

Template Delegation of Duties Log for IMPAACT Studies

Instructions

The attached template may be adapted to fulfill the DAIDS requirement that IMPAACT sites maintain study-specific Delegation of Duties Logs. Sites are permitted to adapt the content and formatting of this template, or to use an alternative template of their choosing, provided that all DAIDS requirements are met. Please refer to the New DAIDS Informed Consent (IC) Process Requirements Instructions memo, released on 31 August 2017. Per the DAIDS requirements, the following elements must be included in all logs:

- Protocol number and name
- Investigator of Record (IoR) name
- Site staff names, roles, and responsibilities
- Start and end dates of site staff roles and responsibilities
- Site staff signatures and/or initials as per institutional policies
- IoR signature and/or initials as per institutional policies

Rows may be added or removed from the log as needed to accommodate the number of site staff assigned/delegated to each study. Below the last row, the IoR must sign and date the log confirming that site staff are appropriately qualified and have received appropriate training related to their roles and responsibilities for the study. The IoR's signature and date must be recorded prior to study initiation at the site.

Code listings of roles and responsibilities may be adapted as needed for each study and to include site-specific job titles. Code listings must be attached to the delegation log sheets.

Delegation of Duties Logs must be updated as staffing changes occur over the period of study conduct at the site (e.g., as new staff are hired, as new roles or responsibilities are assigned). When such changes occur, the IoR's confirmation that site staff involved in the changes are appropriately qualified and trained must also be documented. In the attached template, a column is provided for recording IoR initials and date for this purpose.

The IoR has ultimate responsibility for conduct of the study at the site, and is responsible for ensuring study roles and responsibilities are delegated to qualified staff. The IoR is also responsible for ensuring that site staff receive and maintain appropriate training to remain qualified for their designated roles and responsibilities throughout the period of study conduct at the site.

Delegation of Duties Logs — original versions and all modifications and/or updates — must be maintained in study-specific essential document files.

IMPAACT [####]
[Protocol Title]

Delegation of Duties Log

All personnel directly involved in IMPAACT [####] must be listed on this log. List all study roles and responsibilities for each staff member using the attached codes. Start and end dates refer to the period during which each staff member is directly involved in the roles/responsibilities listed. Start dates must precede the first date each staff member performs the listed roles/responsibilities. Maintain this log with other IMPAACT [####] essential documents and update it whenever study-specific staffing information changes. Initials and signatures must be handwritten by each individual staff member. The Investigator of Record (IoR) must sign and date this log prior to study initiation (see below).

Name	Signature	Initials	Credentials	Roles <i>(indicate all codes that apply)</i>	Responsibilities <i>(indicate all codes that apply)</i>	Start Date	End Date	IoR Initials and Date*

*IoR initials and date are required for all updates recorded on this log after the original IoR signature date shown below.

Name	Signature	Initials	Credentials	Roles <i>(indicate all codes that apply)</i>	Responsibilities <i>(indicate all codes that apply)</i>	Start Date	End Date	IoR Initials and Date*

*IoR initials and date are required for all updates recorded on this log after the original IoR signature date shown below.

By signing this log, the IoR confirms that staff members listed on this log are appropriately qualified and trained to perform their delegated roles and responsibilities. Regardless of these delegations, the IoR remains ultimately responsible for the conduct of the study at the site.

IoR Name: _____ **IoR Signature:** _____ **Date:** _____

CRS Number: _____ **CRS Name:** _____

IMPAACT [####] Delegation of Duties Log

Role and Responsibility Codes

[Note: The code listings shown below may be adapted as needed for each study and to include site-specific job titles.]

ROLE CODES	RESPONSIBILITY CODES
IoR. Investigator of Record IoD. IoR Designee* SI. Co- or Sub-Investigator SC. Study Coordinator RC. Regulatory Coordinator MO. Study Clinician/Medical Officer SN. Study Nurse/Nurse Midwife C. Study Counselor QO. QC/QA Officer QA. QC/QA Assistant DM. Data Manager DA. Data Technician/Assistant LM. Laboratory Manager LT. Laboratory Technologist PoR. Pharmacist of Record P. Pharmacy Technician/Assistant CE. Community Educator OW. Outreach Worker RA. Research/Project Assistant [Other - specify] [Other - specify]	<ol style="list-style-type: none"> 1. Performs participant education/outreach/recruitment 2. Conducts informed consent process 3. Assesses eligibility 4. Confirms/verifies eligibility 5. Enrolls participants using Subject Enrollment System 6. Performs maternal physical exams 7. Performs infant physical exams 8. Performs other clinical assessments (maternal or infant) 9. Directs maternal clinical and toxicity management (including study drug management) 10. Directs infant clinical and toxicity management 11. Administers study drug adherence questionnaires 12. Administers other questionnaires 13. Collects specimens 14. Orders laboratory tests 15. Prescribes study drug 16. Dispenses study drug 17. Provides HIV-related counseling 18. Provides study drug adherence counseling 19. Provides contraception counseling 20. Performs tracing/locator activities 21. Enters electronic case report forms (Rave) 22. Performs administrative duties 23. Performs regulatory duties 24. Performs QC/QA duties 25. [Other - specify] 26. [Other - specify]

*An IoR Designee is a staff member who is authorized to make clinical decisions and/or sign for the IoR in his or her absence.