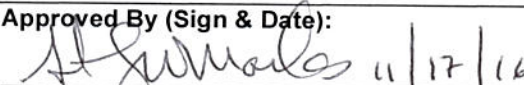
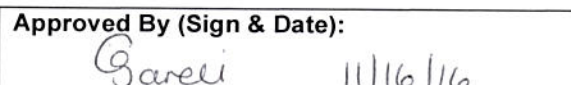


Investigator Standard Operating Procedures

SOP No. 107

SOP No.: Transfer of Principal Investigator Responsibilities	
Author: Office of Human Research	
Effective Date: July 29, 2015	Supersedes document dated: N/A
Last Reviewed on: Nov 2, 2016	Results of Review: Minor edits, no major changes, no new version
This SOP pertains to: Principal Investigator and all other designated individuals responsible for the proper conduct of a trial and the completion of applicable regulatory documents	
Responsibility for executing this SOP: Investigator, replacement Investigator and Designated Research Personnel responsible for overseeing the completion of regulatory documents	
Approved By (Sign & Date):  Senior Vice President & Chief Medical Officer, MHS	Approved By (Sign & Date):  Chief Research Officer, OHR

1 PURPOSE

When a Principal Investigator (PI) leaves the institution (or site) and/or relinquishes his/her role as the person overseeing the trial, the responsibilities must be transferred to a new Principal Investigator who will assume ownership over the study. If a replacement Principal Investigator cannot be identified, the sponsor and IRB should be contacted so that the study can be temporarily suspended at the site, and proper arrangements put in place for those subjects currently active on treatment or in follow-up.

This SOP describes the process that should be implemented to ensure the safety and welfare of the research subjects, and lists the steps to be taken so that all relevant parties are appropriately informed.

2 GENERAL PROCEDURES AND RESPONSIBILITIES

Once the Office of Human Research has been notified that a Principal Investigator will be leaving the institution, or no longer wants to continue in the role of PI, the Chief Medical Research Officer, the Senior VP & Chief Medical Officer, the Research Nurse Manager and the head of the Regulatory team should be informed.

3 SPECIFIC PROCEDURES

The transfer of PI responsibilities is a PROCESS that involves proper notification of all relevant parties and obtaining necessary approvals before proceeding; it will require some time for the transition to take place. There will always be Investigator coverage for the research subjects to ensure their safety and wellbeing while on the study.

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The following steps should be taken once notification has been received that a Principal Investigator (PI) will be relinquishing their role:

1. A new (PI) should be identified, preferably from the Sub-Investigators already trained on the protocol.
2. Note:
 - a. If the outgoing PI's departure is imminent, and a replacement PI has not been identified and/or approved, the study should be suspended to accrual of new patients and the study team notified.
 - b. If the outgoing PI's departure is not imminent, and enough notice has been provided, then the study does not need to be suspended to new patient accrual.
3. The Office of Human Research will draft a Memo to File (MTF) (See Attachment A) notifying the study sponsor, IRB of record and other relevant parties that the previously named PI will be relinquishing their rights to a new PI as of the date signed on the 1572. The MTF will:
 - a. Include details of the relinquishment (if known)
 - b. State that the new PI's responsibilities will become effective from the date of the signature on the 1572.
 - c. Allow active subjects to continue to be seen by the old PI as long as they are still under contract with MHS and still listed on the 1572 and Delegation Log as a Sub-I (Reference SOP 103). The new PI will maintain oversight of the trial from the date of the 1572, but **until the IRB has approved the new Investigator, no new subjects should be enrolled on the study**. Those subjects already active on treatment or in follow-up will be overseen by the new PI to eliminate immediate hazards until IRB approval has been received.
 - d. Be signed by both the outgoing and incoming PI's (where possible).
 - e. Should be sent to the sponsor for approval of the new PI.
4. If the study does not have a 1572, the effective date for the transfer of PI responsibilities will be the date the IRB approves the new PI (see Attachment B)
5. Sponsor

Once approval from the sponsor has been received, the 1572 should be updated to reflect the departure of the outgoing PI with the replacement of the incoming PI.

 - a. The Chief Medical Research Officer will ensure that the incoming PI understands the responsibilities of assuming the PI role.
 - b. The new PI should sign and date the 1572 with their effective start date.
 - c. Designated regulatory staff should verify that the incoming PI has been trained on the requirements of the protocol, completed all sponsor required training, completed the CITI certification, etc.
 - d. The signed 1572 should be submitted to the sponsor.
 - e. The new PI will need to sign the protocol signature page and other required study related documentation.
 - f. The Delegation of Authority log should be updated to reflect appropriate start and stop dates for the incoming and outgoing PIs. The new PI should be clearly listed.
6. IRB

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- a. The IRB should be notified of the PI change after sponsor approval.
 - b. Once IRB approval has been received:
 - i. The study team will be notified of the change
 - ii. The research subjects will be notified of the change per the IRB's direction.
 - c. If IRB approval has not been obtained by the time the outgoing PI leaves MHS, the study will be suspended to enrollment. A MTF will be created (Attachment C) and will be submitted to the sponsor, IRB, sub-investigators and research staff. Accrual to study will be re-implemented upon approval of the new PI.
 - d. If the IRB does not approve the new PI, then the study will be suspended and the relevant parties notified. Accrual to the study will be re-opened upon IRB approval of the new PI.
7. The OHR will work with the sponsor to:
- a. Submit an amendment to the IND notifying the FDA about the new investigator (Reference SOP 201).
 - b. Amend contract with OHR/MHS Legal to remove old investigator and replace with new PI.
 - c. Amend budget to include costs for new submissions to the IRB.
8. Documentation of all correspondence between all involved parties should be kept in the Regulatory binder.
- a. When physical documentation is not available, all conversations should be documented in a follow-up email.

4 REFERENCES TO OTHER APPLICABLE SOPS

- SOP 103 Investigator Responsibility and Delegation of Authority
- SOP 201 Contacts and Submissions for FDA
- SOP 501 Communication

5 ATTACHMENTS

- A. Template for Relinquishment of studies with a 1572
- B. Template for Relinquishment of studies without a 1572
- C. Memo to File template for studies temporarily suspended to accrual

6 APPLICABLE REGULATIONS AND GUIDELINES

- Responsibilities of Sponsors and Investigators (21 CFR 312, Subpart D)
- Responsibilities of Investigators (21 CFR 812, Subpart E)