

Community Participation on Concept and Protocol Teams:

To ensure the HPTN's commitment to community participation in all aspects of the research process, it is critical that community participants be included and supported from the concept development stage forward.

It is expected that site investigators involve the community and share with them the study concepts at the beginning of the concept development process. The appropriate time for sharing a study idea with the community may vary from site to site depending on a number of factors, including the level of site development, the level of community organization, cultural factors, etc.; however, ***it is critical that community input is sought as a study concept is being developed.***

The inclusion of a community representative on a protocol team should in no way substitute for ongoing efforts in the development and fostering of an on-site community involvement process. One person cannot be expected to represent the community's views, nor is having one "community representative" be informed sufficient. Community involvement is the responsibility of the investigators and must be actively sought on a broader basis.

The timelines for concept and protocol development must factor in appropriate time for community education and consultation at each site.

There are **three options** for community representatives to participate on conference calls with the first option the most desirable and the third option being the minimum level of partnership:

1. Site representatives on protocol teams pair with community representatives on calls at the same location using a speakerphone. This has the advantage of allowing for face-to-face discussion before and after the call.
2. Community representatives are called or call in on a separate line phone line to the conference call, followed by discussion of the call between the site and community representatives.
3. Community representative does not participate in the call, but the site representative follows up with the Community Advisory Board or selected community members after each call to share updates and solicit input.

Note that the community representative can be either a layperson representative of the study community or a "gatekeeper" – someone who is community-minded, understands the concerns of the research communities, but who may be in a professional position. Someone not employed by the site is preferable. Clearly the need for support and mentoring may differ, depending on community members' individual needs.

Responsibilities of concept and protocol teams include:

- Commitment to value, foster and take into consideration the input of community representatives when developing concept plans and protocols.

Responsibilities of the site staff and PIs in partnering with the community representative include:

- Provide one-on-one information about the concept/protocol and research in general in a context that is accessible and appropriate.
- Include community representative in all concept/protocol team conversations and communications regarding protocol development (e.g., facilitate inclusion on the conference calls, email exchanges, etc.) to the greatest extent possible.
- Support participation of the community reps at key face-to-face protocol team meetings and site-based scientific training opportunities.

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Responsibilities of the community representative include:

- Commit to provide input about community concerns, beliefs and norms, in conjunction with the site staff.
- Function as a conduit of information between the site and potential research communities (e.g., CABs. Where no CABs are available, NGOs, social organizations, etc.)
- When issues of concern arise, have discussions between calls with the community reps from the other sites involved in the trial, preferably including the PI, and ensure a complete feedback loop in terms of information flow.
- Share information, questions and concerns on quarterly CWG Science Update Calls

Responsibilities of the CORE Community Program Staff include:

- Participate on initial Protocol Team calls to clarify the community program processes and answer any questions.
- Provide technical assistance to sites and community representatives to support community participation in concept and protocol development. Be available to site staff to answer questions.

Responsibilities of the HPTU PI:

- Include sufficient funds in the annual budget request to support participation for protocol community representatives in protocol development (e.g. attendance at face-to-face protocol team meetings, local transportation costs, if needed, for participation in conference calls, etc.).