

Preparing a HPTN 084 manuscript concept

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HPTN 084 Version 4.0 Face to Face

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HPTN

HIV Prevention
Trials Network

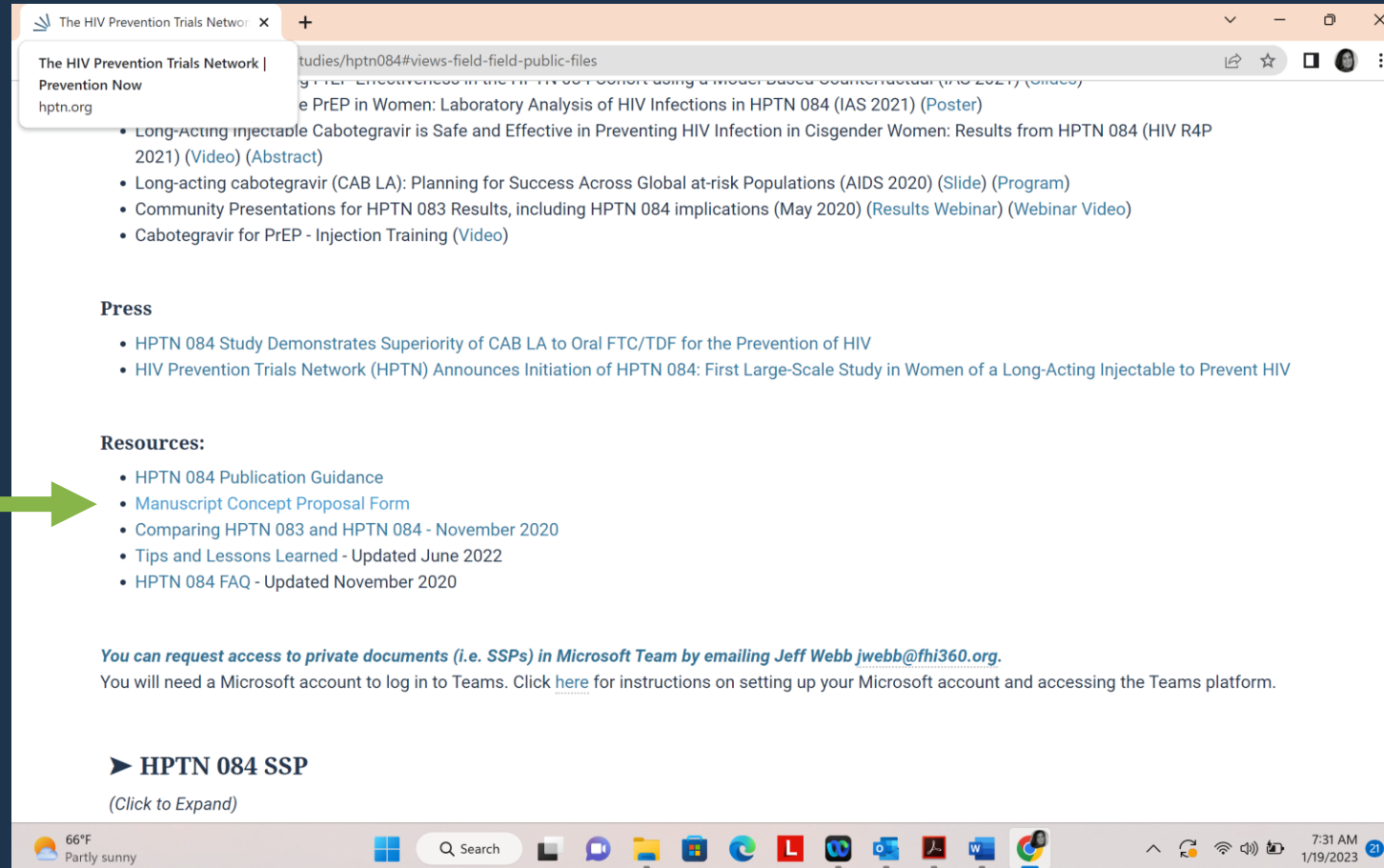


Step 1: Idea Generation

- Have an idea?
- Review Previous 084 publications, abstract and planned publications to verify that it hasn't already been proposed.
 - If proposed- Reach out to the Team to ask to participate
 - If not yet proposed- Develop a new concept

Step 2: Access the “Manuscript Concept Proposal Form” on HPTN website

<https://www.hptn.org/research/studies/hptn084#views-field-field-public-files>



The screenshot shows a web browser window with the URL <https://www.hptn.org/research/studies/hptn084#views-field-field-public-files>. The page content includes a list of links under the heading "Long-Acting injectable Cabotegravir is Safe and Effective in Preventing HIV Infection in Cisgender Women: Results from HPTN 084 (HIV R4P 2021) (Video) (Abstract)". A green arrow points to the "Manuscript Concept Proposal Form" link in the "Resources" section.

Resources:

- [HPTN 084 Publication Guidance](#)
- [Manuscript Concept Proposal Form](#)
- [Comparing HPTN 083 and HPTN 084 - November 2020](#)
- [Tips and Lessons Learned - Updated June 2022](#)
- [HPTN 084 FAQ - Updated November 2020](#)

You can request access to private documents (i.e. SSPs) in Microsoft Team by emailing Jeff Webb jwebb@fhi360.org.

You will need a Microsoft account to log in to Teams. Click [here](#) for instructions on setting up your Microsoft account and accessing the Teams platform.

► HPTN 084 SSP

(Click to Expand)

Step 3:

- Follow Template as instructed
- Should be Brief (1-3 pages)

HPTN 084 Publications Manuscript Concept Proposal Form

Date: _____

Submitter name: _____

Submitter institution: _____

Submitter email address: _____

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

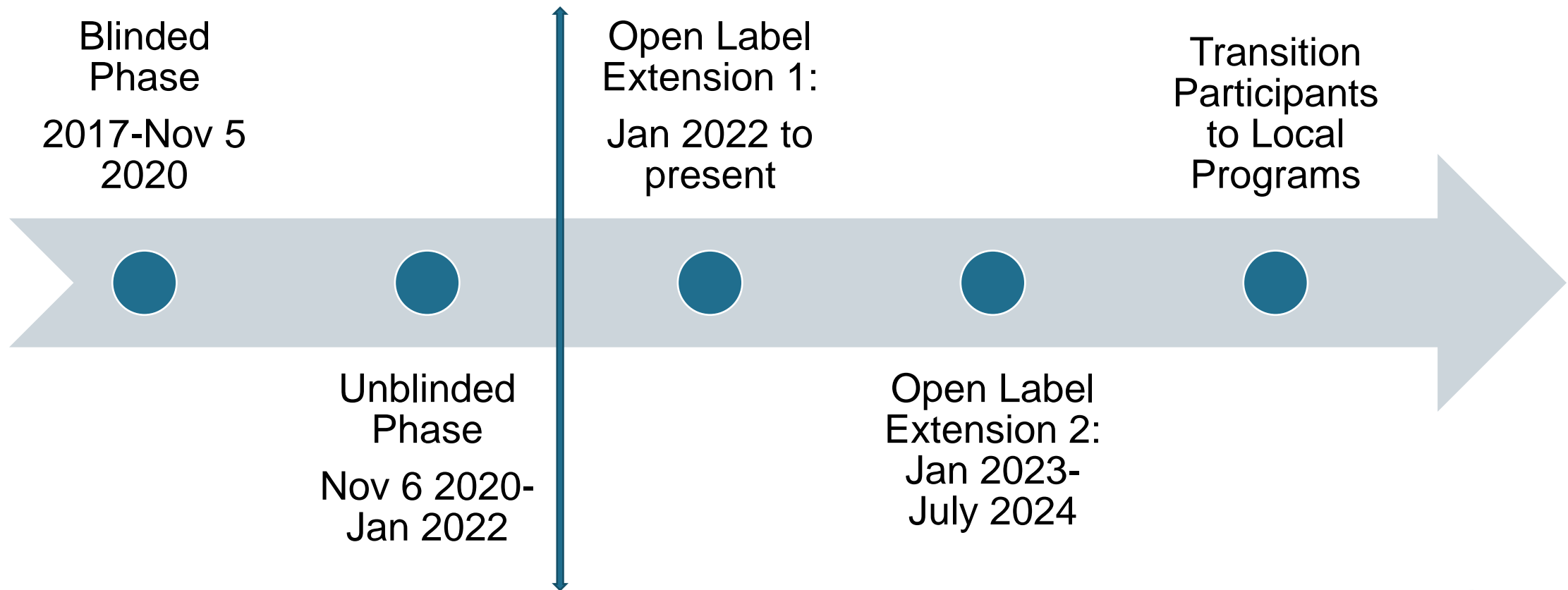
1. Proposed presentation/abstract/manuscript title and names of the lead author as well as potential participating authors (if known).
2. Specify the meeting for presentation or abstract submission, or target journal for publication.
3. Briefly describe the rationale for the proposed concept.
4. Describe major goals of your proposal.
5. Provide details of the proposed outcome(s) and independent variables of primary interest (e.g. risk factors) that support the analysis for the major goals.
6. List study sites from which data will be used for the proposed analysis.
7. Proposed timeline for completion of analysis.
8. OPTIONAL: Most analyses will be performed by the HPTN Statistical and Data Management Center (SDMC). Exceptions should indicate the statistical methods/approaches anticipated for the manuscript and reasons why the analysis should be performed without the SDMC's involvement.

Submit this Proposal Form to Scott Rose (srose@fhi360.org) and Jennifer Farrior (jfarrior@fhi360.org), cc'ing Sinead Delany-Moretlwe (sdelany@wrhi.ac.za) and Mina Hosseinipour (mina_hosseinipour@med.unc.edu).

Tips for the concept

- Think of the data you collected and entered in eCRFs
 - Data must be in the database to be evaluable
 - Consider how it was collected to determine how variables will be considered for your analysis
 - Continuous
 - Dichotomous
- Think of the timeline/implications for your research question

Timeline of HPTN 084



Comparison of Phases

	Blinded	Unblinded	Open Label Extension 1	Open Label Extension 2
Population	Women at Substantial Risk	Same	HPTN 084 + HPTN 084-1 participants	Those who received CAB in OLE 1
HIV Testing	Rapid Antibody (1 or 2) plus Ab/Ag	Rapid Antibody (1 or 2) plus Ab/Ag	Routine VL added to algorithm	Same
Family Planning Requirement	Yes	Yes	No	No
Pregnancy	Stopped CAB, Used TDF/FTC	Stopped CAB, Used TDF/FTC	Pregnancy Study for CAB dosing	Pregnancy Study for CAB dosing
Oral Lead in	Oral Lead in required	Not applicable	Not required	Not applicable

Next Steps

- Review Tables with Statisticians
- Discuss results and if other tables/data are needed
- Once satisfied with Data, write manuscript!