COMPLETION INSTRUCTIONS
FOR
Site Signature and Delegation of Responsibilities Log

Purpose of the Site Signature and Delegation of Responsibility Log:

- To fulfill the requirements stated in ICH GCP E6 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”.
- To meet the expectation of the FDA guidance (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM187772.pdf) –“Investigator responsibilities - Protecting the Rights, Safety and Welfare of Study Subjects”, in particular Section 3 which clarifies the “investigators’ 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”.
- To address the requirement in Section 8 of ICH GCP 8.3.24 “signature sheet” to document signatures and initials of all persons authorized to make entries and/or corrections on CRFs.
- Documents study-specific roles and responsibilities assigned to all staff on the study team by the Principal Investigator (PI).
- FDA regulations 21 CFR 312.53 state a commitment by the investigator that he or she “will ensure that all associates, colleagues, and employees assisting in the conduct of the study (ies) are informed about their obligations”.

General Guidance:

- 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.
- The form may be completed electronically, however the signature and initial columns need to be handwritten to validate signatures / initials used for consenting, source document completion and CRF entry.
- All personnel performing study-related procedures must be listed on the log. If the PI has delegated any tasks as related to the protocol to a staff person, these individuals and the tasks must be listed on the log. The intention of the form is not to capture any task that an individual may perform, but to list the study personnel and the key study tasks that they are delegated. For additional tasks not listed, select “Other”, and work with the sponsor to define additional study-specific tasks.
- Update the log in a timely manner as new personnel are added or removed and/or study roles and responsibilities change. Changes must be approved by PI before they are implemented (as indicated by his/her initials and date recorded next to the changes).
- 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. The evaluation of whether study staff is performing functions within the scope of their professional licensure depends not only on the scope of their licensure, but also on local regulations. Thus, the professional licensing authority in the State(s), Province(s) or Country(ies) in which the study is taking place make the final determination. Each investigational site should be aware of their local regulations as to what the scope of practice is (e.g. Nurse Practitioner and Physician Assistant).
- If extra rows are needed, duplicate the second page of the Site Signature and Delegation of Responsibilities Log and number pages accordingly.
• If extra space is required for any fields, use the next line below.
• If satellite sites are involved in the trial, each site should maintain their own delegation log to ensure timely and accurate completion with a copy maintained at the main site.
• The original form should be retained at the site and a copy sent to the Sponsor at the end of the study (reference ICH GCP section 8.0) http://www.fda.gov/downloads/Drugs/Guidances/ucm073122.pdf

How to use the Log?

• Sponsor or representative: Modify the form as necessary to reflect study- specific tasks in the key study task list and explain those to the site staff.
• Principal Investigator (PI): Upon assignment of the delegation, the PI must initial and date each line on the log to acknowledge that the delegation of tasks is accurate. Follow procedures provided by the sponsor or representative.
• Each site staff member: personally place his/her signature and initials next to their name in the respective boxes.

What needs to be entered in each box of the log?

A. Header

   Protocol/Study Number
   Enter the protocol/study number designated on the protocol.

   Principal Investigator Name
   Print the full legal name of the Principal Investigator (PI).

   Sponsor Name
   Enter the name of the sponsor company.

   Site Number
   Enter the study- specific site number.

   Site Name (if applicable)
   Enter the site name.

B. Principal Investigator (PI) section

   This section is to be completed by the PI by recording his/ her legal name, initials, and the date when the involvement in the study started.

   If there is a new PI, refer to the “How to Handle Site Staff Changes” section below.

C. Site Staff section

   Name
   Print or write legibly the full legal names of the site staff members who will be assigned key study tasks related to the clinical trial. Record only one name per line.
Signature
Each individual assigned a task must sign in the column next to their name. This signature will be used to compare entries made later on study related documentation by the individual. In some regions there may be more than one signature in addition to the English signature; in this case, both signatures should be captured on the log.

Initials
Each individual enters her/his initials as they will appear on any trial related documentation. Initials are generally defined as the first letter of the person’s first (given) name and last (family) name. If another way of recording initials is used as a common practice and this is consistent with all other documents where investigators provide initials, this can be accepted.

Study Role
Enter the site staff’s study-specific role next to their name on each line. Examples of study roles may include but are not limited to:

- SI - Sub-Investigator
- SC - Study Coordinator
- (Blinded) assessor
- Pharmacist
- Study nurse
- Technician (specify)

Key Study Tasks
Use the key located at the bottom of the form to assign the tasks delegated. Record the numbers corresponding to the tasks. Numbers recorded can be consecutive numbers, or range, e.g. 1,3,5,6, or 1-4; 8-11. Ensure that tasks are aligned with the roles, expertise and training of the individuals. If there are additional study-specific tasks that are not included on the form, use the “Other” designation and specify the task. Consult the Sponsor or their representative on what these tasks may be.

Start (format: dd/mmm/yyyy)

“Start” indicates the start date when the individual has been delegated study tasks (not necessarily when the PI has added the staff to the study team). Note: All training should be completed prior to the delegation of the task. No study related tasks can be performed prior to training.

End (format: dd/mmm/yyyy)

“End” indicates the date when the individual is no longer participating on the study. For each site staff individual, this may be a different date depending on when their involvement in the study has concluded. At the initial completion of the log, this column is typically left blank.

The “End Date” should be left blank unless the individual’s involvement concluded prior to the end of the study, at which point, an end date should be entered. If no entry is made in this column, it is assumed that the tasks were conducted until the completion of the study (the date of the close-out visit). After “End Date”,
all accesses for study related IT systems, such as EDC, IWRS and so on, must be terminated.

PI Initials and Date

The PI records his/her initials and the date in which he/she is reviewing the log to acknowledge that the initial or new delegations to the staff are correct. By initializing a row, the PI confirms the particular staff member is authorized, trained and qualified to perform the tasks assigned to him/her. This information about the staff member is not complete without the PI’s initials.

Comments
The PI may use the space below the table to clarify any changes that were not possible to document on the log. An example can be acknowledgement by the new PI that he/she has reviewed and is in agreement with tasks delegated before by the former PI.

D. Investigator End of Study Declaration

The statement related to Investigator and Site Staff electronic signature being the legally binding equivalent of their handwritten signature is included in the Delegation of Responsibility log to comply with FDA’s 21CFR Part 11 (Electronic Records; Electronic Signatures). No completion is required in this field. Site staff has to be provided with explanation of the purpose of this statement.

At the conclusion of the study, the form should be signed and dated in the designated area by the PI after reviewing all entries for accuracy. The completed form should remain at the site with a copy provided to the Sponsor or representative.

How to handle site staff changes?

Principal Investigator Change

If during the course of the trial, there is a change in the PI, the current PI should complete the end date as their final date on the trial in the PI section at the top of the form. The new PI should complete a new line entering their start date which should be the same date or the next day following the end date of the original PI. The new PI may specify in the Comments section that he/she has reviewed all delegated tasks and is in agreement of delegations or to clarify any changes in delegated tasks for site staff members.

Roles or Key Study Tasks Changes

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).

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. The key point is to ensure that it is clear on the form what tasks the individual has been delegated to perform. End dates should be assigned and the new study tasks entered on a new line.
The PI is required to initial and date changes to confirm and acknowledge any additional or deleted tasks.

**General Guidance for aligning this form to FDA Form 1572**

Individuals that have direct and significant contribution to the data should also be recorded on the FDA Form 1572, where applicable and where it is utilized