

## Section 3: The Study Team

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Each trial has a study team that is responsible for its conduct. Study teams for DF/HCC protocols may consist of the following members.

### 3.1 Overall Principal Investigator (Overall PI)\*

The overall PI has ultimate responsibility for the conduct of the research trial. The duties of the PI are outlined in the [FDA form 1572](#). The overall PI is responsible for all aspects of the protocol, including the following aspects of clinical research:

- Coordinating the approval process, scientific and IRB reviews, and department sign offs to approve activation
- Incorporating any necessary changes into the protocol through a formal amendment process, including SRC/PSRC and IRB approval before such changes can be implemented
- Informing fellows, nursing, pharmacy, and other staff about protocol requirements
- Overseeing all study team members
- Reporting trial results in a timely fashion

By definition, overall PIs of designated high-risk trials must be physicians listed as DF/HCC professional medical staff (non-trainees). Protocols that originate at other institutions but are activated at DF/HCC must have a designated DF/HCC chairperson in addition to the overall PI at the originating institution.

### 3.2 Site Principal Investigator (Site PI)\*

Each participating institution will have a designated site PI who is responsible for the conduct of the trial at that particular institution. The site PI is responsible for collaborating with the overall PI to ensure appropriate clinical and study conduct, including reporting of serious adverse events (SAEs) as well as events that are unexpected.

### 3.3 Collaborating Investigators (Co-investigators)\*

Co-investigators are invited by the overall PI to participate in the research trial. They, too, must ensure appropriate clinical and study conduct by adhering to and performing the trial-specific procedures on behalf of the overall PI.

### 3.4 Biostatistician

A biostatistician collaborates on various aspects of protocol development and reporting. He or she works closely with the team to ensure the relevance and appropriateness of statistics generated for the trial. For

DF/HCC initiated trials, the biostatistician will provide a design appropriate to the endpoints specified by the overall PI.

### **3.5 Research Nurse**

The research nurse manages the day-to-day operations of the clinical trial, under the auspices of the overall PI. The research nurse facilitates the protocol process through a number of activities, such as verifying that the required tests are completed and that participants have been properly informed and have signed the appropriate consent form. He or she also assists with eligibility checking, registering participants, monitoring participants for toxicity, making follow-up appointments with participants, and teaching other staff members about the protocol. A research nurse may also assist in preparing standard orders for protocol subject management.

The research nurse is responsible for staff education and participant/family education regarding the clinical trial. If protocol therapy is delivered by an affiliate or community hospital that has IRB approval to participate, it is the research nurse who educates and communicates with the health care providers to ensure protocol compliance.

Although the overall PI is responsible for reporting SAEs to the protocol sponsor and the DFCI IRB, the research nurse may also be involved with the reporting.

### **3.6 Study Coordinator**

The Study Coordinator, sometimes called Clinical Research Coordinator (CRC) or Clinical Research Associate (CRA), is an integral part of the study team and is responsible for reviewing research participant records, abstracting data, and completing the case report forms (CRFs) supplied by QACT (for in-house trials) or the sponsor (i.e., pharmaceutical company, NCI, cooperative group).

The Study Coordinator works closely with the overall PI, the research nurse, and the study data analyst to perform protocol management for each trial. He or she has the primary responsibility of abstracting data from the medical records and other necessary sources. Study coordinators are involved with several areas of the clinical trial process, including protocol review, forms design, data collection, eligibility confirmation, participant registration, and responding to requests for missing data and other queries. Additional responsibilities may include scheduling participants, submitting reports, and preparing IRB submissions, such as amendments, continuing review reports, protocol violation and deviations, investigational new drug (IND) safety reports, and SAE reports.

### **3.7 QACT Data Analyst**

The QACT data analyst is a QACT staff member who ensures the quality of clinical research data generated in DF/HCC in-house protocols. This role includes designing case report forms (CRFs) for data collection, setting up tables in the database, and providing quality control/assurance (QC/QA) for the clinical research data in a variety of ways, including monitoring data collection methods, ensuring consistency in data collection, and creating quality control systems within the computerized database. The data analyst also provides the study team with regular missing-data reports and other data reports as needed. In addition, the data analyst works closely with the biostatistician to prepare data for analysis and trial closure.

**\*Note:** This term is a DF/HCC-specific term and may not be recognized by outside entities (i.e., the

sponsor). For example, the sponsor may refer to a site PI as a “Sub-investigator.” Members of the study team in contact with the sponsor should familiarize themselves with the sponsor’s terminology and adapt as necessary.