July 10, 2018

Dear Protocol Chair/Co-Chair,

The HPTN is committed to the highest level of integrated multidisciplinary research through its leadership teams, clinical trial units, and communities, working closely with other partners and networks. As a HPTN team member, you play a major role in contributing to the ongoing success of HPTN and the broader prevention research agenda and for that, the HPTN leadership thanks you.

We would like to take a moment to highlight your study-related responsibilities and to note a change in policy. Because of the time commitments necessary to successfully implement a study, the HPTN has determined that it is not feasible for investigators to be chairs or co-chairs of more than two HPTN studies in order to provide adequate oversight to the protocols they are involved in.

Protocol team business is planned and managed by the Protocol Chair, in consultation and with the support of the HPTN LOC CRM/PRS and other core team members. Specifics of protocol team management vary according to the type of study (Phase I, II, III, research area, etc.), the number and location of sites involved, and individual leadership and management approaches.

In addition to duties as a protocol team member, the Protocol Chair and Co-Chair(s) are responsible for:

* Providing overall leadership to ensure that the protocol adheres to the projected budget and is completed by the projected timeline;
* Working with the Central Resource partners, to provide detailed projections to the HPTN Leadership of the resources required to conduct the study, including site-specific study costs as well as costs associated with study drug and any potential outside contractors or vendors, where applicable;
* Facilitating final decision making within the protocol team to achieve agreement on scientific or operational issues brought before it; if agreement cannot be reached, referring the issue to the SC for consideration;
* Participating as a member of the Clinical Management Committee, if applicable;
* Together with the lead protocol statistician, reporting on the status of the study at open sessions of the DSMB;
* Coordinating the establishment and dissolution of working groups as necessary to achieve efficiency in the development, implementation, and reporting of the study;
* Overseeing the establishment of writing teams during manuscript preparation (designates writing team members, reviews schedules, monitors progress, helps prioritize analysis, communicates publication plans, responds to the MRC review, and advocates for additional resources as required);
* Ensuring review and approval of all study related manuscripts, abstracts and presentations; and
* Providing status updates to HPTN leadership, as needed

The Protocol Chair(s) will act as a liaison between the team and the:

* SC, EC, and its standing committees with responsibilities for protocol oversight (SRC, SMC, MRC, and PEC);
* LOC and DAIDS to facilitate development, review, approval, and implementation of the protocol in accordance with all applicable clinical trials requirements with available resources;
* LC in the development of the protocol design and its implementation, particularly regarding assay evaluation, protocol training and testing as needed, development and review of study-specific laboratory procedures, and establishment of quality assurance guidelines; and
* SDMC in the design, development, implementation, and reporting of the study

The Protocol Chair(s) and the team responsibilities include but are not limited to:

* Developing the study concept plan and protocol, including responding to requests made by the SRC and DAIDS Prevention Science Review Committee (PSRC) for revisions in the draft protocol;
* Soliciting community input during protocol development and review;
* Developing data collection instruments and instructions for the completion of these instruments, with the SDMC;
* Developing the study-specific procedures (SSP) manual, with the LOC;
* Defining, in collaboration with LOC, SDMC and LC, protocol milestones for monitoring performance;
* Overseeing accrual and retention of study participants and management of these individuals as specified in the protocol;
* Monitoring participant safety;
* Conducting ancillary study review and, when necessary, advocating for additional resources
* Monitoring conduct of the study through reports produced by the SDMC concerning screening, recruitment, retention, data management quality, adherence to intervention, endpoint assessment completion, and safety;
* Developing and carrying out corrective action plans for problems with study implementation;
* Overseeing study conduct and implementation, including compliance with all applicable standards and requirements; and
* Producing scientific publications and making presentations related to study findings in a timely manner

Please sign below confirming your understanding and commitment to the responsibilities and HPTN

procedures outlined above and send this to Scott Rose at srose@fhi360.org.

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| I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, | have read and accept these responsibilities.  |
| (print name) |  |
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| (sign) |  (date) |
| **Protocol Number and Title:** HPTN XXX: |