

Work Instruction
Delegation of Duties Log Instructions

Effective Date: 03/14/19

Document No.: **WI-A15-OPC-001.00**

DIVISION OF AIDS (DAIDS) DELEGATION OF DUTIES LOG (DoD Log) INSTRUCTIONS

All site staff and other individuals who have been delegated significant research study-related duties or tasks, which the investigator/Investigator of Record (IoR) would otherwise do, must be listed on the DoD log. The intention of the DoD log is not to capture every task that an individual may perform, but to list the site staff and other individuals and the significant research study duties/tasks that they have been delegated. Significant research study duties/tasks could impact significantly on participant safety, protocol compliance, and the quality and the integrity of the research study data. The investigator/IoR retains the overall responsibility for the conduct of the clinical research study, including delegated duties/tasks. Site staff and other individuals will not perform research study-related duties/tasks before they complete training. In addition, individuals delegated significant research study-related duties will limit their duties to remain within the scope of their professional licensure. The investigator/IoR must ensure that training documentation supports the delegated duties/tasks.

GENERAL

- Information entered in all fields of the DoD log must be legible and correct.
- A selection of research study tasks is listed in the DoD log; however, protocols may have additional tasks not listed. If there are additional research study-specific tasks that are not included on the DoD log, 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.
- More than one site staff and other individuals may be assigned to the same task.
- If extra space is required for any field, use the next line below.
- If extra rows are needed in the completion of this DoD log, then duplicate the second page of the DoD Log and number pages accordingly.
- Retain the current DoD log as well as all previous original DoD log versions at the site.
- Keep all DoD logs up to date in real-time.
- Note: Ancillary clinical staff with only an occasional role in the conduct of the research (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.

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UPDATES

The DoD log must be updated in real time as site staff and other individuals are added or removed and/or study roles and responsibilities change. Changes must be approved by the investigator/loR (as indicated by his/her initials and date) before they are implemented.

NAME, SIGNATURES AND INITIALS

The investigator/loR, site staff and other individuals who have been delegated significant research study duties/tasks will use the same signature and initials, as provided on the DAIDS DoD Log, when signing and initialing participant source documentation, case report forms records and any research study-related documents (essential documents). The signature and initial columns need to be handwritten to allow validation of signatures/initials used for study- related documentation (e.g. consent form, source documents, CRF entry, study product logs).

NAME

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

SIGNATURES

Site 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 the site staff and other individuals in essential documents. Note, in some regions there may be one signature in addition to the English signature; in this case, 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 site staff and other individuals (e.g., if there are two individuals with the initial "NM", then one staff must also use a middle initial).

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DAIDS DELEGATION OF DUTIES LOG

Protocol Number:	Enter protocol number
Investigator/IoR Name:	Enter Investigator/IoR Name
Clinical Research Site Name:	Enter Site Name
Clinical Research Site Number:	Enter Site Number

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

CHANGE OF INVESTIGATOR/INVESTIGATOR of RECORD

If there is a change in the investigator/IoR, the new investigator/IoR reviews the DoD log and initials and dates beside all the previous investigators'/IoRs' initials on the log indicating agreement with each individual duty/task delegation. Any changes to the delegated duties/tasks are specified on a new line. Alternatively, the new investigator/IoR completes a new DoD log. Retain the current DoD log as well as all previous original DoD log versions at the site.

Significant Research Study Duty/Task Key

Use the Significant Research 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 are aligned with the expertise and training of the individuals. If there are additional research

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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.

<ol style="list-style-type: none"> 1. Coordinates IRB/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 SAEs/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 CRFs/eCRFs 	<ol style="list-style-type: none"> 18. Conducts QA/QC Procedures 19. Provides/Administers Study Drug/Product 20. Make study-related medical decisions* 21. Assess AEs/SAEs/EAEs* 22. Study Product Management* 23. Lab/Sample processing and/or shipment 24. Make entries/corrections on (e)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):
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Staff Information					Start Date and Investigator/IoR Delegation Approval/Date		Stop Date and Investigator/IoR Confirm Delegation End/Date	
Staff Full Legal Name	Staff Signature	Staff Initials and Date	Research Study Role	Key Study Task(s) (choose from list)	Start Date (dd/mm/yyyy)	Investigator /IoR Initials	End Date (dd/mm/yyyy)	Investigator/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 research study	A selection of study duties/tasks is listed on the DoD log	Date when the duty or task was delegated	Initials by the investigator/IoR to confirm delegation	Date duty or task ended	Initials by the investigator/IoR to confirm that the duty or task ended.

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Start of duty/task (format: dd/mm/yyyy)

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

Note: Site 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 site staff or other individual is no longer participating on the research study or performing a delegated duty/task. Enter the “End Date” when the site staff’s or other individual’s involvement concludes prior to the date of investigator/IoR End of Study Declaration. Site 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 research study (date of investigator/IoR End of Study Declaration).

Investigator/IoR Initials

The investigator/IoR records his/her initials and dates at the time of adding to or making changes to the DoD log to acknowledge that the delegations to the site staff and other individuals are correct. By initialing the “Start Date”, the investigator/IoR confirms the site staff and other individuals are authorized, trained appropriately to the role and qualified to perform the duties/tasks assigned. The entry for each site staff and other individuals is not complete without the investigator/IoR’s initials and date. Once the site staff and other individuals are no longer delegated the duty/task, the investigator/IoR must initial and date to verify this fact.

Significant Research Study Duties/Tasks Change

The investigator/IoR updates the DoD log in real time as new site staff and other individuals are added or removed and/or research study roles and responsibilities change. The investigator/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.

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Comments

The investigator/loR 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 investigator/loR that he/she has reviewed and agrees with duties/tasks delegated by the previous investigator/loR.

Investigator/loR's End of Study Declaration

At the end of the clinical research study, the investigator/loR will sign and date the DoD Log in the designated area after reviewing all entries for accuracy. Retain the current completed DoD log as well as all previous original DoD log versions at the site in accordance with the DAIDS Essential Documents Policy and The Storage and Retention of Clinical Research Records Policy.

REVISION HISTORY

WI-A15-OPC-001.00 is the original version of this work instruction.