

3.2 Stakeholder advisory mechanisms

3.2.A. Definition

The term “stakeholder advisory mechanisms” refers to strategies or approaches that facilitate meaningful dialogue among research teams and relevant stakeholders about planned or ongoing clinical trials. Stakeholder advisory mechanisms provide research teams with information about relevant stakeholders’ perspectives on the design, planning, and implementation of a specific clinical trial and facilitate open communication about research goals, processes, and results. These mechanisms also provide relevant stakeholders with the opportunity to engage with research teams during the life-cycle of a trial.

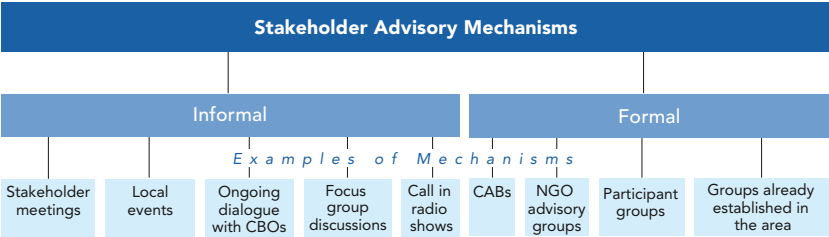
Stakeholder advisory mechanisms may be informal or formal. They can be built and sustained by the trial site or may already exist in the area.

1. Informal stakeholder advisory mechanisms may be events or less formal means by which research teams seek relevant stakeholders’ views on proposed or ongoing research. Examples include stakeholder meetings, local events, focus group discussions, interviews, consultations, and suggestion boxes. They may involve individuals, existing organisations, local employer associations, local government or traditional committees, or other advocacy, charitable, cultural, political, religious, or social groups.
2. Formal stakeholder advisory mechanisms typically involve established groups that develop an ongoing relationship with the research team at a particular trial site. Examples are trial participant groups (former or current participants), professional groups (local scientists, service providers, media, or experts on local socio-cultural issues), non-governmental organisation advisory groups (with representatives from different non-governmental organisations or community-based organisations), and community advisory boards (see definition below).
3. Community advisory boards (CABs), also referred to as community advisory groups (CAGs), are a common example of a formal stakeholder advisory mechanism. They are composed of individuals or stakeholder representatives

and provide an independent advisory voice. They facilitate community stakeholder participation and involvement in the research process. They meet regularly with research team representatives, inform community stakeholders about proposed and ongoing research, and provide feedback to research teams about local norms and beliefs, as well as local views and concerns that arise during specific trials.

The composition of community advisory boards or groups varies from site to site but is intended to reflect the diversity of community stakeholder interests and needs. They may include members or representatives of the surrounding area, individuals in the population from which participants will be recruited, people living with or affected by HIV, current or former trial participants, religious or opinion leaders, and representatives of other sections of society as determined by the trial’s location and eligibility criteria.

Figure 5. Examples of Stakeholder Advisory Mechanisms



Stakeholder advisory mechanisms can include informal and formal stakeholder advisory mechanisms (see definition 3.2.A). All of these mechanisms, as well as others, may be used to facilitate important dialogue between research teams and other stakeholders. While community advisory boards (CABs) are one example of a stakeholder advisory mechanism, there are many other ways that research teams can effectively engage with stakeholders.

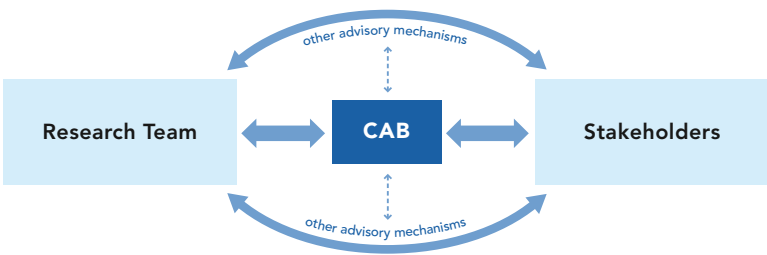
3.2.B. Relevance to good participatory practice

Establishment, maintenance, and engagement of stakeholder advisory mechanisms throughout the research process are key to establishing meaningful partnerships with community stakeholders and to ensuring continuous dialogue about biomedical HIV prevention research and specific trials.

3.2.C. Special considerations

1. Community advisory boards or groups were first developed in the context of HIV research in the United States of America and Europe. Over the past two decades, they have become a standard element of HIV research worldwide. Nonetheless, the establishment of a community advisory board or group may not always translate as best practice in all locations globally. In many settings, they are necessary but not sufficient for gaining adequate and appropriate community stakeholder input. Careful consideration needs to be given to the range of stakeholder advisory mechanisms that are required to best support effective participatory practices.
2. The need to identify and establish new stakeholder advisory mechanisms may vary from site to site and within a single site, over time. Stakeholder identification and inclusion considers the dynamic stakeholder landscape, as well as whether a trial is conducted in a research-naïve area or at a well-established research facility.
3. Formative research activities (see Section 3.1) help research teams to comprehensively identify which groups or individuals are relevant stakeholders and why.
4. While community advisory boards or groups can assist research teams in thinking about best strategies for trial recruitment, individual members of community advisory boards or groups are not research staff and do not participate in implementing actual trial procedures such as recruitment of prospective participants.
5. While community advisory boards or groups are often funded by research networks or trial sites, they are intended to be an independent advisory voice that is free to express concerns about proposed or ongoing research.

Figure 6. The Role of Community Advisory Boards



Community advisory boards (CABs) can play an important role in translating information between research teams and stakeholders. While community advisory boards are a key mechanism by which research teams inform stakeholders and receive their feedback, research teams are responsible for using other advisory mechanisms in addition to CABs to reach a broader range of stakeholders.

Figure 7. Examples of How Research Teams can Engage with Stakeholders



Examples of advisory mechanisms that research teams may use to engage with stakeholders to facilitate ongoing communication and collaboration.

3.2.D. Good participatory practices for stakeholder advisory mechanisms

1. Research teams comprehensively identify and map local stakeholders in order to determine which are relevant to trial implementation and key to sustained stakeholder engagement (see Section 1.2).
2. Research teams designate trial site staff responsible for managing activities and relationships involving stakeholder advisory mechanisms.
3. Research teams ensure that the development or identification of stakeholder advisory mechanisms is transparent to community stakeholders.
4. Research teams and relevant stakeholders identify stakeholder advisory mechanisms needed to ensure greater and more inclusive involvement of relevant stakeholders, in addition to community advisory boards or groups.
5. Research teams ensure that representation of stakeholders is comprehensive, including representatives of populations that will be recruited into trials, and that interactions with stakeholders are meaningful and responsive for all parties.
6. Research teams and relevant stakeholders identify the training needs of members of advisory mechanisms and build their capacity to understand concepts, purposes, practices, and limitations of clinical trials, increasing their ability to provide meaningful input to the research process.
7. Research teams review on an ongoing basis the composition of existing mechanisms and the need for new advisory mechanisms to ensure that relevant stakeholders continue to be represented during the course of a trial.
8. Research teams describe in their stakeholder engagement plans (see Section 3.3) strategies for the identification, establishment, and maintenance of stakeholder advisory mechanisms.
9. Research teams maintain clear written records of discussions and agreements with relevant stakeholders, including requests, concerns, recommendations, actions taken by the research team, and any unresolved issues that require follow-up.

10. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support establishment, ongoing capacity-building, maintenance, and activities of stakeholder advisory mechanisms.
11. For formal stakeholder advisory mechanisms, research teams and relevant stakeholders determine:
 - a. The purpose of each stakeholder advisory mechanism, which may result in establishing terms of reference or by-laws.
 - b. The scope of responsibilities of each stakeholder advisory mechanism, such as the responsibility to develop, review, discuss, and provide input on relevant trial documents and procedures.
 - c. The structure of each stakeholder advisory mechanism, which may result in establishing guidelines to elect a chair-person and define the duration of service for members.
 - d. The frequency of meetings, the frequency with which principal investigators or other key trial staff members attend meetings, and the ways in which members can communicate with research teams between meetings.
 - e. Reimbursement policies, if appropriate.
 - f. Mechanisms by which individuals or groups can raise concerns with research teams and with off-site trial sponsors in the event that a conflict or concern related to the site emerges.

3.2.E. Additional guidance

See *Recommendations for Community Involvement in National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research*.²⁷

3.3 Stakeholder engagement plan^a

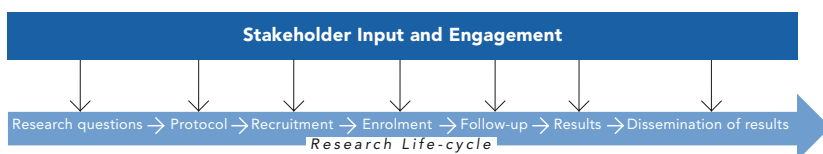
3.3.A. Definition

The stakeholder engagement plan describes strategies and mechanisms for building relationships and constructively engaging with a broad range of local, national, and international stakeholders.

3.3.B. Relevance to good participatory practice

A comprehensive stakeholder engagement plan enables research teams to collaborate with stakeholders and facilitate a more participatory approach to biomedical HIV prevention research. An effective stakeholder engagement plan will help research teams design and implement research that is effective and locally acceptable, and also lays the foundation for a supportive environment for research that extends beyond the lifespan of a specific biomedical HIV prevention trial.

Figure 8. Stakeholder Engagement through the Research Life-cycle



Robust stakeholder engagement occurs at all stages of the research life-cycle, including during trial design, recruitment, implementation, trial closure, results dissemination, negotiations of next steps, and development of future research questions.

^a Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

3.3.C. Special considerations

Being familiar with and appreciating the relationship dynamics among different stakeholders increases the research team's ability to effectively and constructively engage with a broad range of relevant stakeholders, deepens understanding of local context, and will inform the development of the stakeholder engagement plan.

3.3.D. Good participatory practices for stakeholder engagement planning

1. Research teams comprehensively identify relevant stakeholders (see Section 1.2 and Section 3.1) within and surrounding the research area as well as regionally, nationally, and internationally.
2. Research teams designate trial site staff responsible for managing activities and relationships involving stakeholder engagement planning.
3. Research teams and relevant stakeholders discuss and negotiate a stakeholder engagement plan to cover the life-cycle of the trial. The plan defines the following:
 - a. The range of different stakeholders to be engaged, specifically ensuring inclusion of relevant non-governmental organisations and community-based organisations and groups.
 - b. The type of engagement that is appropriate for each stakeholder, such as being informed, consulted, collaborated with, or empowered to make decisions.
 - c. The frequency and type of engagement methods to be used, such as public meetings, workshops, joint decision-making models, or delegated decision-making.
 - d. The process by which new relevant stakeholders will be identified and engaged.
 - e. The frequency with which the engagement plan will be reviewed.
 - f. The criteria by which to review the success of the engagement plan.

4. Research teams implement the plan and maintain clear written records of discussions and agreements, as well as stakeholder engagement activities. This includes stakeholder recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to manage activities and relationships involved in stakeholder engagement plans.

3.4 Stakeholder education plan^b

3.4.A. Definition

The stakeholder education plan describes strategies and mechanisms for providing relevant education about a specific planned trial—and about biomedical HIV prevention research in general—in order to enhance research literacy.

3.4.B. Relevance to good participatory practice

Effective stakeholder education is key to building research literacy and, ultimately, empowering community stakeholders as decision-making agents. Building research literacy lays the foundation for a supportive environment for research that extends beyond the lifespan of a specific biomedical HIV prevention trial.

3.4.C. Special considerations

1. While it is important that all relevant stakeholders improve their knowledge of research processes, enhancing research literacy for community stakeholders will foster more equitable relationships.
2. The goals and outcomes of stakeholder education are different from those of recruitment activities. While stakeholder

^b Stakeholder engagement, education, communications, and issues management (see Sections 3.3, 3.4, 3.5, and 3.6) are four different areas of planning to be addressed during the trial planning phase. Research teams may decide to create separate plans for each of these topic areas, or may decide to combine some or all of these plans as needed. The plans are described separately in the GPP guidelines so that the unique objectives and activities of each plan are clear.

education can positively influence trial recruitment activities, a stakeholder education plan can help clarify the differences between participant recruitment and stakeholder education.

3.4.D. Good participatory practices for stakeholder education planning

1. Research teams, with input from relevant stakeholders, determine what education is needed in order to enhance stakeholder understanding of, and engagement with, a specific planned trial and biomedical HIV prevention research more generally.
2. Research teams and relevant stakeholders discuss and negotiate a stakeholder education plan to cover the life-cycle of the trial. The plan defines the following:
 - a. The range of different stakeholders that could benefit from specific education about HIV, HIV prevention options, and general research literacy.
 - b. The level of knowledge that is optimal and desired by stakeholders to support effective engagement. This will be influenced by the type of engagement defined for each stakeholder in the stakeholder engagement plan (see Section 3.3).
 - c. The methods and frequency of educational activities.
 - d. The stakeholders who could also deliver or facilitate the delivery of activities in the stakeholder education plan.
 - e. The frequency with which the stakeholder education plan will be reviewed.
 - f. The criteria by which to review the success of the stakeholder education plan.
3. Research teams implement the plan and document stakeholder education activities, including questions that arise, topics that cause confusion, and suggestions for future educational activities.
4. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support activities outlined in the stakeholder education plan.