SOP TITLE: DELEGATION OF AUTHORITY

1 PURPOSE

1.1 This procedure establishes the method by which the Principal Investigator (PI) of studies conducted within the Center for Clinical Research (CCR) delegates the authority to conduct clinical study procedures and tasks to other qualified study personnel, including CCR personnel.

1.2 The process begins when the PI identifies and assigns to or expects of any individual the performance of study-specific duties, procedures, or tasks.

1.3 The process ends when all study-specific duties, procedures, or tasks are complete (i.e., the study is complete).

2 REVISIONS FROM PREVIOUS VERSION

2.1 None

3 GUIDANCE

3.1 The PI conducting a clinical trial must follow all applicable Office for Human Research Protections (OHRP) human subjects research regulations, including those governing informed consent, IRB review and approval and, if the study involves an investigational product, the relevant Food and Drug Administration (FDA) regulations for drugs or devices.

3.1.1 FDA regulated studies require specific regulatory records, including the FDA Form 1572 or investigator agreement, which must accurately reflect the locations and personnel who are directly involved in the treatment and/or evaluation of research participants.

3.1.2 In delegating authority for study tasks to sub-investigators and study personnel for FDA regulated studies, the PI should consider the following:

3.1.2.1 Generally, physician and mid-level (nurse practitioners, physician assistants) sub-investigators who have a permanent and specific role in the study and who are directly involved in the treatment or evaluation of research participants should be included on the FDA Form 1572 and the delegation log.

3.1.2.2 Generally, individuals without a dedicated or permanent role on the study, or who are otherwise performing roles that are routine for their daily job, such as electrocardiogram technicians, hospital nursing staff, scheduling teams, or administrative personnel, do not need to be listed on the FDA Form 1572 and the delegation log.

3.1.2.3 Generally, the assistant clinical director would sign the DOA log on behalf of clinic nurses asserting that staff have been or will be trained on study specific activities.

3.2 The PI may delegate, with adequate oversight, the authority for other qualified members of the study team to carry out tasks and duties required by regulation and otherwise associated with study conduct.

3.3 The PI remains responsible for the overall study conduct and for compliance with the principles of Good Clinical Practice (GCP) and applicable local and national regulations and guidance.

3.4 The PI must maintain a list of qualified investigators and personnel to whom study-specific tasks are delegated, and this list, or log, may be recorded on a form provided by the sponsor,

created by the investigator, or obtained from another appropriate source, including, for example, CCR-XXX FORM: Delegation Log, or equivalent.

4 RESPONSIBILITIES

4.1 The CCR director and CCR assistant clinical director are responsible for providing the study PI with a copy of this procedure.

4.2 The study PI is responsible for carrying out these procedures.

5 PROCEDURE

5.1 The PI, or designee, determines the method and format for creating the delegation of authority record.

5.2 The PI selects qualified study sub-investigators and personnel to carry out study tasks.

5.2.1 The delegation of authority record-keeping should start as study personnel and associated tasks are assigned.

5.2.2 The delegation log should be completed at study initiation and updated thereafter throughout the study, accounting for new study personnel and personnel turnover.

5.3 The PI or designee ensures that all personnel to whom tasks are delegated are captured on the delegation log and that the log is current.

5.4 The PI or designee ensures that the log is verified, completed, and retained at the end of the study.

6 MATERIALS

6.1 CCC-XXX FORM: Delegation Log

7 REFERENCES

7.1 CCR-001 Definitions

7.2 21CFR312.60 – General responsibilities of investigators.

7.3 21CFR312.62 – Investigator recordkeeping and record retention.

7.4 21CFR Part 812 Subpart E – Responsibilities of Investigators. (Medical Devices)

7.5 21CFR Part 812 Subpart G – Records and Reports. (Medical Devices)

7.6 21CFR Part 50 – Protection of Human Subjects

7.7 45CFR Part 46 – Protection of Human Subjects

7.8 Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects – FDA Guidance

7.9 OHRP Regulations, Policy & Guidance

7.10 ICH guideline for good clinical practice (R2)

7.11 NIH Forms and Logs – Sample Delegation of Authority Log