HPTN
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Trials Network

HPTN 074 Publications and closeout

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Site Responsibilities

Data Management (should be completed by September 2017)

- ❒ 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 (should be completed by March 2018)

- ❒ 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 <u>as soon as possible</u> 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.

Regulatory Documents (will go on until July 2018)

- ❒ 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).

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. DAIDS must be consulted prior to destroying any records.

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

IRB/EC (dependent on local regulations)

- ❒ 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 (may occur in October 2017)

- ❒ 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.

Closeout

- Continue exiting study participants as planned
- Last visits to take place by 15 June 2017
- Closeout Checklist
- Databased to be locked approximately Oct 2017
- Laboratory QA/QC to continue for several months thereafter
- Plan on staffing!

	Working Title/Brief Description	Proposed Lead Author	Statistical Support	Timeframe/comments
	TIER ONE (main findings)			
1.1	Recruitment and Enrollment in 074, Baseline: Characteristics and feasibility to recruit and enroll index and network members	Bill and Irving and Scott and Kathy, site leaders	SCHARP and UNC	To begin when enrollment is complete. June, 2016 Intro and Methods can begin anytime
1.2	074 Primary findings: Retention, uptake of intervention, ART and substance use treatment, and incidence by arm	Bill and Irving and Scott, site leaders	SCHARP and UNC	To begin when the study is complete. June 2017
1.3	Feasibility and Barriers of Intervention: quantitative and qualitative	Carl, Kathy and Vivian, Rebecca	UNC	June 2017
1.4	Multi-level Facilitators and Barriers to uptake of ART: a qualitative analysis	Vivian, Rebecca Tetiana	UNC (qual analysis)	Summer 2017
1.5	**Regional Differences in Injection Drug Use Behaviors– Baseline Results from the HPTN 074 Vanguard HIV Prevention Trial**	Bill	Brent and Michael	Abstract accepted IAS 2017
	TIER TWO (secondary findings, all sites)			
2.1	Description of Size and Stability of networks and how this relates to recruitment, retention, uptake of intervention and incidence.	Site leader	SCHARP and UNC	
2.2	Spatial analysis of networks, by HIV status, incidence and uptake of HIV and drug treatment services	Site leader	SCHARP and UNC	
2.3	Social Harms and benefits of 074	Site leader	SCHARP and UNC	
2.4	Phylogenetics and transmission dynamics	Lab	SCHARP and UNC	
2.5	Intervention: Implementation development and hybrid model, operationalization, and monitoring/feedback	Carl, Kathy and Vivian	UNC	After release of baseline manuscript

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	TIER THREE – Site specific or additional analyses			
3.1	Geobehavioural analysis to understand linkages between Drug, Distance and Distribution of IDUs: A case study of Jakarta	Indonesia		Poster presented at NIDA forum June 2016
3.3	A Geospatial Approach for Participant Recruitment of HPTN 074 Study in Jakarta	Indonesia		Poster presented at NIDA forum June 2016
3.4	Alcohol compensatory behavior	Kathy, Vivian, Carl		
3.5	HIV- and drug use-related stigma	Erica, Rebecca		
3.6	HPTN 074: Spatial Accessibility to ART, SUT and NEP Services among PWID in Jakarta	Muslim		Poster accepted to NIDA forum in January 2017
3.7	HPTN 074: Clinical Characteristics of HPTN 074 Screened PWID in Jakarta	Susami		Poster accepted to NIDA forum in early 2017