Good Participatory Practice Tools

Community Stakeholder Checklist

What is the GPP Community Stakeholder Checklist?

The UNAIDS/AVAC *Good Participatory Practice (GPP) guidelines for biomedical HIV prevention trials, Second Edition*, aim to provide trial funders, sponsors, and implementers with systematic guidance on how to effectively engage with all stakeholders in the design and conduct of biomedical HIV prevention trials, such as microbicides, vaccine or PrEP clinical trials.

The Good Participatory Practice (GPP) Community Stakeholder Checklist serves as a companion tool to the GPP Guidelines. The comprehensive set of questions in this checklist are intended to help community stakeholders monitor a research team's compliance with Good Participatory Practices when conducting a biomedical HIV prevention trial. Using this checklist may help community stakeholders determine what areas of participatory practice a research team is doing well and also to identify where the research team can improve.

Who should use the GPP Community Stakeholder Checklist?

This checklist was designed for community stakeholders such as community groups, nongovernmental organizations (NGOs), or community-based organizations (CBOs) that would like to engage with research teams conducting specific biomedical HIV prevention trials in their location.

How do we use the GPP Community Stakeholder Checklist?

Community stakeholders can complete just part or the entire checklist. It is up to each organization or user to determine how they use checklist, in order to meet their objectives. We encourage users to modify, adapt, add questions and make changes to this checklist as necessary. Users can refer to Section 3 of the GPP Guidelines; sub-section D in each of the GPP topic areas to develop their own sets of questions to monitor how well a research team is complying with the Good Participatory Practices.

Why should our organization use the GPP Community Stakeholder Checklist?

- Community stakeholders may use the checklist as a starting point to begin to assess stakeholder engagement activities of a trial site.
- Community stakeholders may choose to use the checklist to begin a dialogue with research teams on how to improve engagement practices.
- Community stakeholders may use the checklist to share their experiences about a research team's stakeholder engagement process with other organizations or community groups.
- Community stakeholders may use the checklist to garner support from other stakeholders if they feel stakeholder engagement activities have not been satisfactory by a research team.
- In more challenging situations, community stakeholders may use the checklist to share more widely that they have used the GPP guidelines to monitor a research team's engagement and to demonstrate that the practices are in need of improvement.

1 Your Organization

A. What is the full name and contact details of your organization?
B. How does your organization categorize itself (for example NGO, CBO, community group)?
C. What is the name of the trial site or research entity that your organization is engaged with or would like to engage with more?
D. How would you describe your organization's relationship with the research team at the trial site?
E. What is the current or upcoming biomedical HIV prevention trial of interest that is being conducted?
F. What is the name and role of the individual who completed this checklist?

2 Initial Stakeholder Contact and Consultation

A. Was your organization contacted by the research team to discuss your organization's opinion or interest in the clinical trial?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Were the purpose and objectives of the clinical trial adequately explained?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Were the research team's reasons for consulting with you or your organization adequately explained?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Did your organization have an opportunity to discuss its roles, responsibilities, or expected participation throughout the research process?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
F. Did the research team explain types of information needed from your organization and how they will be used in the research decision-making process?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
G. Were any concerns that your organization identified adequately addressed by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

3 Formative Research Activities

A. Was your organization contacted by the research team to discuss its formative research activities before the trial began?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Did the research team ask for your organization's advice or expertise on understanding some of the sociocultural issues or perspectives of relevant stakeholder groups, information about the populations to be recruited, or any local politics or other issues relevant to the trial, in order to help guide them in their work?	Yes ☐ No ☐ Comments ☐
Comments:	
D. Was your organization asked to provide suggestions about names of other stakeholder groups that the research team should consult for information or during their stakeholder engagement process?	Yes ☐ No ☐ Comments ☐
Comments:	

4 Stakeholder Advisory Mechanisms

A. Was your organization contacted by the research team about their stakeholder advisory process and activities for the clinical trial?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. In what ways has the research team reached out to your organization or other community stakeholders?	Local meetings ☐ Local events ☐ Ongoing discussion ☐ Focus group ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
D. Were you or your organization invited to join any kind of an advisory group? If yes, specify type of group and briefly rate your satisfaction with the process in the comments section below.	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

D. Did your organization give the research team suggestions for other ways to engage stakeholders?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
E. Were some of your organization's suggestions ultimately used by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

5 Stakeholder Engagement

A. Was your organization contacted by the research team about their stakeholder engagement plans for the clinical trial?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	Local meetings ☐ Local events ☐ Ongoing discussion ☐ Focus group ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Does the research team have a written engagement plan for stakeholders to review or would the research team like your input in developing one in the near future?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

D. What are some of the methods that the research team will use to engage with your organization during the research process?	Interviews ☐ Discussions ☐ Ongoing communications ☐ Surveys and questionnaires ☐ Workshops ☐ Focus Groups ☐ Meetings ☐ Online forums ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
E. Did your organization have the opportunity to give your opinion about these engagement methods or make suggestions for other engagement methods?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
F. What are some of the main activities specified in the research team's stakeholder engagement plans? Briefly describe 3 main activities in the section below.	
Activities: 1. 2. 3.	
G. Was the frequency of research team's engagement activities clearly explained?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

H. What is your organization's opinion about the frequency of these engagement activities?	Too much ☐ Too little ☐ Just right ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
I. Does your organization have opinions about the success or effectiveness of the research team's planned or past stakeholder engagement activities? If yes, please specify in the comments section below.	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
J. Did the research team specify who would coordinate these activities and be your organization's point of contact during the trial?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
K. Were ways of providing your organization with ongoing feedback on the progress of the stakeholder engagement plan clearly explained?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
L. Were methods for keeping your organization involved in the engagement process throughout the research process established and explained?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

M. Were your organization's opinions and recommendations ultimately incorporated into the research team's engagement plans, process or activities?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
N. Were any concerns that your organization identified adequately addressed by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

6 Stakeholder Education

A. Was your organization contacted by the research team about their stakeholder education process and activities for the clinical trial?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Was your organization asked their opinion about what types of education are needed to improve their understanding of how biomedical HIV prevention research is conducted?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Has your organization attended an educational activity or event held by the research team? If yes, please specify when and what type in the comments section below.	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Was your overall rating of this activity, in terms of its effectiveness in improving your organization's overall understanding of the research process? Briefly explain your rating in the comments section below.	Satisfactory ☐ Needs improvement ☐ Unsatisfactory ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
F. If your organization's opinions and recommendations about ongoing educational activities were sought, were they ultimately incorporated into the site's education plans or activities?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
G. Were any concerns that your organization identified adequately addressed by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

7 Communication

A. Was your organization contacted by the research team about their communications plan for the clinical trial?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Did your organization have the opportunity to iscuss and give suggestions about recommended channels of communication for your organization or other stakeholders?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Did your organization have the opportunity to discuss what types of information should be exchanged between the research team and your organization or other stakeholders?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Did your organization have the opportunity to discuss or suggest which other stakeholders would be critical to communicate with?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
F. Did your organization have the opportunity to provide advice that the research team could use to address potential concerns or queries with the media and other external groups?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
G. Were your organization's opinions and recommendations ultimately incorporated into their communication planning?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
H. Have there been any communication issues or challenges with the research team that needed to be addressed, were of concern for your organization, or that your organization reacted to? If yes, briefly explain in the comments section below.	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
I. Were these issues or challenges adequately resolved by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

8 Issues Management

A. Was your organization consulted by the research team about how to manage any anticipated issues related to the clinical trial such as the protocol design, target population and socio-cultural or political environments? If yes, please briefly specify in comments section below.	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Were there any difficult or challenging issues or external conflicts that emerged during the conduct of the trial? If yes, briefly explain in the comments section below.	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. If so, did the research team seek your organization's advice about how to handle these issues?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. If applicable, briefly describe in the comments section below, how your organization helped the research team to address or resolve these issues?
Comments:

9 Protocol Development

A. Was your organization contacted by the research team to discuss their trial protocol?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Has the technical information contained in the protocol been made available to your organization in a way that is easily understood? For example, was the information summarized or translated into your local language?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Did your organization have the opportunity to provide input and make recommendations on the protocol before the trial began?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Was your organization informed about protocol approval processes as well as the research team's plan for providing them with regular updates about the process?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
F. Were some of your opinions and recommendations ultimately incorporated into the final protocol?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
G. Were any concerns that your organization identified adequately addressed by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

10 Informed Consent and Recruitment Strategies

A. Was your organization contacted by the research team to discuss some of their strategies for informed consent and participant recruitment?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Did your organization have the opportunity to discuss and make recommendations aboutculturally acceptable strategies for these procedures?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Were your opinions and recommendations ultimately incorporated into the trial procedures?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Were any concerns that your organization identified adequately addressed by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

11 Standard of HIV Prevention

A. Was your organization contacted by the research team to discuss the HIV prevention package that will be or is offered to trial participants?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Did you have the opportunity to discuss and negotiate the components of the HIV prevention package?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Were your opinions and recommendations ultimately incorporated into the research team's planning and decision making about the HIV prevention package?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Were any concerns that your organization identified adequately addressed by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

12 Access to HIV Care and Treatment

A. Was your organization contacted by the research team to discuss the HIV care and treatment services that will be offered to trial participants?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Did your organization have the opportunity to discuss the kinds of HIV-related services that are available in your location?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Did your organization have the opportunity to discuss its expectations about the type of HIV care and treatment services that the trial should offer or provide referral to?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Did your organization have the opportunity to discuss ways which individuals screened and enrolled will access and be referred to HIV care and treatment during the trial?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
F. Were your opinions and recommendations ultimately incorporated into the research team's plan for ensuring HIV care and services for trial participants?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
G. Were any concerns that your organization identified adequately addressed by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

13 Social Harms

A. Was your organization contacted by the research team to discuss the proposed trial and your organizations views on the possible social harms someone might experience by participating in that specific trial?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Did your organization have the opportunity to discuss and make suggestions about potential social harms it thinks a trial participant might experience for the particular protocol?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Were your opinions and recommendations ultimately incorporated into the research team's plan for managing and reducing these potential harms?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Were any concerns that your organization identified adequately addressed by the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

14 Trial Closure and Trial Results Dissemination

A. Was your organization contacted by the research team to discuss trial closure and results dissemination?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Did the research team explain to you the circumstances of why the trial might close, such as planned closure per protocol, early closure due to evidence of harm, futility, or clear protective effect or early closure due to unforeseen circumstances?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Did the research team inform you of the trial results when they came out?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. How was your organization informed of trial results? Briefly specify in comments section below.	
Comments:	
F. Did your organization have an opportunity to discuss the trial results with the research team?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

15 Post-Trial Access to Trial Products and Procedures

A. Was your organization contacted by the research team to discuss post-trial access to the trial product or procedure should the product be found to be safe and effective?	Yes ☐ No ☐ Comments ☐
Comments:	
B. How was this consultation process with your organization conducted?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
C. Did your organization have the opportunity to give its opinion on these access issues early in the research process?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
D. Was your organization involved in any negotiations with the research team, sponsors, government representatives, or regulators around these issues? If yes, briefly explain in the comments section below.	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

16 Follow-up and Evaluation

A. Overall, how did your organization feel about the way the research team engaged with your organization or other stakeholders during the trial life-cycle or research process?	Satisfactory ☐ Needs improvement ☐ Unsatisfactory ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
B. What does your organization think the research team did well regarding stakeholder engagement during the research process?	
C. Does your organization have any suggestions for improvement for the research team? If yes, please list these suggestions below in the comments section.	Yes ☐ No ☐ Comments ☐
Comments:	
D. Does your organization feel that its contributions improved aspects of the research process, such as protocol design, trial procedures, stakeholder engagement methods, etc? If yes, explain in the comments section below.	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	

E. Did the research team report key issues, concerns, and follow up actions back to your organization on an ongoing basis during the research process?	Yes ☐ No ☐ Don't know/Not sure ☐ Comments ☐
Comments:	
F. What does your organization feel is still needed to help improve its ability to work collaboratively with the research team?	In-person discussion or Interview ☐ Telephone ☐ Email ☐ Other ☐ Please specify: _____ _____ Comments ☐
Comments:	
G. What does your organization feel is still needed to help improve the research team's ability to work collaboratively with other stakeholders? Briefly explain in the comments section below.	
Comments:	
H. In your organization's opinion, how would you know when a true partnership between the research team and your organization exists? What would it look like? Specify in the comments section below.	
Comments:	

I. Does your organization have other concerns or comments about the research team's stakeholder engagement process? If yes, briefly describe in the comments section below.	Yes ☐ No ☐ Comments ☐
Comments:	
J. Does your organization have comments related to other topic areas covered in GPP that were discussed or experienced with the research team during the research process? If yes, briefly specify the name of the topic area and list your comments in the boxes below.	
Name of topic area: **Comments:**	
Name of topic area: **Comments:**	
Name of topic area: **Comments:**	
Name of topic area: **Comments:**	
Name of topic area: **Comments:**	