**HPTN 061 Data Request Application Form**

**A. GENERAL INFORMATION**

**1. Proposed project title:**

**2. Lead Investigator(s):**

Institution:

Address:

 Telephone Number:

 Email:

**3. Co-investigator(s):**

**4. Type of data access being requested:**

|  |  |
| --- | --- |
| [ ]  Baseline only | [ ]  Longitudinal |

**6. Purpose of data request:**

|  |  |
| --- | --- |
| [ ]  Local community use | [ ]  Website/blog |
| [ ]  Grant preparation | [ ]  Presentation |
| [ ]  Basis for grant proposal  | [ ]  Webinar |
| [ ]  Manuscript (peer-review)  | [ ]  Other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Manuscript (non-peer review)  | [ ]  Other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| [ ]  Local report  | [ ]  Other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**8. Summary of Changes**: If submission is a revision (to a previously rejected) or an amendment (to a previously approved) existing application, please summarize all changes. (**NOTE:** In addition, please highlight all changes to previously submitted concept sheet.)

**9. If you are requesting baseline data, do you plan to work with someone from a HPTN 061 study team or HPTN Black Caucus throughout your project? (*Note*: Longitudinal data requires working with a study team or Black Caucus member).**

 [ ]  Yes, working with baseline data            [ ]  No, working with baseline data

 [ ]  Yes, working with longitudinal data

If yes, and you already have a collaborator in mind, provide the following information:

 Name:

 Institution:

 E-mail Address:

**11. IRB & Human Subjects Protections:**

1. Does this project have IRB approval? [ ]  No [ ]  Exempt [ ]  Expedited [ ]  Full
2. If no, was another status given? [ ]  Non-human subjects determination [ ]  Pending
3. Local IRB reference #:      Letter attached? [ ]
4. Have all the investigators obtained human subjects protections training?

[ ]  Yes

 Training certifications are attached for the following investigators:

**14. Review the list of completed and proposed manuscripts for HPTN 061 at** <https://www.hptn.org/research/studies/hptn061/dataset>**.**

 Identify any completed or proposed manuscripts that have the potential to overlap with what you are proposing:

If you do not see any overlap or potential overlap with what you are proposing, read the following statement and tick the check box if it applies:

I have reviewed the completed and proposed manuscripts for HPTN 061 and see no potential of overlap with the project I am proposing: [ ]

**15. Will the investigators** **adhere to the data use agreement?** [ ]  Yes [ ]  No

**B. STUDY DESIGN** (*Use the following organization to present your study plan. Take whatever space is necessary to respond completely to each section.*)

**For all data requests:**

 **1.** **Lay Language Summary** (*Provide a one paragraph summary of the study and its impact on participants, written for a 10th grade reading level.*)

 **2. Work Will Be Completed by** (*Anticipated month and year in which the work will be completed.*)

 Month Year

**For longitudinal data requests only:**

 **1. Background** (*Provide a brief description of the rationale for the study, including key references.*)

 **2.** **Specific Aims and Hypotheses**

 **3 Relevance to HPTN 061 and/or BMSM HIV prevention research or community engagement**

 **4. Study Design and Analysis (include data analysis plan and/or table shells as appropriate)**

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**Signature Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Printed Name**