UNIVERSITY OF SOUTH ALABAMA

CT-206 DELEGATION LOG

EFFECTIVE DATE: January 2024

Purpose

The purpose of this policy and procedure is to outline which Investigator(s) and research personnel are required to be listed on the Delegation of Authority (DOA) log and in which instances delegation logs are required. This policy and procedure satisfies the requirements set forth in Good Clinical Practice.

Scope

This SOP applies to all research performed under the Clinical Trial Office. All clinical trials, regardless of the funding source, are required to complete and maintain a delegation log. USA recognizes that some external sponsors, networks, and funders may require the use of their own SOPs for the good governance of research. In such cases it is the responsibility of the site to ensure that the external SOP is compatible with the procedure outlined below. If the external SOP contradicts with this SOP, then approval must be sought in writing from the Director of Clinical Trials.

Policy

Overall, the PI is ultimately responsible for the conduct of his/her clinical trials. However, he/she may delegate study specific procedures to properly trained study staff. Additionally, the PI is responsible for the oversight and training of these delegated study staff.

Each clinical trial must have its own Delegation of Authority (DOA) log. Study-specific DOA logs must be completed for all therapeutic and non-therapeutic industry and cooperative group (i.e., NCI) clinical research. Investigator initiated studies should be reviewed for applicability and feasibility of a DOA and will be determined by the CTO if one is necessary. The PI is responsible for selecting appropriately qualified study staff. The selection of appropriately qualified study staff for significant trial related duties is as per ICH GCP 4.1.5 and USA Clinical Trial Policy CT102.

All studies requiring a DOA log will use our site-specific document. The site-specific document may be a physical paper log or an electronic log using the site's CTMS. Sponsor specific DOA logs will no longer be completed for studies in which the USA CTO was selected as a site after July 1, 2023.

Non-research staff who perform only research specific procedures in connection with the protocol and which follow the scope of practice assigned to the specific role (e.g., Phlebotomists, EKG Technicians, Lab Technicians, Interventional Radiologists, Infusion Center Nursing Staff, Medical Assistants, etc.) are not required to be listed on the DOA Log as per the ICH GCP Guidelines in section 4.1.5, as these individuals are not performing significant trial-related duties and do not require study specific training to perform these procedures. Additionally, for in-patient trials, Hospitalists, Nurse Practitioners, Residents, or Fellows who only provide ancillary or intermittent care for the study patients, but do not make a direct or significant contribution to the clinical data (i.e., evaluate AEs, sign drug order forms, consent study patients, etc.) are not required to be listed on the DOA Form.

Additionally, the PI is responsible for ensuring that updates to the DOA log for clinical research personnel changes are completed in a timely manner by the corresponding study staff.

Procedures

1. Information entered in all sections of the log should be legible, correct and completed in English. The PI and site staff should use the same signature and initials when signing and initialing patient records and any study related documents to ensure consistency and to be identifiable.

2. When using an electronic delegation log or when paper delegation logs are signed electronically, a signature sample must be obtained from each researcher listed. This signature sample can be used for audit verification purposes to validate signature/initials used for consenting, source document completion, and CRF entry. Individual signature logs may be used across multiple studies.

3. The delegation log should contain the following information:
   3.1. Protocol name and/or number
   3.2. Site number
   3.3. Principal Investigator Name and signature
   3.4. Delegate's Name
   3.5. Delegate's signature and initials
   3.6. The task(s) being delegated
   3.7. Delegate's Start Date
   3.8. Delegate's End Date
   3.9. PI's Initials and Date for each delegate

4. Only those performing significant, trial related tasks should be delegated on the delegation log. Examples of significant, trial related task include, but is not limited to:
   4.1. Informed Consent
   4.2. Source documentation completion
   4.3. Assessment of Inclusion/Exclusion Criteria

4.4. Physical Exam
4.5. Adverse Event reporting and/or assessment
4.6. Unblinding
4.7. Preparing and/or dispensing Study intervention

5. All staff delegated to significant study related duties must show evidence of appropriate education and training to confirm they are qualified to perform the delegated task.

6. USA non-research personnel who perform trial related tasks are not required to be on the delegation log if the research task is within their normal scope of practice and/or duties. The non-research personnel must still be properly trained per SOP 205 Training Records.

7. The delegation log must be updated throughout the study to account for changes in delegated tasks, the addition of new personnel, and the removal of personnel who no longer work on the study.

8. Changes to the delegation log must be approved by the Principal Investigator.

Principal Investigator Change

1. There are two options for updating the delegation log for a change in PI. Either option is acceptable; however, Option A is preferred.

   OPTION 1 - Preferred (start a new log)

   - Outgoing PI will sign and date the PI signature line on the bottom of page 1.
   - Enter a statement in the comment section of the form to indicate there was a change in PI.
   - The new PI will start a new DOA form by signing and dating a new page 1.
   - Delegation by the new PI for all site staff is documented on the new form. Date listed should be the date the new PI signed the new form.

   OPTION 2 (keep existing delegations and start a new log)

   - Enter a statement in the comment section of the form to indicate there was a change in PI.
   - The new PI will start a new DOA form by signing and dating the top section of a new page 1
   - The new PI will enter a statement in the comments section of the original DOA form agreeing with the existing delegations.
   - Changes or new additions to the DOA that occur after a new PI begins will be made on the new DOA log.

Roles or Key Study Tasks Changes

1. If the role of a staff member changes during the course of the trial, an end date should be entered at the time the role is no longer being completed by the individual (e.g. Sub-I, becomes the new PI).

2. If there are any changes to study tasks for an individual, the current delegation line should be updated with an end date. A new line is then started with the updated delegated study tasks. End dates should be assigned and the new study tasks entered on a new line.

3. The PI is required to initial and date changes to confirm and acknowledge any additional or deleted tasks.

Additional Resources

RELATED POLICIES:

- **CT102 QUALIFIED INVESTIGATORS AND RESEARCH STAFF**
- **CT205 PROTOCOL TRAINING RECORDS**

History

N/A

Next Review Date

January 2027

Responsible Party

Director, Clinical Trials Office