**Sample Study Close-out Checklist**

**Protocol Title and Number:**

**Site Name and Location:**

The following checklist is intended for Operational Close-out for study sites registered to a specific protocol in the HPTN and should be completed following IRB/Ethics Committee (IRB/EC) notification of the end of participant follow-up, reconciliation and shipment (when applicable) of samples, and database lock. The original study close-out checklist should be kept on file at the study site.

**Site Responsibilities**

**Data Management**

* Complete and submit all required Case Report Forms (CRFs) to SDMC.
* Once all CRFs are submitted, resolve all outstanding data QC notes, including those related to laboratory testing (SDMC will provide reports of outstanding QCs).
* Site, LC and SDMC to work together in order to resolve any outstanding LDMS discrepancies; once this is completed, protocol related testing is completed and the database is locked, SDMC will provide a list identifying which participants did and did not consent to long-term storage of samples.
* Resolve any pending monitoring/auditing findings/queries, if visits have been conducted.

**Laboratory**

* Resolve any outstanding LDMS discrepancies as noted above.
* LC will provide a shipping list to the site from which the site will be required to ship all requested samples for the primary and secondary analysis to the LC. Please note that an IATA certified and LDMS trained laboratory staff member should be readily available until all shipments have been sent. The timing of requests for shipments will vary per protocol but could be more than one year from last study visit
* LC may also provide a shipping list to the site from which the site will be required to ship all requested samples for storage to either the LC or a DAIDS repository. Please note that an IATA certified and LDMS trained laboratory staff member should be readily available until all shipments have been sent. The timing of requests for shipments will vary per protocol but could be more than one year from last study visit

***\*All shipments must be sent to the HPTN LC as soon as possible after receipt of the shipping list.***

* Collaborate with LOC, the SDMC and LC to resolve any discrepant laboratory test results and finalize endpoint-related documentation.
* All participant samples that have not been shipped to LC must remain in storage until notified by SDMC and the LC. These samples will be held until primary and secondary laboratory data analysis and the manuscripts are completed. The timing will vary per protocol but should be held until permission to destroy is received from the HPTN Leadership.
* *Non US sites – resolve all associated proficiency testing issues*
* *Non US sites – resolve all relevant DAIDS contractor audit findings that may affect endpoint data*
* Once all other laboratory steps are complete and only with LC approval, destroy any samples for participants that did not consent to long-term storage.

**Pharmacy**

* Reconcile all study product records as soon as possible after the last participant visit.
* Apply to PAB for destruction of study product. Once PAB approval is granted, document and destroy all remaining study product on site OR ship all remaining supplies for destruction.

**Regulatory Documents**

* After all laboratory and data management requirements above are complete, review and assemble for long-term storage all required essential documents, including:
* Administrative and regulatory documentation.
* Log linking participant names and PTIDs (which also serves as the completed participant identification code list required by ICH GCP guidelines).
* All study documents bearing participant names.
* All study documents bearing participant ID numbers.
* All specimen processing laboratory documents, such as processing worksheets, deviations, competency test results, training records, equipment calibration records, SOPs.
* Study product records.
* Notification to IRB/Ethics Committee that participant follow-up is complete, OR IRB/ EC closeout letter.
* Prepare a written inventory of all documentation and storage locations (check only one below).
* IND requirements

The Investigator will retain all study records for at least two years following the date of approval of any labeling change for this licensed product and at least three years after the completion of research. If no marketing application is filed, or if the application is not approved, the records must be retained for two years after the FDA is notified that the IND is discontinued, 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/EC-approved research plan
* All analysis of identifiable private information described in the IRB/EC-approved research plan
* Primary analysis of either identifiable private or de-identified information

Study records include administrative documentation — including protocol registration documents and all reports and correspondence relating to the study — as well as documentation related to each participant screened and/or enrolled in the study — including informed consent forms, locator forms, case report forms, notations of all contacts with the participant, and all other source documents.

* Non-IND requirements

The Investigator will maintain, and store in a secure manner, complete, accurate, and current study records throughout the study. Under the HHS regulations, the Investigator is required to retain all study records relating to research for at least three [3] 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/EC-approved research plan
* All analysis of identifiable private information described in the IRB/EC-approved research plan
* Primary analysis of either identifiable private or de-identified information.

Study records include administrative documentation — including protocol registration documents and all reports and correspondence relating to the study — as well as documentation related to each participant screened and/or enrolled in the study — including informed consent forms, locator forms, case report forms, notations of all contacts with the participant, and all other source documents.

To the extent possible, organize and categorize all study documentation according to ICH GCP guidelines (ICH E6, Section 8.4).

**IRB/EC**

* In accordance with IRB/EC requirements, inform all responsible IRBs/ECs of the end of participant follow-up and database lock. This step typically occurs after SDMC has released the site-specific closeout report. Forward a copy of this IRB letter to the LOC.

**RSC**

* Deregister the protocol with RSC for your site. Note: this step is different from and independent of the IRB closure.

**General**

* Complete, sign and date this checklist once all items are completed. File original with other study documentation and send a copy to the LOC.

**Responsibilities of LOC, LC, SDMC**

* SDMC site-specific study close-out report submitted to site after database lock including: Date last participant follow-up visit was completed
* Number of participants enrolled at the site
* Number of participants who completed the study at the site
* Number of participants who withdrew, or were withdrawn (as defined by the protocol team), from the study prior to completion
* List of Social Impact Reports
* List of SAE/SUSAR events

*LC to provide study closure information to DAIDS contractors so that Proficiency (protocol related) panels, if not needed for other protocols, are cancelled.*

Investigator of Record Signature Date

Investigator of Record Name

CRS Name/ DAIDS ES number