions asked throughout the study
... Research Participant

- Inform staff if:
  - Other medical care is needed while on the study
  - There are questions they would rather not answer
  - They decide to withdraw consent
- Report symptoms and other problems they experience during the study
- Keep:
  - Information about the study confidential, if asked to do so
  - Staff informed when contact information changes
Additional Research Personnel?
Professional Organizations

- Association of Clinical Research Professionals (ACRP)
- International Association of Clinical Research Nurses (IACRN)
- Society for Clinical Research Associates (SoCRA)
- Society of Clinical Data Managers (SCDM)
Association of Clinical Research Professionals (ACRP)

- International association (>18,000; members >70 countries)
- Established in 1976
- Provide education and networking
- Target clinical research professionals in industry and in hospital, academic medical centers and physician office settings.

http://www.acrpnet.org/
International Association of Clinical Research Nurses (IACRN)

• International professional nursing organization (<257 members; 22 countries)
• Established in 2007
• Dedicated to supporting educational and professional needs of clinical research nurses
• ANA recognition of Clinical Research Nursing as a specialty practice with associated Scope and Standards of Practice
• Working towards CRN certification
• https://iacrn.wildapricot.org/
Society of Clinical Data Management (SCDM)

- International organization (>2,400 members)
- Established 1994
- Founded to advance the discipline of clinical data management and support Clinical Data Management professionals
- Annual meeting and other educational offerings
- Developed professional standard for good clinical data management practices
- [http://www.scdm.org/](http://www.scdm.org/)
Society of Clinical Research Associates (SoCRA), Inc.

- International organization (> 14,300 members)
- Established in 1991
- Provides educational programs and a forum for research professionals to exchange information
- Originally started for research professionals at a site
- Membership expanded to include monitors, data managers, and regulatory representatives from industry, academia, research centers, NIH and regulatory agencies
Research Certification

- ACRP
  - Certified Clinical Research Associate (CCRA®)
  - Certified Clinical Research Coordinator (CCRC®)
  - Certified Principal Investigator (CPI®)
  - ACRP Certified Professional (ACRP-CP)

- IACRN
  - In development, via professional portfolio

- SoCRA®
  - Certified Clinical Research Professional (CCRP®)

- SCDM
  - Certified Clinical Data Manager (CCDM®)
Resources

- ACRP’s *Introduction to Clinical Trials*
- Center for Cancer Research [clinical trials orientation modules](https://www.coursera.org/courses?query=clinical%20trials)
- Coursera (clinical trial search)
  - [https://www.coursera.org/courses?query=clinical%20trials](https://www.coursera.org/courses?query=clinical%20trials)
- OHRP
  - [Online education](https://www.coursera.org/courses?query=clinical%20trials)
  - [Guidance documents](https://www.coursera.org/courses?query=clinical%20trials)
- FDA [clinical trial guidance documents](https://www.coursera.org/courses?query=clinical%20trials)
- [ICH GCP Guidelines](https://www.coursera.org/courses?query=clinical%20trials)
- Institutional policies and standard operating procedures
- Protocol specific manual of operations
Regardless of Your Role: Be Your Own Best Advocate

- Protect your time & get organized
- Learn as much as you can about:
  - clinical trials
  - disease/condition
  - your particular interventions
  - your database/software programs
- Know how/where to get training & do it
- Join a professional organization & get involved
- Teach something new & you will learn
- Teach someone new & you will grow
**Upcoming Free Webinar**

If Informed Consent is an Ongoing Process, what does re-consent mean?

Monday, June 1, 2020
2:00 – 3:00 PM ET

IACRN will be providing their members FREE contact hours, non-IACRN members can purchase contact hours for $10. After the webinar, nurses will receive an email from IACRN outlining instructions to complete the evaluation and receive the contact hours. To receive full contact-hour credit (one contact hour) for this CNE activity, you must: be registered, attend at least 80% of the webinar, and complete an on-line evaluation.

This nursing continuing professional development activity was approved by the Ohio Nurses Association, an accredited approver by the American Nurses Credentialing Center’s Commission on Accreditation (OBN-001-91)

Please call Tricia Clarke at 443-640-1041 for more information about contact hours.
QUESTIONS

nesse@nih.gov