Roles and Responsibilities of the Clinical Research Team

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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?

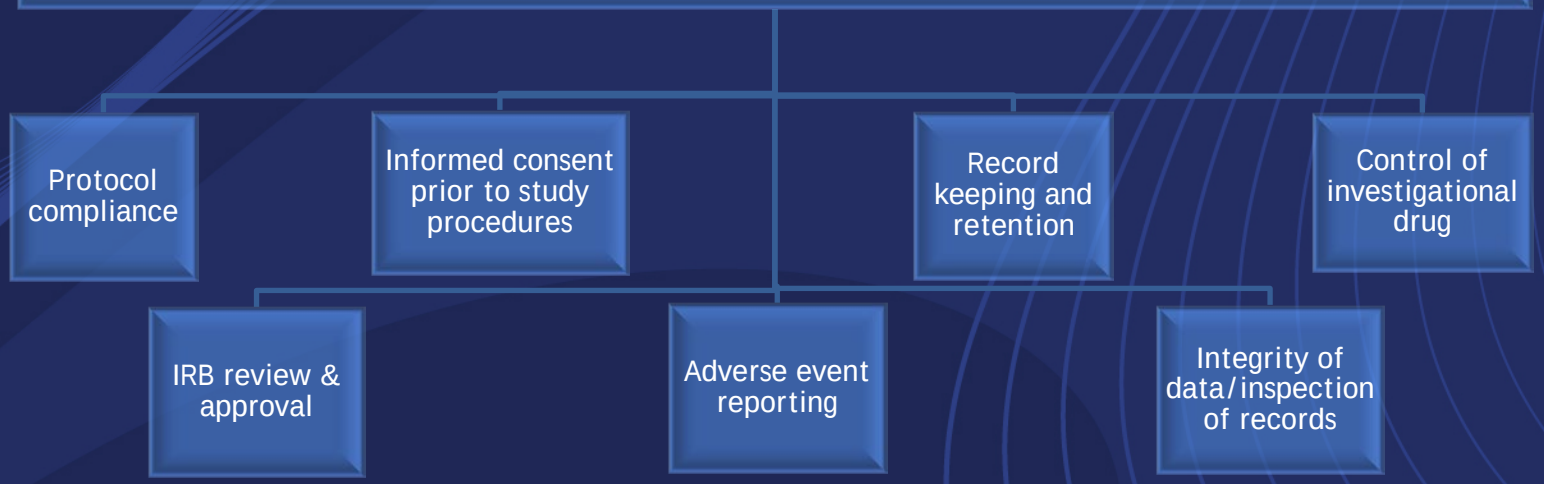
- Principal Investigator (PI)
- Sub Investigator (Sub I)
- Clinical Research Nurse Coordinator (CRNC)
- Clinical Research Coordinator (CRC)
- Regulatory Coordinator
- Key Personnel

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.

Principal Investigator Responsibilities

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



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)
-ICH E6 Guidelines 4.1- 4.13

The investigator must also be aware of any local rules or regulations in addition to those outlined in the CFR.

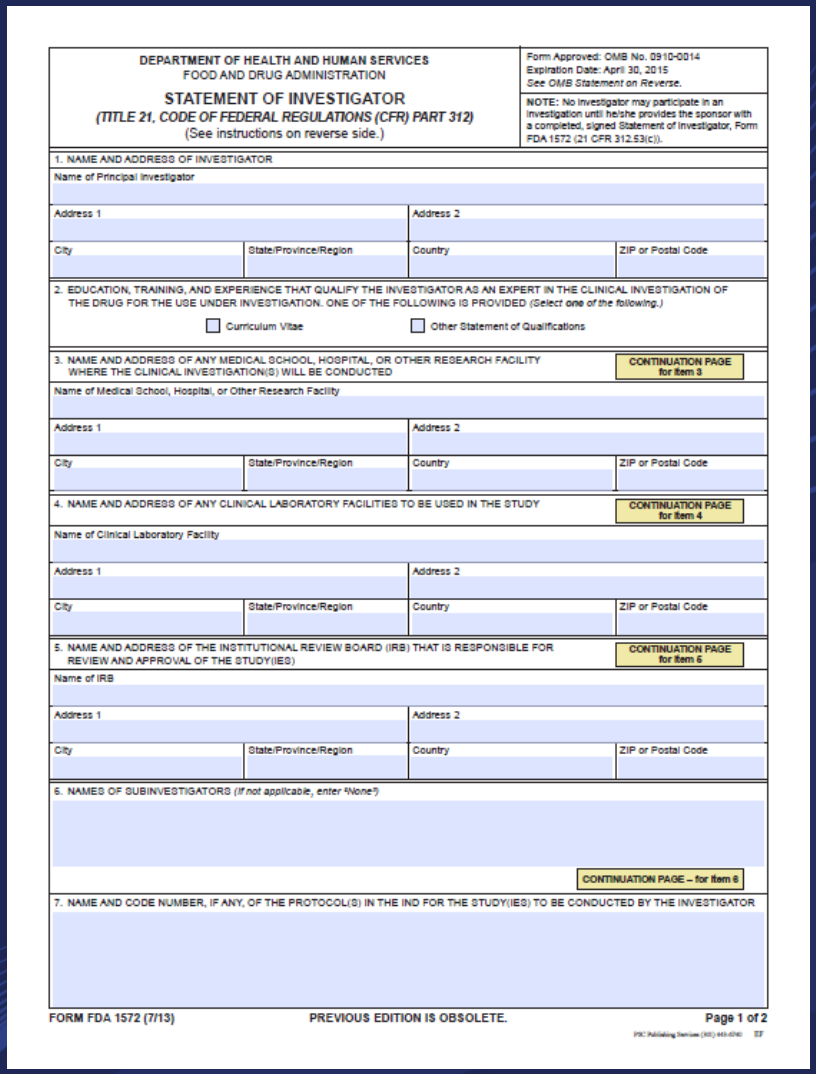
Investigator Statement: Form FDA 1572

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



DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR

(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)

(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: April 30, 2015
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Principal Investigator

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED *(Select one of the following.)*

☐ Curriculum Vitae ☐ Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED — CONTINUATION PAGE for item 3

Name of Medical School, Hospital, or Other Research Facility

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY — CONTINUATION PAGE for item 4

Name of Clinical Laboratory Facility

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES) — CONTINUATION PAGE for item 6

Name of IRB

Address 1 | Address 2

City | State/Province/Region | Country | ZIP or Postal Code

6. NAMES OF SUBINVESTIGATORS *(If not applicable, enter "None")*

CONTINUATION PAGE – for item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

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8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. *(Select one of the following.)*

☐ For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.

☐ For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and Institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE *(mm/dd/yyyy)* | 11. SIGNATURE OF INVESTIGATOR — Sign

(**WARNING:** A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DO NOT SEND YOUR COMPLETED FORM TO THIS PRA STAFF EMAIL ADDRESS.

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http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074728.pdf

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

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

Adapted from the CTSA Research Coordinator Taskforce
Critical Needs for CRC Training Support and Career Development slides
January 11-12, 2011

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Image courtesy of the Joint Task Force for Clinical Trial Competency (JTFCTC)

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

    http://www.jefferson.edu/content/dam/tju/human_research/irb/documents/PolicyandProceduresManual/20150528%20DO%20NOT%20MODIFY%20Policy%20and%20Procedure%20Manual%20COMPLETE%20CLEAN.pdf

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Questions?