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## Standard Operating Procedure – Site Signature and Delegation of Authority

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**Category:** Research  
**Responsible Office:** Vice President for Research  
**Responsible Executive:** Assistant Provost for Research Compliance & Regulatory Affairs

**Date Established:** 10.9.20  
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### Summary

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This Standard Operating Procedure (SOP) describes the site signature and delegation of responsibilities for individuals involved in the coordination of any human subject research in which key responsibilities are delegated by the Principal Investigator (PI). This process applies to the PI, sub-investigators and clinical site research personnel at the study site. This SOP is designed to promote efficient human subject research administration through the delegation of responsibilities while ensuring that all study personnel are informed of the duties of the research staff.

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### Responsibilities

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Principal Investigator  
Study staff delegated responsibility for regulatory compliance

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### Procedure

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#### Purpose

The purpose of this SOP is to:

- A. Fulfill the requirements stated in ICH GCP E6 (R2) Guideline Section 4.1.5: “the investigator should maintain a list of appropriately qualified and trained persons to whom the investigator has delegated significant trial-related duties”.
- B. To meet the expectation of the FDA guidance – “Investigator responsibilities - Protecting the Rights, Safety and Welfare of Study Subjects”, in particular Section 3, which clarifies the investigator’s responsibility to supervise the conduct of the clinical investigation and to protect the rights, safety and welfare of participants in drug and medical device clinical trials.

#### Procedures

The process of Delegation of Authority:

- A. Prior to beginning research-specific tasks, the PI, with the assistance from the study team, will complete and keep current the Delegation of Authority (DOA) log. An example of a DOA log that can be used is available from TransCelerate, or an electronic DOA log within the 21 CFR Part 11 Compliant eRegulatory (eReg) documentation management system. The PI will review the protocol documents to identify any protocol-specific tasks that may be delegated to study team members.

- B. Per International Conference on Harmonization Good Clinical Practice (ICH GCP) a DOA log must be used for all prospective interventional trials (e.g. device, biologic, behavioral, drug). At MUSC a DOA log will also be maintained and on file for all other human subject research in which key responsibilities are delegated by the PI. There must be a separate DOA log for each applicable protocol. Only one original DOA log will be maintained and filed with the corresponding study's regulatory files. Studies may have a combination of a hard copy and electronic DOA log when transitioning to using the eReg system, or when one of these documentation formats alone is not optimal for the study.
- C. For sponsored trials, the sponsor may provide a DOA log, but the study team is not required to use that version. It is acceptable for study teams to use the TransCelerate DOA log, Sponsor DOA log, eReg DOA log or an internally-developed DOA log. In the event that the Sponsor does not provide a DOA log the study team will be responsible for ensuring one is created and maintained throughout the duration of the study.
- D. The name of each study team member that will have significant trial-related duties as determined by the PI will be listed on the DOA log and the log will be maintained as part of the regulatory files for all applicable trials. Duties that are considered significant may vary by study, but are generally duties that could impact subject safety, protocol compliance, and data quality/integrity. Examples of significant duties include, but are not limited to: obtaining informed consent, performing study-specific procedures (not related to standard of care or normal job duties), collecting data, regulatory compliance, assessment of the primary endpoints, attribution of adverse events, and dispensation of investigational product.
- a. When multiple persons on a clinical unit (e.g. Investigational Pharmacy, Nexus Clinic, MUHA/MUSCP clinical units, laboratory) are considered by the PI as key personnel in conducting study procedures, the unit manager should be added to the DOA log. Only the unit manager's signature or designee will serve as the official signature for the clinical unit and representing all staff within that unit who may perform the study activities. The person who signs the DOA on behalf of a clinical unit will also complete and document any study specific training, as required. They will also be responsible for ensuring that all necessary competencies/trainings for other clinical staff serving as key personnel are maintained and documented. Training documentation supporting the DOA log must be made available upon request.
  - b. Personnel listed on the DOA log may need to be submitted to/approved by the IRB of record for the trial. The investigator should review the requirements of the reviewing IRB to determine which personnel require IRB submission/approval.
- E. Personnel that perform administrative tasks or perform routine procedures, e.g., commercial services or standard of care assessments, are not considered key personnel and will not be listed on the DOA log. As such, inpatient or clinic/infusion nurses, radiologists, pathologists, technicians (pharmacy, phlebotomists, ECG technicians),

residents, fellows, interns and office staff are not included on the DOA log unless determined by the PI that they make a direct and significant contribution to the research.

- a. The evaluation of whether personnel are performing functions within the scope of their professional licensure depends not only on the scope of their licensure, but also on local regulations.
  - b. Additional qualifications or restrictions detailed in the protocol documents take precedence over policy and state law.
- F. All staff delegated to significant study-related duties must complete appropriate education and training as directed by the study sponsor and/or institution to ensure they are qualified to perform the delegated task. Documentation of such training should be maintained and made available upon request within a timely manner.
- G. At a minimum, Curriculum Vitae (CV) and licenses (if applicable) should be on file for all investigators listed on the DOA log, demonstrating their qualifications.
- H. Each study staff member will acknowledge the duties delegated to him/her by the PI by signing/dating and initialing the DOA log. When using eReg, the study staff member acknowledgment will be documented as an electronic signature/date within the DOA log.
- I. Specific tasks or responsibilities must be documented for each person listed on the DOA log and will include start and end dates for the individual's involvement with the protocol.
- J. For all active studies, the PI with the study team will ensure that the DOA log is maintained, reviewed, and signed off on by the PI in a timely manner.
- K. The DOA log is an official regulatory document and is often requested during audits and inspections.
- L. For studies that are under an investigational new drug application, study team members who will make a "direct and significant contribution" to study data as determined by the PI should also be individually listed in Section 6 of the 1572.
- a. Study team members listed in the role of "Sub-Investigator" or "Co-Investigator" on the DOA should be listed in Section 6 of the 1572 as individuals in this role will always make a "direct and significant contribution" to the study data.
  - b. Unless specified by the PI, MUSC does not typically list RNs, pharmacists, study coordinators or support staff in Section 6 of the 1572 unless they are responsible for:
    - i. Clinical and safety decisions of study participants
    - ii. Authorized to prescribe study medications
    - iii. Evaluating and interpreting clinician rated assessments

- c. All persons listed on the 1572 in Section 6 must have a Financial Disclosure Agreement on file.

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## Related Information

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### Other Documents/Information:

- ICH Guideline for Good Clinical Practice E6(R2)
- FDA Guidance for Industry: Investigator Responsibilities – Protecting the Rights, Safety, and Welfare of Study Subjects (October 2009)
- 21 CFR 50 – Protection of Human Research Subjects
- 45 CFR 46 – Protection of Human Subjects
- Form FDA 1572
- HRRP 5.3 Education and Training Requirements for Individuals Involved in Human Research
- HRPP 5.2 Principal Investigator Responsibilities-Record Keeping and Record Retention Requirements
- HRPP 5.1 Principal Investigator Responsibilities - Supervision of Staff and Protection of Subjects
- [TransCelerate Site Signature and Delegation of Responsibilities Log](#)
- [TransCelerate Information and Guidance Document for Completion of the Site Signature and Delegation of Responsibilities Log](#)
- [Advarra/Forte eRegulatory \(eReg\) documentation and management system](#)



10/9/2020

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Signature/Approval:Date:

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