| **TITLE:** Documenting Delegation of Authority | | |
|---|---|---|
| **SOP #:** RCO-200 *(formerly ET-202)* | **Page:** 1 of 4 | **Effective Date:** 3/1/14 |

## 1. POLICY STATEMENT:

The Overall Principal Investigator (PI) is responsible for ensuring that only individuals qualified by means of education, training and experience are charged with the authority to perform research-related tasks.

## 2. BACKGROUND:

U.S. regulations require that the Principal Investigator (PI) exercise personal supervision over the conduct of research under his/her name; however, research is a team effort and delegation of research-related tasks allows other individuals to actively participate in the implementation and conduct of research.

While authority to perform specified tasks may be delegated, the responsibility for those tasks always remains with the Overall PI.

## 3. RESPONSIBLE PERSONNEL:

3.1. Overall Principal Investigator (PI)
3.2. Site Responsible Investigator
3.3. Subinvestigator
3.4. Research Nurse
3.5. Study Coordinator

## 4. DEFINITIONS:

4.1. **Investigator:** An individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a participant.) In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. At DF/HCC, this is the Overall PI.

4.2. **Site Responsible Investigator:** An individual located at a specific DF/HCC site and designated by the Overall PI to assist with the clinical conduct of the research at that site.

4.3. **Subinvestigator:** Any other member of the research team who will make clinical decisions during the research or make a direct and significant contribution to the data. The ICH GCP guideline defines subinvestigator as "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".

| **TITLE:** Documenting Delegation of Authority | | |
|---|---|---|
| **SOP #:** RCO-200 *(formerly ET-202)* | **Page:** 2 of 4 | **Effective Date:** 3/1/14 |

## 5. PROCEDURE:

5.1. The Overall PI will review the protocol documents to identify those tasks that are suitable for delegation to the research team.

5.1.1. Note that any additional qualifications or restrictions detailed in the protocol documents take precedence over state law. For example, if state law permits nurse practitioners to perform physical examinations under physician supervision but the protocol specifies that a physician must do the physical examination, the protocol's requirements take precedence to the extent that they do not contravene state law.

5.2. The Overall PI must keep a Delegation of Authority Log of appropriately qualified individuals that have been delegated significant research-specific tasks. This log must include the following: printed name of each individual and their signature, delegated tasks; and dates of involvement in the research.

5.2.1. Only key staff members are identified on the Delegation of Authority Log. Other staff members, such as infusion unit or inpatient nurses, radiologists, pathologists, pharmacy technicians, Tumor Imaging Metrics Core (TIMC) staff, residents, fellows and office staff are not included unless determined by the Overall PI that they make a direct and significant contribution to the data. Staff members performing routine procedures (i.e. commercial services or standard of care assessments) will not be listed.

5.2.2. There must be a separate log per study.

5.3. Prior to beginning research-specific tasks and as needed when new research team members are added, the Overall PI and the research team will complete the Delegation of Authority Log.

5.3.1. Record the name of each individual who will play a significant role in the research. At a minimum, assure that all individuals who will be delegated to perform any activity regulated by the Food and Drug Administration (FDA) such as informed consent, screening evaluations, physical examinations, assessment of primary endpoints, evaluation of adverse events, etc. are listed on the form.

5.3.2. Describe the role of the individual. Note that since the Overall PI is responsible for all aspects of the research, it is not necessary to list the Overall PI on the form.

5.3.3. Enter the tasks the individual will be performing.

5.3.4. Record the date the responsibilities will begin.

5.3.5. Have the individual both initial (if applicable) and sign the form. No individual can sign or print initials for another individual.

5.3.6. Have the Overall PI officially approve the individual by signing and/or initialing and dating the form.

5.4. The Overall PI with the research team will assure that the Delegation of Authority Log is periodically reviewed to assure that it is kept up-to-date.

5.4.1. If any changes occur during the course of the research, the Overall PI must acknowledge his/her continued approval on the Delegation of Authority Log.

5.4.2. If an individual's involvement ends prior to the conclusion of the research, an end date must be entered on the form.

5.4.3. If an individual's involvement lasts during the duration of the research, enter "study end" as the date the responsibility ended. Otherwise, complete the end date as instructed by the study sponsor.

5.5. The completed Delegation of Authority Log will be maintained in the essential regulatory documents for the lead institution. A copy is kept at each specific site conducting the research.

5.6. A Delegation of Authority Log is required for all non-exempt human subject research excluding banking studies. A Delegation of Authority Log is recommended for banking (e.g. banking and tissue) studies.

5.6.1. If a sponsor does not provide a Delegation of Authority Log, a form provided by the institutional clinical trials office or one of the DF/HCC sample logs may be used.

5.7. The Overall PI or an appropriately delegated designee can be responsible for concurrently updating documents pertinent to delegation of authority as changes occur. When individuals are removed from or newly assigned to the research and when responsibilities are changed, all documents in the regulatory files will be revised, appended, or re-executed as applicable. These documents may include such items as the Form FDA 1572, Curriculum Vitae (C.V.) with applicable license(s), and training documentation on each assigned protocol.

5.8. All documents described in this policy must be available for review by the sponsor, Quality Assurance Office for Clinical Trials (QACT) Clinical Research Auditors and any representative of the Food and Drug Administration (FDA) or other regulatory entity.

## 6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 – Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811
Form FDA1572

## 7. RELATED REFERENCES:

International Conference on Harmonisation – E6
Protocol Documents

## 8. RELATED FORMS & TOOLS:

DF/HCC Guidance on Delegation of Tasks for Research Involving a Drug or Device
DF/HCC Sample Group Delegation of Authority and Signature Log
DF/HCC Sample Individual Delegation of Authority and Signature Log