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18 STUDY-SPECIFIC CLOSEOUT

The term “closeout” refers to procedures undertaken to fulfill administrative, regulatory, and human participant requirements after participant follow-up in a [Division of AIDS \(DAIDS\)](#)-sponsored HPTN study has been completed at the Network Central Resources [HPTN Leadership and Operations Center (LOC), Laboratory Center (LC), and Statistical and Data Management Center (SDMC)], and at Clinical Research Sites (CRS).

For the purposes of a DAIDS sponsored study, study closeout may be defined as the period when all participant visits have been completed, the database has been locked or frozen, and all lab specimens are accounted for/reconciled. This definition is independent of the CRS study closure with their Institutional Review Boards/Ethics Committees (IRBs/ECs).

For studies not sponsored by DAIDS, the requirements of the respective sponsor (e.g., a pharmaceutical company or other funding agency) should be followed.

18.1 Study-Specific Closeout Activities

Study-specific closeout at the CRS is separate from overall study closure (in the case of a multi-site study) and site closure, both of which involve [Office of Clinical Site Oversight \(OCSO\)](#). OCSO is not involved in CRS study-specific closeout.

To facilitate planning for study-specific closeout, the SDMC will provide protocol teams with information on the projected final participant follow-up visit date for each participating study site and the study overall.

Projections initially will be made upon completion of accrual into the study. Thereafter, projections will be updated as needed depending on the study design and planned duration of participant follow-up.

HPTN Central Resources will begin planning for study-specific closeout prior to completion of participant follow-up. This planning will include the following:

- Development of the study-specific closeout checklist, primarily coordinated by the HPTN LOC but in conjunction with SDMC, LC, Protocol Chairs, DAIDS Medical Officer, and DAIDS Pharmaceutical Affairs Branch (if applicable)
- If applicable, development of plans, procedures, and materials for unblinding the protocol team, study staff, and participants (see Section 12.1.5 for participant unblinding)
- Development of plans, procedures, and materials for release of study results to the protocol team, study staff, participants, and participant communities (see Section 21.2 for the release of HPTN data from the SDMC)
- Development of plans for data analysis, manuscript preparation, and publications, taking into account that the first draft of the primary manuscript should be distributed to the co-authors for review within eight months of the last participant's scheduled follow-up visit. For information about publications, see Section 21
- The SDMC will develop a plan for data cleaning, database lock, data analysis, and final study data submission for studies under Clinical Trial Agreement.
- The SDMC will provide technical assistance or reports as needed to study sites or the HPTN LOC single IRB coordinator to fulfill Institutional Review Board (IRB)/Ethics Committee study closeout reporting requirements

- If applicable, the SDMC will provide the LC with a listing of study participants who did not provide informed consent for post-study specimen storage and possible future research testing, so that the LC may coordinate sample destruction (see Section 18.3)
- The LC will develop a plan to complete all required post-study laboratory testing, including testing performed for verification of study endpoints. The LC also will inform study sites when all protocol-specified testing has been completed
- The DAIDS Prevention Sciences Program (PSP) Medical Officer will inform all relevant parties at DAIDS of the projected end date for participant follow-up at each study site; at a minimum this will include within-DAIDS communication to begin planning for the study closing at the site
- The CRS Pharmacist of Record must adhere to final disposition procedures for study product(s) as outlined in the protocol and the *Pharmacy Guidelines and Instructions for DAIDS Clinical Trials Networks*
- The SDMC, LC, and CRS will work together to reconcile the database to each specific sample (type and number of aliquots) collected during the study, available on site, and available at the LC

Each participating study site will begin planning for study-specific closeout prior to completion of participant follow-up at that site. As part of this planning, the site will:

- Notify the responsible IRBs/Ethics Committees of CRS study closeout according to the IRBs/Ethics Committees procedures (to be done in consultation with the HPTN LOC single IRB coordinator, for sites overseen by the single IRB)
- In consultation with site-specific study staff and community representatives, tailor plans, procedures, and materials for unblinding study staff (if applicable) or release of study results to staff, participants and communities to suit local site needs
- Develop operational and staffing plans for completion of all required study closeout procedures as listed on the study specific closeout checklist

After participant follow-up has been completed, protocol teams and study sites will implement all plans listed above. Study sites will complete all required study-specific closeout procedures as listed on the study-specific closeout checklist.

It is recognized that closeout procedures need not be completed in the order listed on the checklist, and that some procedures will require considerably more time (up to several months) than others. Study sites should complete each requirement in as timely a manner as possible and use the checklist to document progress toward meeting all requirements throughout the closeout process.

If applicable, site staff will de-register the protocol through the [DAIDS Protocol Registration System](#) (DPRS) according to instructions on the DAIDS [Regulatory Support Center](#) (RSC) website and in the [DAIDS Protocol Registration Manual](#).

Deregistration can occur when:

- The CRS no longer has participants on study (all follow-up has been completed) and does not plan to enroll additional subjects
- If no participants were ever enrolled at the CRS and the study has closed to accrual

The DAIDS deregistration process is independent of a CRS's closure/termination of a study at their IRB/Ethics Committee. The IRB/Ethics Committee's determination to close or terminate a study is NOT required for a CRS to deregister with DAIDS. Completion of the DAIDS deregistration process indicates that a CRS's participation in a study is complete but does not reflect the closure of a multi-center study at all CRSs participating in the study. Refer to the DAIDS Protocol Registration Manual for complete deregistration details

After all requirements have been met, the study site Investigator of Record will sign and date the checklist, file the signed original on site, and forward a copy to the HPTN Clinical Research Manager (CRM). The HPTN CRM will forward a copy to the DAIDS PSP Medical Officer.

All study records must be retained in accordance with the DAIDS Policy on Essential Documents found in the [DAIDS SCORE Manual](#).

18.2 Long-term Storage of Study Records

Investigational New Drug (IND) Application

For studies under an IND, investigators must retain study records for a period of at least two years following the date of approval of the product or any labeling change of a licensed product and at least three years after the completion of research or as applicable. If no marketing application is filed, or if the application is not approved, the records must be retained for two years after the US [Food and Drug Administration](#) is notified that the IND is discontinued ([21 CFR 312.6221 CFR 312.62](#)), or longer if needed to comply with local regulations. Studies filed with other regulatory authorities may require longer periods.

Completion of a clinical research study occurs when the following activities have been completed:

- All research-related interventions or interactions with human subjects (e.g. when all subjects are off study)
- All protocol-required data collection of identifiable private information described in the IRB/Ethics Committee-approved research plan
- All analysis of identifiable private information described in the IRB/Ethics Committee-approved research plan
- Primary analysis of either identifiable private or de-identified information

Non-IND Studies

For studies not under an IND, investigators must retain study records for a minimum of three years after completion of the research, or longer if needed to comply with local regulations. Completion of a clinical research study occurs when the following activities have been completed:

- All research-related interventions or interactions with human subjects (e.g., when all subjects are off study)
- All protocol-required data collection of identifiable private information described in the IRB/Ethics Committee-approved research plan
- All analysis of identifiable private information described in the IRB/Ethics Committee-approved research plan
- Primary analysis of either identifiable private or de-identified information

For more information see [DAIDS Policy on Essential Documents](#) in the [DAIDS SCORE Manual](#). For all studies, retention of study records must also be in accordance with local regulatory requirements as well as local IRB/EC policies and procedures.

No study records are permitted to be destroyed before the study to which the records relate are included on one of the lists for transfer or destruction of records. Refer to the DAIDS [RSC website](#) for information.

18.3 Sample Destruction

Study site staff must store all specimens collected during a study unless otherwise specified. Specimens collected during the study may not be destroyed without prior permission of the LC unless specifically requested by study participant(s).

Study participants are asked to provide written informed consent for their specimens to be stored after the end of the study for possible future testing. If participants do not consent to long-term storage and additional testing of their specimens, study staff must destroy the specimens at the end of the study after all protocol-related and quality assurance testing has been performed, the data have been cleaned, and primary and secondary analyses are completed (unless otherwise specified); the SDMC will provide the LC with a listing of study participants who did not provide informed consent for post-study specimen storage and possible future research testing so that the LC may coordinate sample destruction. Study staff must obtain permission from the LC before destroying specimens.