**MTN Ancillary Study Application (Multi-Page Application Form)**

**Instructions:**

To request approval of an ancillary study, as defined in the MTN Manual of Operational Procedures (MOP), complete this form, then print it, hand sign and hand date the form, and send a scanned copy of your signed and dated application to the FHI 360 Clinical Research Manager for the MTN Protocol that this relates to. See the MTN MOP Section titled, *Ancillary Study Proposal, Secondary Data Analysis Requests and Request for Data Sets*, for more detailed information.

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| **1. Application date** |  |
| **2. Number and title of primary MTN study to which the proposed Ancillary Study is linked** |  |
| **3. Name and contact information for proposing MTN investigator (include institutional affiliation/email/phone)** |  |
| **4. Name and contact information for non-MTN collaborating investigator, if applicable (institutional affiliation/email/phone)** | ***Note****: All non-MTN investigators using biological specimens from MTN studies must complete an MTN materials transfer agreement. If applicable, please attach a copy of the signed agreement.* |
| **5. Is the proposed study prospective (that is, to be done concurrently with all or part of the primary MTN study) or retrospective (that is, using specimens or data collected during an MTN study after its completion)?** | Prospective only  Retrospective only  Combination of retrospective and prospective |
| **6. Description of proposed study, including rationale, purpose, objectives, methods, assessments to be performed, necessary staff and other resources, where activities will be carried out, if and how the primary study will be affected by the proposed investigation, and other relevant information** | (Attach additional sheets as needed.) |
| **7. Will separate informed consent be necessary for the proposed study (that is, in addition to the primary MTN study informed consent)?** | Yes  No (Specify reason and attach additional sheets as needed.)  Not yet sure  ***Note****: The responsible IRBs/ECs will ultimately determine whether separate consent must be obtained; documentation of this determination is required.* |
| **8. How will data from the proposed study be managed and analyzed?** | Specify who will be responsible (e.g. MTN SDMC) and where data will be managed and analyzed; attach additional sheets as needed. NOTE: Prior agreement with the MTN SDMC or the responsible party for managing and analyzing data must be obtained prior to submitting this Application to the Protocol Team. |
| **9. Are supplemental MTN funds required for the proposed study?** | Yes (Specify amount and purpose of funds requested (attach additional sheets as needed.)  No (Specify source of funding.)  Provide total estimated budget needed to complete work: |
| **10. Will the proposed study involve use of biological specimens from participants in a primary MTN study? (If no, skip to question 11)** | Yes, stored specimens to be used  Yes, additional specimens or volume to be obtained from subjects specifically for the Ancillary Study  No biological specimens involved |
| **10a. Where will the proposed laboratory testing be done, if applicable?** | Note: Prior agreement with the responsible laboratories must be obtained prior to submitting this Application to the Protocol Team.  Not applicable  At local site lab(s)  At MTN LC  Other (Specify institution/lab name and location and attach additional sheets as needed.) |
| **10b. What laboratory assays are to be performed, if any?** |  |
| **10c. What type and quantity of specimens are to be used (for example, 5 ml plasma from six time points), if any?** |  |
| **10d. Will the results of the proposed testing be linked to data collected in the primary MTN study for purposes of analysis (for example, identifiers, demographics, HIV risk behaviors, clinical and lab outcomes)?** | Yes (Explain and attach additional sheets as needed.)  No |
| **10e. Will results of the proposed testing be given to the participants who provided the specimens?** | Yes  No (Explain and attach additional sheets as needed.) |
| **11. If the proposed investigation involves use of stored specimens from a primary MTN study, have the following been completed?**   * **All primary-study endpoints ascertained and confirmed by the SDMC and LC** * **All protocol-specified testing involving the stored specimens proposed to be used in the Ancillary Study completed** | Not applicable — no stored biological specimens to be used  Yes (Attach documentation.)  No, primary study not yet completed  No (Explain.) |

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Signature of Investigator Submitting the Application Date

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Printed or Typed Name of Investigator Submitting the Application