

## How May Stakeholders Benefit from BSS Input?

BSS plays a valuable role in engaging numerous stakeholders over the lifecycle of a clinical trial. Some examples of how BSS could contribute to the successful development and execution of clinical research include:

### Community

- Partnering in research and care
- Research literacy
- Input into protocol development
- Community Advisory Board creation and composition

### Local Opinion Leaders & Community Advocates

- Partnering in research and care
- Research literacy
- Developing research aims and study design

### Trial Participants

- Recruitment
- Retention
- Adherence

### Family & Friends of Participants

- Research literacy
- Recruitment
- Retention

### Research Teams

- Study design and conduct
- Recruitment
- Participant safety and confidentiality

### Academia & Healthcare Providers

- Validity of research
- Community messaging
- Study design and conduct

### Regulatory Authorities

- Study design and conduct
- Participant safety and confidentiality
- Communication of findings

### Funders

- Study design and conduct
- Participant safety and confidentiality
- Interpretation of results
- Communication of findings

## Take Home Messages

- Sustained community engagement and stakeholder input throughout a clinical trial is critical to trial success.
- Study stakeholders include trial participants, relatives and friends of participants, local opinion leaders, researchers, clinical teams, regulatory authorities, local experts, funders, and advocates.
- Stakeholder input may be obtained through a formalized group, such as a Community Advisory Board, through planned community meetings, or through informal communications with stakeholders. Stakeholders provide input at all stages of a clinical trial, from concept development to protocol implementation to dissemination of results.
- Research on community engagement (informed consent comprehension or community perceptions of clinical trials) may benefit future trials.
- Genuine community engagement involves a true partnership between community members and researchers that is beneficial for all. The community benefits through empowering community members to take an active role in influencing the research and researchers benefit by understanding local factors that may influence study participation or outcomes.

For questions or comments, please email the NIAID NIMH Behavioral and Social Sciences Project Team at [NIAIDNIMHBSSPT@mail.nih.gov](mailto:NIAIDNIMHBSSPT@mail.nih.gov).



# Community Engagement in HIV Biomedical Clinical Research

<https://daidslearningportal.niaid.nih.gov/local/pages/?id=8>

## What is Community Engagement?

- Because every community is different, and differences are multiplied when multi-country research is involved, biomedical clinical research must start with community engagement research and conduct rigorous site assessments of the issues that matter to stakeholders in their own settings.
- Proper stakeholder engagement strives to ensure that key groups genuinely understand and support a study's objectives, design and methods in order to carry out a well-run trial.
- Stakeholder input may be obtained through a formalized group, through planned community meetings and processes, or through informal communications with stakeholders.

## Who are the Community Stakeholders?

- Study stakeholders include the communities where the trial will take place; the volunteers and their relatives and friends, local opinion leaders, researchers, the clinical teams, national regulatory authorities, local experts including academics, health service providers, HIV advocates and funders.
- It is important to utilize a range of mechanisms and avenues to facilitate the widest possible participation from stakeholder groups.

## How can Community Engagement Research Help?

- Clinical trials can include formalized, scientific research on community engagement within their aims. Research on community engagement adds scientific value to the protocol and advances a knowledge base that can benefit future trials.
- Scientific research on community engagement could include evaluating novel channels for community input, recruitment strategy productivity, informed consent procedure comprehension, community clinical trial perceptions, and many other topics.

# Community Stakeholder Engagement

Examples at each step in the life cycle of a clinical trial

