TITLE: Documenting Delegation of Authority		
SOP #: RCO-200	**Page:** 1 of 3	**Effective Date:** 2/28/17

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. POLICY:

4.1. Delegation of Authority documentation is required for all non-exempt human subject research, excluding banking and tissue collection studies. A Delegation of Authority Log is recommended for banking and tissue collection studies.

4.2. The Overall PI must maintain Delegation of Authority documentation for all individuals who will be delegated to perform any research activity regulated by the Food and Drug Administration (FDA).

4.2.1. Staff members performing routine procedures (i.e. commercial services or standard of care assessments) will not be listed. Therefore, 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 research.

4.2.2. Delegation of Authority documentation is not required for sponsor responsibilities (21 CFR 312 parts 50 through 59).

4.2.3. Since the Overall PI is responsible for all aspects of the research, it is not necessary to list the Overall PI on the form.

4.3. Delegation of Authority documentation must be completed prior to an individual beginning research-specific tasks. This documentation must include the following elements: printed name of each individual and their signature, delegated tasks, dates of involvement in the research.

4.3.1. There must be a separate log for each protocol. However, information that is common to all studies may be maintained centrally (e.g., a common task key for each role, a central signature log) provided that all required elements are documented appropriately.

4.4. The Overall PI will review the protocol documents to identify any protocol-specific tasks that require delegation to the research team.

4.4.1. Note that any additional qualifications or restrictions detailed in the protocol documents take precedence over DF/HCC policy and 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.

4.5. 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.

4.5.1. The Overall PI must acknowledge his/her approval of any changes.

5. 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 FDA 1572

6. RELATED REFERENCES:
International Conference on Harmonisation – E6

7. 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
DF/HCC Sample Central Delegation of Authority Signature Log
DF/HCC Sample Protocol-Specific Delegation of Authority Log