Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual Appendix:

Guidance on Completion of Delegation of Duties Log

All Clinical Research Site (CRS) staff and other individuals who have been delegated significant study-related duties or tasks, which the Principal Investigator (PI)/Investigator of Record (IoR) would otherwise do, must be listed on the Delegation of Duties (DoD) log. The DoD log is used to name the responsible CRS staff/applicable individuals and the significant study duties/tasks that the PI/IoR delegated to these individuals—not to capture every task an individual may perform. Significant study duties/tasks could impact participant safety, protocol compliance, and clinical trial data quality and integrity. The PI/IoR retains the overall responsibility for the conduct of the clinical trial, including delegated duties/ tasks. CRS staff and other individuals will not perform study-related duties/tasks before they complete training. In addition, individuals delegated significant study-related duties will limit their duties to remain within the scope of their professional licensure. The PI/IoR must ensure that training documentation supports the delegated duties/tasks.

Note: While DAIDS allows CRSs to use a site-specific/customized DoD log in lieu of the DAIDS DoD template, CRS DoD logs must be protocol specific and include **all** fields from the DAIDS template.

General

- Information entered in all DoD log fields must be legible and correct.
- The DoD log lists common study tasks; however, CRSs must also add study-specific tasks mandated by study protocols in the “Other” designation and specify the duty/task. CRSs may add lines to create additional “Other” task categories, if needed; ensure numbering remains in sequential order.
- More than one CRS staff and other individuals may be assigned the same task.
- If extra space is required for any field, use the next line below.
- If extra rows are needed to complete this DoD log, duplicate the second page of the Log and number the pages accordingly.

- Retain the current DoD log and all previous original DoD log versions at the CRS.
- Keep all DoD logs up to date in real time.

Note: Ancillary staff with an occasional role in conducting a clinical trial (e.g., staff who intermittently provide a service or consultation such as a hospital radiologist) do not need to be included on the DoD log unless the duty/task is part of the study endpoints.

Name, Signatures, and Initials

The PI/IoR, CRS staff, and other individuals who have been delegated significant study duties/tasks use the same signature and initials, as provided on the DoD log, when signing and initialing source documentation, case report forms and any study-related documents (essential documents).

Name

Print the names of the CRS staff and other individuals who will be assigned significant study duties/tasks. Record only one name per line.

Signatures

CRS staff and other individuals assigned a duty/task must sign using a full signature, in the column next to their name. This signature will be used to later compare entries made by them in essential documents. Note that some regions require a signature in addition to the English-language signature; in this case, CRSs must capture both signatures on the DoD log.

Initials

Individuals enter their initials as they will appear on any essential documents. Initials must be unique for all CRS staff and other individuals (e.g., if two individuals have the initial “NM”, one staff must also use a middle initial).

DIVISION OF AIDS (DAIDS) DELEGATION OF DUTIES LOG TEMPLATE

Protocol/Study Number:	Enter protocol number
Principal Investigator (PI)/Investigator of Record (IoR) Name:	Enter PI/IoR Name
Clinical Research Site (CRS) Name:	Enter CRS Name
Clinical Research Site Number:	Enter CRS Number

PI/IoR Name	PI/IoR Signature	Initials and Date	Start Date (dd/mm/yyyy)	End Date (dd/mm/yyyy) (complete only if prior to end of study)
Enter PI/IoR's name	Enter PI/IoR's signature	Enter PI/IoR's initials and date. Use (dd/mm/yyyy) format	Date the PI/IoR started any study-related activities. Use (dd/mm/yyyy) format	Date the PI/IoR ended study related activities due to the study ending or a change in PI/IoR. Use (dd/mm/yyyy) format

Change of Principal Investigator/Investigator of Record

If the PI/IoR changes during a study, the new PI/IoR must review the DoD log and initial/date beside the previous PIs'/ IoRs' initials on the log to indicate agreement with each individual duty/task delegation. Any changes to the delegated duties/tasks must be specified on a new line. Alternately, the new PI/IoR may complete a new DoD log.

Significant Study Duty/Task

Use the Significant Study Duty/Task Key to assign the duties/tasks delegated. Record the numbers corresponding to the duties/tasks. Numbers recorded can be consecutive numbers, or range, e.g. 1,3,5,6, or 1-4; 8-11. Ensure that duties/tasks align with the expertise and training of the individuals. If there are additional study-specific tasks that are not included on the DoD log, do not delete duties/tasks; use the "Other" designation and specify the duty/task. Create additional "Other" tasks categories if more lines are needed. Be sure to keep the numbers in sequential order.

1. Coordinates Institutional Review Board (IRB)/Ethics Committee (EC) communications 2. Perform participant selection/recruitment* 3. Confirm eligibility (review inclusion/exclusion criteria) * 4. Obtain and document medical history (source documents) 5. Obtain re-consent 6. Enters/Manages data 7. Manages regulatory documents/submissions 8. Perform significant study specific assessments* 9. Evaluate study related test results* 10. Report serious adverse events (SAEs)/expedited adverse events (EAEs) 11. Lab/Sample collection 12. Prescribing study product* 13. Resolve data queries 14. Perform counseling (HIV testing, adherence, etc.) * 15. Obtain and document informed consent * 16. Perform and document physical exam* 17. Signs off on case report forms (CRFs)	18. Conducts quality assurance (QA)/quality control (QC) procedures 19. Provides/Administers study drug/product 20. Make study-related medical decisions* 21. Assess adverse events (AEs)/SAEs/EAEs* 22. Study Product Management* 23. Laboratory/Sample processing and/or shipment 24. Make entries/corrections on (e)Case Report Forms (CRFs) 25. Maintain essential documents 26. Perform study specific procedures that require special training (lumbar puncture, leukapherisis, etc.) * 27. Other(specify): 28. Other (specify): 29. Other (specify): 30. Other (specify): 31. Other (specify): 32. Other (specify): 33. Other (specify): 34. Other (specify):

Staff Information					**Start Date and PI/IoR Delegation Approval/Date**		**Stop Date and PI/IoR Confirm Delegation End/Date**	
Staff Full Legal Name	**Staff Signature**	**Staff Initials and Date**	**Study Role**	**Key Study Task(s) (choose from list)**	**Start Date (dd/mm/yyyy)**	**PI/IoR Initials**	**End Date (dd/mm/yyyy)**	**PI/IoR Initials**
Name of person who will have duties/tasks delegated to them.	Signature of person performing delegated duties/ tasks	Initials of person performing duties/ tasks	Role of person in the study	A selection of study duties/tasks is listed on the DoD log	Date when the duty or task was delegated	Initials by the PI/ IoR to confirm delegation	Date duty or task ended	Initials by the PI/IoR to confirm that the duty or task ended.

Start of Duty/Task (format: dd/mm/yyyy)

"Start" indicates the start date when the individual has been delegated study duties/tasks (not necessarily when the PI/IoR has added the staff to the study team).

Note*:* CRS staff and other individuals will not be delegated to perform study-specific-related duties before they complete their protocol training.

End of Task (format: dd/mm/yyyy)

“End” indicates the date when the CRS staff or other individual is no longer participating on the study or performing a delegated duty/task. Enter the “End Date” when the CRS staff’s or other individual’s involvement concludes prior to the date of PI/IoR End-of-Study Declaration. CRS staff and other individuals will not undertake any delegated duties/tasks after the entered “End Date”. If no entry is made in this column, this indicates that the duties/tasks were conducted until the completion of the study (date of PI/IoR End-of-Study Declaration).

Principal Investigator/Investigator of Record Initials

PIs/IoRs must initial and date all applicable changes and additions to the DoD log immediately to acknowledge that named staff and delegated duties are correct. Each entry for CRS staff and other individuals is not complete without the PI´s/IoR’s initials and date. By initialing the “Start Date,” the PI/IoR confirms the CRS staff and other individuals are authorized, trained appropriately to the role, and qualified to perform the duties/tasks assigned, but this field should not be used as the sole evidence that staff are trained. If/When CRS staff and other individuals are no longer responsible for the delegated the duty/task, PIs/IoRs must initial and date the log to verify this fact.

Significant Study Duties/Tasks Change

The PI/IoR updates the DoD log in real time as new CRS staff and other individuals are added or removed and/or study roles and responsibilities change. The PI/IoR updates the current delegation line with an end date and starts a new line with the updated delegated study duties/tasks. It is important to ensure that it is clear on the DoD log what duties/tasks the individual has been delegated to perform and the effective start date.

Comments

The PI/IoR may use this space to clarify any changes that were not possible to document on the DoD log fields. An example can be acknowledgement by the new PI/IoR that he/she has reviewed and agrees with duties/tasks delegated by the previous investigator/IoR.

Principal Investigator/Investigator of Record End-of-Study Declaration

At the end of a study, the PI/IoR will sign and date the DoD Log in the designated area after reviewing all entries for accuracy. They must retain the current, completed DoD log and all previous original DoD log versions at the CRS according to the DAIDS requirements described in the SCORE Manual's Essential Documents section.

Version Control

CRSs are required to maintain version control of the DoD log and ensure the version is documented on each page of the document (i.e., footer). In case the document is revised, for example adding a new field, a new version number should be included.

The first final version of a document should be Version 1.0 and should include the date when the document becomes final/effective. Subsequent revised documents will have an increase of "1.0" in the version number (2.0, 3.0, etc.).