**USAGE AGREEMENT FOR INVESTIGATORS REQUESTING ACCESS TO HPTN 061 DATA BUT NOT WORKING WITH A 061 TEAM MEMBER OR BLACK CAUCUS REPRESENTATIVE**

 *[Investigator name]* (hereafter known as RECIPIENT) at *[Investigator’s institution]* (hereafter known as INVESTIGATOR’S INSTITUTION) is requesting access to HPTN 061 data, to use for analysis or data inquiry.

RECIPIENT hereby acknowledges that, if RECIPIENT is provided with access to HPTN 061 data, the conditions for use of this research material are governed by the policies and procedures of the HIV Prevention Trials Network (HPTN), by the Institutional Review Board (IRB) or Ethics Committee at the PROPOSING INVESTIGATOR's INSTITUTION and by the IRBs at the relevant study sites, in accordance with the U.S. Department of Health and Human Services regulations at [45 CFR 46](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html).

RECIPIENT hereby acknowledges that RECIPIENT has reviewed the consent form of the HPTN 061 study (found in the appendix to the study protocol available [here](https://www.hptn.org/sites/default/files/2016-05/HPTN_061_Protocol_Version_2.0_dated_02_April_09_0.pdf)) and that RECIPIENT’S proposed use of the data is consistent with this consent.

RECIPIENT will work with a member of the HPTN 061 study team and/or a member of the HPTN Black Caucus to receive orientation to the study background and dataset.

RECIPIENT will not provide any HPTN 061 data to any other party, other than those working under the RECIPIENT’s direct supervision on the proposed analysis and who have current GCP and human subjects protections training and have met any other institutional requirements to engage in human subjects research. At the completion of the analysis, it will be the RECIPIENT’S responsibility to ensure that data are not further disseminated and that all staff have expunged the data from their computing devices and portable media. Any additional use of the requested MATERIALS requires prior review and approval by the HPTN and by the IRB at the PROPOSING INVESTIGATOR's INSTITUTION, which must be convened under an Office for Human Research Protections (OHRP) approved Assurance, where applicable.

RECIPIENT will neither sell the data nor use for commercial purposes.

RECIPIENT will take no action, either directly or indirectly, that could allow the identity of study participants who provided any of these data to become known to RECIPIENT or to any other individual or organization. RECIPIENT will inform SCHARP (the HPTN Statistical and Data Management Center) of any disclosure of participant identity.

RECIPIENT remains participant to applicable Country, State, or local laws or regulations and institutional policies which provide additional protections for human participants.

If RECIPIENT violates this Usage Agreement, the HPTN’s response may include punitive action as determined by the HPTN Executive Committee and reporting to funding and regulatory agencies or entities as applicable.

The RECIPIENT agrees to acknowledge the HPTN, including appropriate funding sources, in any publications or presentations resulting from this work, using template language provided to the RECIPIENT by the HPTN 061 study team. This language will make it clear that this work is not a product of the HPTN Study Team nor is it endorsed by the HPTN.

The RECIPIENT will Inform the 061 Study Team of the outcome of the product(s) produced from the HPTN 061 data (journal or grant submission, publication, grant award, etc.) and provide copy of final product(s) to 061 study team.

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| Signature of RECIPIENT |  | Date |
|  |  |  |
| RECIPIENT’s printed or typed name |  | RECIPIENT’s Title |