

## HPTN 052 Publication Guidance

It is the intention of the HPTN 052 Protocol Team group that:

1. HPTN 052 data are cleaned and analyses are completed for publication as soon as possible.
2. Writing assignments are clearly defined and fairly distributed among HPTN 052 investigators.
3. Manuscripts utilizing HPTN 052 data are published as expeditiously as possible.

Designated HPTN 052 Protocol representatives, herein referred to as the HPTN 052 Publications Committee Co-Chairs, will oversee the HPTN 052 publications process, as determined by the current Publications Committee. If issues or conflicts arise that cannot be settled by the HPTN 052 Publications Committee, those issues will be resolved by the HPTN 052 Publications Committee Co-Chairs.

The HPTN 052 Publications Committee will triage proposals from investigators for use of data collected from HPTN 052. The use of any data collected as part of HPTN 052, whether for an abstract, manuscript, or presentation, must undergo this triage and review process. The HPTN 052 Publications Committee will perform its duties to assist the HPTN 052 Publications Committee Co-Chairs in realizing the following goals:

1. Setting priorities for HPTN 052 data analyses;
2. Determining the appropriate composition of HPTN 052 analysis and writing teams;
3. Agreeing on authorship for all HPTN 052 publications;
4. Assisting protocol team members in becoming active participants in the analysis and writing process; and
5. Disseminating and publishing as much information as is possible from the data collected during the course of HPTN 052.

These goals will be accomplished using the guidance of the HPTN Publications Policy. The following comprises suggested guidance on authorship for HPTN 052 publications:

- Authorship should be reflective of the multi-site nature of HPTN 052, HPTN publication policies, and generally accepted authorship guidelines. Authorship should be based on substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; drafting the abstract or revising it critically for important intellectual content; and final approval of the version to be presented/published. Acquisition of funding, collection of data, or general supervision of the research group, alone, does not justify authorship. Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. The following approach for operationalizing these authorship guidelines will be adopted:

- The person leading the data analysis, data interpretation, and writing of the abstract/manuscript should be the first author.
- Team members who contributed substantially to the conceptualization, design, and/or implementation of specific aspects of the study should be included as first author or co-author on abstracts/manuscripts related to that aspect of the study (e.g., safety measures, behavioral measures, informed consent issues).
- If data from more than one site are included in an abstract/manuscript, a representative from each site should be included as a co-author whenever possible. The site Investigator of Record is responsible for designating the most appropriate site representative to the authorship team. When abstract submission guidelines limit the number of co-authors, the Publications Committee Co-Chairs will facilitate decision-making on site representation in the authorship team, making every effort to ensure parity across sites over time. All authorship lists for abstracts/manuscripts that include data from more than one site should include “on behalf of the HPTN 052 Protocol Team” at the end of the authorship list.
- The SCHARP statistician who works with the first author to analyze the data for the abstract (if applicable) should be included as a co-author. The Protocol Statisticians are responsible for designating the most appropriate SCHARP staff member to the authorship team.
- A representative from FHI should be considered for authorship on abstracts/manuscripts as appropriate
- A representative from the HPTN Network Laboratory should be considered for authorship on abstracts/manuscripts as appropriate.
- A representative from DAIDS should be considered for authorship on abstracts/manuscripts as appropriate.
- For abstracts/manuscripts presenting data on primary and secondary study objectives, the Protocol Chair should be given the option of being included as a co-author.
- As sites and individuals submit ideas for publication, the first entity (site or individual) to submit the idea will be given priority for authorship, as long as they make substantial contributions to the resulting manuscript.

The HPTN 052 Publications Committee members will serve for two (2) years on a rotating basis. The Committee membership will include four international (non-U.S.) investigators, and four U.S. investigators. The Protocol Chair will serve as a permanent co-chair of the 052 Publications Committee, and one other member of the Publications Committee will serve as co-chair and will rotate off as the membership of the Committee changes every two (2) years.

Proposals for publications (abstracts or manuscripts), presentations and/or use of biological specimens should be submitted to the HPTN 052 Publications Committee, utilizing the attached form. These include proposals for both multi-site and single-site analyses. From these submissions, the HPTN 052 Publications Committee will compile a list of all requests for analyses/publications and will work to ensure that each proposed publication on the list is appropriately evaluated for scientific merit and feasibility. In addition, the HPTN 052 Publications Committee may take pro-active steps like undertake an exercise to list all potential analyses/publications and propose an allocation of these potential analyses/publications to specific members of the HPTN 052 team to the HPTN 052 Protocol Co-Chairs for approval.

The HPTN 052 Publications Committee will assign lead writing roles among the project investigators/team members based on the above-listed principles, the expressed interest of the specific investigators/team members, and a desire to distribute lead writing assignments as equally as possible among the investigators and the team. These assignments will be approved by the HPTN 052 Publications Committee Co-Chairs.

Investigators/team members who accept a lead writing assignment will be expected to produce their manuscripts in a timely fashion. For those failing to do so, the HPTN 052 Publications Committee has the authority to re-assign lead writing assignments.

Priority will be given to analyses addressing primary and secondary study objectives of HPTN 052; however, other analysis proposals will be considered on their merits. In general, access to data/biologic specimens will be made available according to a plan that allows access in the following sequence:

1. HPTN 052 Chair and Study-Site Investigator of Record Investigators
2. All the other members of the HPTN 052 team
3. Faculty members and/or staff at the participating HPTN 052 institutions
4. Faculty members and/or staff at non-052 but member HPTN institutions; and then
5. Faculty members and/or staff from non-HPTN institutions.

Such a plan will allow faculty members and/or staff from those institutions that have supported the HPTN 052 project to benefit first, while ultimately allowing the data/specimens to be available to the wider research community. The HPTN 052 Publications Committee will decide on the timing of the access to the data/specimens by various groups.

**HPTN 052 Publications  
Proposal Form**

**Date:** \_\_\_\_\_

**Investigator/team member name:** \_\_\_\_\_

**Investigator/team member institution:** \_\_\_\_\_

**Investigator/team member email address:** \_\_\_\_\_

This proposal should be brief (1-3 pages) and include the following:

1. Proposed abstract/manuscript title and names of the lead writer as well as potential participating investigators (if known).
2. Briefly describe the rationale for the proposed research topic.
3. Describe major goals of your proposal. List specific research hypotheses and how these relate to the primary or secondary objectives of HPTN 052.
4. List analysis variables including dependent variables (e.g., outcome variables), independent variables of primary interest (e.g., risk factors), and other variables to control in the analysis.
5. If repository specimens are needed to generate data for this analysis, indicate the specimen type and visit number(s), along with minimum amount/volume required. For example, "0.5 mL plasma specimens from the \_\_\_ weeks gestation visit."
6. Proposed timeline for completion of analysis.
7. **OPTIONAL:** Statistical methods/approaches anticipated for the manuscript (unless the statistical analyses have already been determined and/or are to be done outside of SCHARP, an 052 statistician will be assigned to be a member of the writing team once a proposed publication has been reviewed and approved by the HPTN 052 Publications Committee).

Submit this Proposal Form to the HPTN 052 Publications Committee for review via Jackie Talley (jtalley@fhi.org).