Center for Clinical and Translational Science

STUDY SIGNATURE AND DELEGATION LOG INSTRUCTIONS

PURPOSE

This log has two purposes; First, it documents the signatures and initials of all staff that collect and record study data so that study documentation attributed to specific staff members may be verified. Second, it lists the study-related activities that the study team member is responsible for, as delegated to them by the Principal Investigator.

HOW TO USE

- Complete the form header by adding the Protocol name, Principal Investigator's name and IRB number.
- List the names of study staff members and record the study role and responsibilities that have been assigned to them using the task list provided in the Delegated Tasks section.
- Revise the Delegated Tasks section as needed to reflect study-specific needs, utilizing the "Other" category to specify protocol duties not included elsewhere.
- Each study staff member listed should initial and sign to indicate their understanding of the responsibilities assigned.
- Please ensure that all staff listed on this log are also IRB-approved to do the task to which they are assigned (i.e. such as consenting participants).
- Study staff should be qualified by training, education, and licensed (as appropriate) to complete the tasks that have been delegated to them.
- A study start date should be assigned and entered for each study team member. This is the date the individual began working on the study.
- The site PI should initial and date each line of the form as entries are recorded. The PI's signature at the bottom of each form is required at the conclusion of the study.
- Update the log as needed following any change in site study personnel.
- If newly delegated duties are added, the appropriate boxes are checked and the PI initials and dates those changes.
- If delegated duties are removed for a study team member, complete the end date (the date the individual completed their work on the study) and relist the individual indicating the start date of current duties.
- Number each page and maintain this log in the Regulatory Documents Binder

- At the conclusion of the study, update the log adding end dates for those study personnel who have not yet completed their responsibilities on the study.
- Identify the final page of the log by completing the entry line in the footer.
- Have the PI sign the signature line on the bottom of each page.

GOOD PRACTICE RECOMMENDATIONS

- Review the log periodically, updating as needed to keep it is current