

HPTN Ancillary Study Application

Ancillary studies may involve collection of additional data and/or samples from primary study participants, or use of existing data and/or samples for analyses or laboratory assessments that are not directly related to the specific objectives of the primary study as defined in the protocol document.

Please complete this application as it pertains to your proposed ancillary study. The application must be reviewed by the primary study protocol team, including the Protocol Chair(s), Statistical and Data Management Center (SDMC), HPTN Laboratory Center (LC) and HPTN Leadership and Operations Center (LOC) representatives. The Investigator of Record for each study site to be involved in or affected by the ancillary study must also review the application as well.

After the primary study protocol team has reviewed the application, the HPTN LOC will request signature approvals from the Protocol Chair(s), SDMC, LC, and LOC representatives, as applicable. After these approvals are obtained, the HPTN LOC will send the application to the HPTN Executive Committee for final review and approval.

**General Study Information**

1. Title of proposed ancillary study: Click or tap here to enter text.
2. Number and title of primary HPTN study to which the proposed ancillary study is linked: Click or tap here to enter text.
3. Name and contact information for proposing HPTN Investigator(s) (include institutional affiliation, email, phone): Click or tap here to enter text.
4. Name and contact information for non-HPTN Investigator(s) (include institutional affiliation, email, phone), if applicable: Click or tap here to enter text.

*Note: All non-HPTN Investigators using biological specimens from HPTN studies must complete an HPTN Materials Transfer Agreement.*
5. Justification for the ancillary study -- why is an ancillary study needed rather than a stand-alone study? Click or tap here to enter text.
6. Study population of the ancillary study: Click or tap here to enter text.
7. Duration of the ancillary study: Click or tap here to enter text.
8. Location of the ancillary study: Click or tap here to enter text.
9. Rationale of the ancillary study: Click or tap here to enter text.
10. Primary objectives of the ancillary study: Click or tap here to enter text.
11. Secondary objectives of the ancillary study: Click or tap here to enter text.
12. Methods of the ancillary study (include materials, staff resources, laboratory assays, data collection tools, shipping, etc.): Click or tap here to enter text.
13. Study assessments: Click or tap here to enter text.
14. Confidentiality and consent issues: Click or tap here to enter text.
15. Possible future use of the research: Click or tap here to enter text.
16. Ancillary study effect on the primary study: Click or tap here to enter text.
17. Funding source: Click or tap here to enter text.
18. Is the proposed study prospective (to be done concurrently with all or part of the primary HPTN study) or retrospective (using specimens or data collected in a completed HPTN study)?

[ ]  Prospective only (will collect new data and/or biological specimens)

[ ]  Retrospective only

[ ]  Combination of retrospective and prospective

1. Will the proposed study require IRB approval?

[ ]  Yes

[ ]  No - specify reason: Click or tap here to enter text.

1. Will separate informed consent be necessary for the ancillary study (in addition to the primary HPTN study informed consent)?

*Note: The IRB/EC is ultimately responsible for determining whether separate consent must be obtained. Documentation of this determination by the IRB/EC is required. Verification of documentation is the responsibility of the proposing Investigator/ designee.*

[ ]  Yes

[ ]  No - specify reason: Click or tap here to enter text.

**Use of Biological Specimens**

1. Will the ancillary study involve use of biological specimens from participants in the primary HPTN study?

[ ]  Yes, leftover stored specimens that were collected as part of the primary HPTN study will be used

[ ]  Yes, additional specimens or an increased volume of specimen must be obtained from subjects specifically for the ancillary study

[ ]  No biological specimens involved

1. If yes to Question 1, please provide the following information below:
* Type of assays to be performed
* Type and quantify of specimens to be used (e.g., 1 mL plasma from 6 time points)
* Whether the results of the proposed testing will be linked to data collected in the primary HPTN study (e.g., identifiers, demographics, HIV risk behaviors, clinical and lab outcomes)
* Whether the results of the proposed testing will be given to the participants who provided the specimens (provide the rationale)

Click or tap here to enter text.

1. If yes to Question 1, does the primary HPTN study informed consent allow for the testing proposed on stored specimens?

[ ]  Yes

[ ]  No

**LOC Resources**

1. Will HPTN Leadership and Operations Center (LOC) resources be required (includes protocol development, administrative help in scheduling calls, coordination, project management, etc.)?

[ ]  Yes

[ ]  No - Explain why LOC resources will not be required, then skip to the next section: Click or tap here to enter text.

1. Will you require LOC assistance with the budget?

[ ]  Yes

[ ]  No

1. Will administrative assistance with scheduling calls be required? *Note: Administrative Assistant only -- does not include involvement of Clinical Research Manager or Clinical Trials Assistant.*

[ ]  Yes, during Protocol Development only (less than 5 calls)

[ ]  Yes, during Protocol Development only (5 calls or more)

[ ]  Yes, for the life of the study

[ ]  No

1. Will a Clinical Research Manager and/or Clinical Trials Assistant be required for any of the following tasks?

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Coordination of ancillary study protocol writing |[ ] [ ]
| Regulatory submissions to HPTN and DAIDS review committees |[ ] [ ]
| Project management of study implementation beyond protocol generation (e.g. involvement in study procedure development, oversight of site implementation, regulatory filing etc.) |[ ] [ ]
| Coordination of manuscript writing |[ ] [ ]
| Additional assistance not listed above (please specify): Click or tap here to enter text. |[ ] [ ]

**SDMC Resources**

1. Will Statistical and Data Management Center (SDMC) resources be required (includes accessing study data, preparing shipping lists, statistical analysis, etc.)?

[ ]  Yes

[ ]  No - explain why SDMC resources will not be required, then skip to the next section: Click or tap here to enter text.

1. Will SDMC resources be required for CRF and database development, data entry and QC?

[ ]  Yes, explain type and amount of help needed: Click or tap here to enter text.

[ ]  No

1. Will SDMC resources be required for specimen management and shipping lists?

[ ]  Yes, specimens and shipping will continue as for the main study

[ ]  No

1. Will SDMC resources be required for A/CASI development?

[ ]  Yes, explain type and amount of help needed: Click or tap here to enter text.

[ ]  No

1. Will SDMC resources be required for analysis?

[ ]  Yes, analysis assistant is needed for the observational period

[ ]  No

1. Will SDMC resources be required for datasets?

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Main study data  |[ ] [ ]
| Ancillary study data (if SCHARP is developing CRFs and database)  |[ ] [ ]
| De-identified  |[ ] [ ]
| Other, specify: Click or tap here to enter text. |[ ] [ ]

**LC Resources**

1. Will Laboratory Center (LC) resources be required (includes shipping and receiving specimens, assistance with study design, testing, etc.)?

[ ]  Yes

[ ]  No - Explain why LC resources will not be required: Click or tap here to enter text.

1. Status of LC testing and type of LC services needed:

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| Stored specimens needed -- if yes, specify explain the specimen type, amount (volume) needed and visits: Click or tap here to enter text.  |[ ] [ ]
| LC QA/QC testing completed  |[ ] [ ]
| Protocol-related testing completed  |[ ] [ ]
| LC lab investigations completed  |[ ] [ ]

1. Is consent provided for long-term storage and possible future research testing and/or use of specimens specifically for the proposed investigation?

[ ]  Yes

[ ]  No, not specified, or specimens cannot be used for this purpose

[ ]  Additional guidance is needed to determine if specimens can be used for this purpose

1. Will specimen testing be done at the LC?

[ ]  Yes

[ ]  No, propose where testing will take place: Click or tap here to enter text.

[ ]  Other, specify: Click or tap here to enter text.

1. Are specimen shipments needed from the LC to the proposed testing site?

[ ]  Yes (include shipping costs in budget)

[ ]  No

1. Are specimen shipments needed from study sites to the proposed testing site?

[ ]  Yes (include shipping costs in budget)

[ ]  No

1. Are Material Transfer Agreements and or CDC importation permits needed from the LC and/or study sites?

[ ]  Yes (include costs in budget)

[ ]  No

1. Is LC assistance needed for data analysis and/or manuscript preparation?

[ ]  Yes (include costs in budget)

[ ]  No