Good Participatory Practice Tools

GPP Trial Site Binder

Introduction to the GPP Trial Site Binder

Objective of the GPP Trial Site Binder:

The GPP Trial Site Binder serves as a companion tool to the UNAIDS/AVAC *Good Participatory Practice: guidelines for biomedical HIV prevention trials, second edition* (2011). This binder template will help research teams plan, document, and organize their stakeholder engagement activities and records. Instructions outlined in the file will facilitate the development of a comprehensive dossier of stakeholder engagement at a particular research site, which can then be referred to regarding GPP compliance.

Contents of the GPP Trial Site Binder:

The GPP Trial Site Binder is divided into sections according to the 16 GPP Topic Areas outlined in Section 3 of the GPP guidelines. Each section of the binder provides:

- A list of key steps to help trial site staff follow the practices outlined in subsection D under each of the GPP topic areas.
- Templates for written plans, meeting minutes, work plans, and other tables to organize information and document key consultative activities with stakeholders for each Topic Area.
- A place to file draft documents for review with stakeholders, supplementary materials for review, reports, articles, or additional documents that may be developed and used, such as questions and answer sheets about the trial.

How to Use the GPP Trial Site Binder:

Research teams should read each section of the GPP Trial Site Binder to see key steps for following the participatory practices in each Topic Area of the research lifecycle. The GPP guidelines should be consulted for full details on the practices for each Topic Area.

Research teams can use the templates provided in the GPP Trial Site Binder as they appear, modify the templates to suit specific needs, or use the templates as guidance to create a site-specific set of files to document stakeholder engagement efforts. Research teams may want to keep GPP records and documentation in one single file, by cutting and pasting information directly into the binder sections below, or refer to corresponding documents as attachments in each section. Research teams may also decide to create a physical GPP Trial Site Binder, with separate sections that correspond to the headings in this binder. The physical binder might also have a corresponding electronic folder containing this file and all corresponding documents.

A research team's GPP Trial Site Binder should be updated on a regular basis. The binder should be filed with the site's regulatory or working files for a trial protocol. The GPP Trial Site Binder can then be used to help the research team or other entities monitor and evaluate its stakeholder engagement efforts.

Section 1: Formative Research Activities

Formative research activities usually constitute the initial phase of stakeholder engagement and involve identifying key trial stakeholders. Formative research activities enable research teams to gain an informed understanding of local populations, socio-cultural norms and practices, local power dynamics, local perceptions, channels of communication and decision-making, and local history of research, as well as the needs and priorities of people who are locally affected by and able to influence the trial. Use this section to file records and documents related to your formative research activities.

KEY STEPS

- Identify the target trial population to be recruited for this trial.
- Identify some of the local organizations that work with or are represented by the main trial population.
- Identify the influential organizations or individuals in the local area that can affect or will be affected by the trial.
- Determine who can obstruct a decision if not involved.
- Determine each stakeholder group's interest in the trial and potential areas of collaboration.
- Create a list of key stakeholders.
- Document outcomes of stakeholder consultations and ongoing information about formative research activities in this section of the GPP Trial Site Binder.

Key Stakeholders				
Name of Key Stakeholder	**What is their interest in the trial?**	**What are the GPP topic areas for consultation and collaboration?**	**Stakeholder's Contact Details (e.g. phone, email)**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 2: Stakeholder Advisory Mechanisms

Stakeholder advisory mechanisms refer 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. Use this section to file information related to the site's stakeholder advisory mechanisms that will be used for gaining adequate and appropriate stakeholder input throughout the course of the trial.

List the Stakeholder Advisory Mechanisms that your team will consult with during the course of the trial:

Formal Stakeholder Advisory Mechanisms *(i.e. NGO advisory groups, CAB, community groups)*		
Description of Mechanism	**Scope of Responsibility During the Trial**	**Comments**

Informal Stakeholder Advisory Mechanisms *(i.e. events, meetings, focus groups, dialogue with community groups)*			
Description	**Topic Areas for Consultation**	**Date**	**Comments**

Community Advisory Board (CAB)

Use this section to file key CAB documents, e.g. CAB roster, CAB terms of reference, meeting schedule, by-laws, minutes, and annual work plan. Alternatively, you may also list these files as references or attachments and indicate their location in the regulatory files.

Stakeholder Advisory Mechanism Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholder advisory mechanisms. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 3: Stakeholder Engagement Plan*

The stakeholder engagement plan describes strategies and mechanisms for building relationships and constructively engaging with a broad range of local, national, and international stakeholders before, during, and after the trial. Use this section to file your trial site's written stakeholder engagement plan.

*Stakeholder engagement, education, communications, and issues management (Sections 3, 4, 5 and 6) are four different areas of planning to be addressed during the trial planning phase. These plans may be combined as determined necessary and relevant by the site. Accordingly, research teams may decide to file documents for these topic areas together or separately. The topic areas are described separately in GPP and in the binder to clarify their unique objectives and associated activities.

KEY STEPS

- Determine your key goals for engaging stakeholders in the trial. We suggest limiting this to approximately three goals.
- For each goal, identify long- and/or short-term objectives.
- Determine the key stakeholders you need to engage with throughout the course of the trial to achieve your objectives and goals.
- Determine engagement activities and stakeholders to be involved in each activity.
- Identify key stakeholders to provide insight and advice into this planning process.
- Consider how feedback from the stakeholder engagement process will be used in your team's decision-making and how these engagement plans and processes will be reviewed and/or evaluated.
- Create a written stakeholder engagement plan.
- Document outcomes of stakeholder consultations and ongoing information about stakeholder engagement plans and processes in this section of the GPP Trial Site Binder.

Stakeholder Engagement Plan

Trial Site Name:

Purpose:
To describe procedures for stakeholder engagement methods and activities throughout the lifecycle of the trial.

Responsibilities:
(Insert name of trial staff job title) is responsible for day-to-day oversight of the plan as well as activities stipulated in the plan.

Part A: Stakeholder List
List the stakeholders your research team will be engaging with before, during, and after the trial.

Part B: Stakeholder Engagement Work plan
Complete a work plan, with specific engagement strategies, timeline, and stakeholders that your team will engage with throughout the trial, and any required resources for the execution of the activities (see table below entitled Stakeholder Engagement Work plan). Add as many rows to the work plan as is needed.

Part C: Description of the Stakeholder Engagement Plan and Consultation Process
Provide a narrative description of the stakeholder engagement plan. Describe your consultation process with key stakeholders regarding the content of the plan, including a brief list of key stakeholder with whom you consulted. Consider how feedback from the stakeholder engagement process will be used in your team's decision-making and how the plan will be evaluated and reviewed by the research team.

History:

Version Number	Date Plan Becomes Effective	Supercedes *(e.g. the version and date of the previous plan)*	Review Date	Key Changes Between Versions
1.0				Initial release

Approval

Principal Investigator Signature _____ Date _____

Stakeholder Engagement Work Plan				
Name of Stakeholder Engagement Activity	**Activity Date**	**Stakeholder Groups to be Included**	**Cost and Resources Required**	**Comments**
Before Trial				
During Trial				
After Trial				

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

4 Section 4: Stakeholder Education Plan

The stakeholder education plan describes strategies and mechanisms for providing relevant education to stakeholders, in order to enhance their overall research literacy and their understanding about a specific trial. Use this section to file your trial site's written stakeholder education plan, as well as a record of trainings and educational activities conducted for stakeholders during the course of the trial.

KEY STEPS

- Determine (based on Stakeholder Engagement Plan) the objectives of training for various audiences and stakeholders.
- Determine key stakeholders who require training or education, and training content.
- Determine educational activities or training for each stakeholder and timings for activities.
- Consider how your educational activities will be monitored and evaluated.
- Create a written stakeholder education plan.
- Gain advice from key stakeholders about the plan, and modify accordingly.
- Document outcomes of stakeholder consultations and ongoing information about stakeholder education plans and processes in this section of the GPP Trial Site Binder.

Stakeholder Education Plan

Trial Site Name:

Purpose:
To describe a research team's stakeholder education activities throughout the lifecycle of the trial, which aim to increase stakeholders' research literacy and understanding of biomedical HIV prevention research.

Responsibilities:
(Insert name of trial staff job title) is responsible for day-to-day oversight of the plan as well as activities stipulated in the plan.

Part A: Stakeholder List
List stakeholder groups who require education or training to increase their research literacy or understanding of the research process.

Part B: Stakeholder Educational Activities
List the types of stakeholder education or training activities that are relevant and appropriate for each of these stakeholders.

Part C: Description of the Stakeholder Education Plan and Consultation Process
Provide a narrative description of the stakeholder education plan. Describe your consultation process regarding the content of the plan, including a brief list of key stakeholders with whom you have consulted. Consider how the plan and its activities will be evaluated and reviewed.

Part D: Stakeholder Education Work plan
Complete a work plan, with specific educational activities, timeline, names of targeted stakeholders, and any required resources to execute the activities (see table entitled Stakeholder Education Work plan). Add as many rows as are necessary.

Part E: Stakeholder Training Record
Record trainings conducted during the course of the trial, including type of training or educational activity, number of attendees, and date (see table entitled Stakeholder Training Record).

History:

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1.0				Initial Release

Approval

Principal Investigator Signature _____ Date _____

Stakeholder Education Work Plan				
Name of Stakeholder Engagement Activity	**Activity Date**	**Stakeholder Groups to be Included**	**Cost and Resources Required**	**Comments**
Before a Trial				
During a Trial				
After a Trial				

Stakeholder Training Record				
Name or Type of Training	Description of the Training	Total Number of Attendees	Date and Location of Training	Comments

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 5: Communication Plan

The communications plan describes strategies and mechanisms that will ensure ongoing and transparent communication and the dissemination of information between the research team and relevant stakeholders. During the course of the trial, your research team will develop key messages and communications channels to facilitate interactions with the local media and other stakeholders. Use this section to file your trial site's written communications plan.

KEY STEPS

- Determine stakeholders and other potential audiences, including media contacts, with whom the research team needs to communicate about this trial, regionally, nationally, and internationally.
- Determine the information needs of each stakeholder
- Determine communication methods to be used with each of these stakeholders, taking into account literacy levels and language needs.
- Create key messages about the purpose, design, timeline, and other aspects of the trial to be communicated with stakeholders.
- Consider how the processes and activities will be reviewed and evaluated.
- Create a written communications plan.
- Document outcomes of stakeholder consultations and ongoing information about communications plans and processes in this section of the GPP Trial Site Binder.

Communications Plan

Trial Site Name:

Purpose:

To describe a research team's communication strategies and channels with stakeholders during the course of the trial.

Responsibilities:

(Insert name of trial staff job title) is responsible for day-to-day oversight of the plan as well as activities stipulated in the plan.

Part A: Media Contacts

List key media contacts with whom the research team should communicate about this trial (see table entitled 'Key Media Contacts').

Part B: Other Communication Contacts

List stakeholders with whom the research team needs to communicate about this trial, regionally, nationally, and internationally.

Part C: Communication Channels

Describe the information needs of and communication methods to be used with each of these stakeholders, taking into account literacy levels and language needs**.**

Part D: Key Messages

List key messages about the purpose, design, timeline, and other aspects of the trial to be communicated with stakeholders.

Part E: Description of the Communications Plan and Consultation Process

Provide a narrative description of the communications plan. Describe your consultation process with key stakeholders regarding the content of the plan, including a brief list of key stakeholders with whom you consulted. Consider how the plan will be evaluated and reviewed.

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Principal Investigator Signature

Date

Key Media Contacts		
Name of Media Contact	**Contact Details (including email and phone)**	**Comments**

Non-Media Stakeholder Communication Contacts		
Name of Contact	**Contact Details (including email and phone)**	**Comments**

Key Messages

Key messages are short statements that explain your trial or address an issue related to your research. Use this section to file your trial site's key media messages. You may list below, cut and paste from a separate document, or refer to a separate file.

Questions and Answers

Use this section to list anticipated 'Questions' from stakeholders as well as relevant 'Answers.'

Q:

A:

Q:

A:

Q:

A:

Q:

A:

Q:

A:

Media Coverage

Use this section to file articles or other materials or stories about your trial that have appeared in the media.

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 6: Issues Management Plan

The issues management plan describes how research teams intend to manage issues of concern or any unexpected developments that may emerge before, during, or after the trial. Use this section to file your trial site's written issues management plan.

KEY STEPS

- Identify known challenging issues that might emerge and that could undermine the success of the trial before, during, and after trial completion.
- Determine key stakeholders who can help the research team manage these issues and can act as advisors to the research team.
- Create key messages to address anticipated concerns. Messages may be created according to intended audience, if necessary.
- Determine site-level strategies about how to manage unexpected developments, including how media reports and requests will be addressed.
- Create a written issues management plan.
- Document outcomes of stakeholder consultations and ongoing information about issues management plans and processes in this section of the GPP Trial Site Binder.

Issues Management Plan

Trial Site Name:

Purpose:
To describe procedures for managing issues of concern or unexpected developments that may emerge before, during, or after a trial.

Responsibilities:
(Insert name of trial staff job title) is responsible for day-to-day oversight of the plan as well as activities stipulated in the plan.

Part A: Anticipated Issues
Describe known challenging issues that might emerge and that could undermine the success of the trial before, during, and after trial completion.

Part B: Key Messages
List key messages to address anticipated concerns during the trial.

Part C: Stakeholder Advisors
List key stakeholders who can help the research team manage these issues and who can act as advisors to the research team.

Part D: Description of the Issues Management Plan and Consultation Process
Describe site-level strategies about how to manage unexpected developments, including how media reports and requests will be addressed. Include a description of the stakeholder consultation process for content in the plan, including a brief list of key stakeholders with whom you consulted.

Part E: Issue Tracking
Record all significant issues experienced during the trial and their outcomes (see table entitled Issues Management).

History:

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Approval

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Issue Management			
Description of Issue	**Date of Occurrence**	**Resolution**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 7: Site Selection

Site selection is the process by which trial funders, sponsors, or networks evaluate trial sites for provision of funding for a trial protocol, inclusion in a multisite trial, or inclusion in a trial network. Use this section to plan for meetings and visits with trial funders, sponsors, or networks who are assessing your site, with respect to stakeholder engagement processes.

KEY STEPS

Below are some specific questions that can help you prepare for stakeholder engagement assessment at a site visit:

» What is the date of the visit?

_____

» Who will be visiting your trial site?

_____

_____

» Who will meet with the visiting team to discuss your stakeholder engagement program or plans?

_____

_____

» Which documents evidencing your stakeholder engagement program or plans will you provide to the visiting team?

_____

_____

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_____

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Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 8: Protocol Development

Protocol development is the process of creating and modifying a trial protocol. A range of stakeholders can provide meaningful input into many aspects of trial protocol development and can bring expertise to assist research teams in ensuring that protocol designs and procedures are locally appropriate, are acceptable to the trial population, and optimize successful implementation of the trial. Use this section to identify stakeholders who will give input into the trial protocol and to record the key outcomes of stakeholder consultations.

Protocols may not be developed at the trial site level; especially in the case of multi-country or multisite trials, protocol development may be largely centralized. Although not necessarily the responsibility of the trial site in such instances, mechanisms for stakeholder review at sponsor or other level may be documented here.

KEY STEPS

- Based on where the protocol was or will be developed, identify key stakeholders or mechanisms for protocol consultation.
- Conduct meetings and consultations to discuss, review, and gain meaningful stakeholder input on the trial protocol. If meetings and consultations have already occurred, or will occur at sponsor or other global level, obtain reports, relevant information around plans, or other relevant documents.
- Integrate comments and suggestions as appropriate into the trial protocol. If consultations have already occurred, obtain information on the incorporation of stakeholder suggestions.
- Document outcomes of stakeholder consultations and ongoing information about protocol development in this section of the GPP Trial Site Binder.

Consultations on Trial Protocol		
Name of Stakeholder and Contact Details	**Suggested Key Changes to Protocol**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Protocol Materials

Use this section to file draft versions of the trial protocol, summaries, translations, or other protocol-related materials to be shared with stakeholders and used in consultations.

Section 9: Informed Consent Process

The informed consent process is relevant to good participatory practice because a wide range of stakeholders can help research teams develop locally acceptable and effective informed consent procedures and materials. Use this section to file information related to consultations with stakeholders on the informed consent forms, informed consent process, and supporting materials.

KEY STEPS

- Determine the key stakeholders you will consult about the development of the informed consent forms, informed consent process, and supporting materials.
- Conduct meetings and consultations to discuss and gain meaningful stakeholder input on the informed consent forms, informed consent process, and supporting materials.
- Integrate comments and suggestions into consenting practices and procedures.
- Document outcomes of stakeholder consultations and ongoing information about stakeholder engagement around the informed consent process in this section of the GPP Trial Site Binder.

Recommendations for Informed Consent Process and Materials			
Name of Stakeholder and Contact Details	**Suggested Changes to Informed Consent Form**	**Suggested Ideas for Improving Informed Consent Process**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Draft Informed Consent Forms

Use this section to file any draft versions of the informed consent forms for review and discussion with stakeholders.

Informed Consent Supporting Materials

Use this section to file any materials to support the informed consent process such as literacy assessment tools, comprehension assessment tools, and explanatory materials or aids.

Section 10: Standard of HIV Prevention*

The term "standard of HIV prevention" refers to the package of comprehensive counseling and state-of-the-art HIV risk reduction methods provided or made available to participants in biomedical HIV prevention trials. Use this section to list stakeholders who will negotiate and discuss the components of the HIV prevention package with your research team and to record the key outcomes of these stakeholder consultations.

*Records of stakeholder consultations for and key documents on standard of HIV prevention, access to HIV care and treatment, and non HIV-related care (binder Sections 10, 11, and 12) may be filed separately or together. Research teams may decide to combine some or all of these documents as needed.

KEY STEPS

- Determine the key stakeholders who you will consult to provide advice and insight on the appropriate HIV prevention package being offered to trial participants.
- Work with stakeholders to map local services and create a referral system in which you partner with other providers where necessary.
- Discuss and agree on the components of the HIV prevention package.
- Compile documentation of agreement with stakeholders on the HIV prevention package and how the package will be implemented.
- Document any ongoing information about the HIV prevention package in this section of the GPP Trial Site Binder.

Consultations on HIV Prevention Package				
Name of Stakeholder and Contact Details	**Suggestions or Comments from Stakeholder**	**Action Agreed Upon**	**Person/Party Responsible**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 11: Access to HIV Care and Treatment

Access to comprehensive HIV care and treatment refers to care and treatment services made available to individuals who are identified as HIV-positive during the screening process and to trial participants who acquire HIV infection during the trial. Use this section to identify stakeholders who will be consulted to discuss the components of the HIV care and treatment services for trial participants and to record the key outcomes of these stakeholder consultations.

KEY STEPS

- Determine key stakeholders you will consult to discuss the HIV care and treatment services being offered to trial participants or to which they will be referred.
- Conduct meetings and consultations, as necessary, to gain meaningful stakeholder input, including how to create a practical and sustainable referral system, partnering with local providers and how to collect information on participants' access to services.
- Consider and discuss the impact your trial will have on existing public health systems.
- Compile documentation of agreements with stakeholders on the appropriate package of HIV care and treatment services and referral mechanisms.
- Document any ongoing information about the HIV care and treatment services and referrals in this section of the GPP Trial Site Binder.

Consultations on Access to HIV Care and Treatment				
Name of Stakeholder and Contact Details	**Suggestions or comments from Stakeholder**	**Action Agreed Upon**	**Person/Party Responsible**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 12: Non HIV Related Care

Non HIV-related care refers to health and social care services provided or made available to trial participants that are not directly related to HIV prevention, HIV care and treatment, or trial-related harm. Examples could include provision of female or male sexual and reproductive health care, management of infectious diseases, nutritional health, psychiatric care, and psychosocial services. Use this section to file information related to consultations with stakeholders about the appropriate package of general health services to offer trial participants and, where appropriate, their partners.

KEY STEPS

- Determine the key stakeholders who you will consult to discuss the appropriate package of general health services being offered to trial participants.
- Consult local stakeholders to map existing services for primary and social care, as well as other diagnostic and treatment services.
- Compile documentation of agreements with stakeholders on the appropriate package of general health services for trial participants.
- Document ongoing information about non HIV-related care in this section of the GPP Trial Site Binder.

Consultations on Non HIV Related Care				
Name of Stakeholder and Contact Details	**Suggestions or Comments from Stakeholder**	**Action Agreed Upon**	**Person/Party Responsible**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 13: Policies on Trial-related Harms

Policies on trial-related harms describe how research teams will treat and compensate trial participants should they experience physical or social harms that are determined to be associated with trial participation, as well as how such harms will be addressed and mitigated. Use this section to ensure stakeholder input on your trial site's written policy on trial-related harms.

KEY STEPS

- Determine key stakeholders you will consult to discuss the policy on trial related harms.
- Conduct meetings and consultations to gain stakeholders' insight on an existing or draft trial-related harm policy. Discuss potential harms as well as how they can be prevented, mitigated and addressed if they occur.
- Incorporate stakeholder suggestions into the policy as appropriate.
- Document outcomes of stakeholder consultations and ongoing information about the trial-related harms policy in this section of the GPP Trial Site Binder.

Trial-Related Harms Policy

Note: Most trial sites have existing trial-related harms policies in place as part of Good Clinical Practice and ethical requirements for trial conduct. In such cases, documentation of the plan is not necessary in the GPP file, but should be referenced. However, documentation of stakeholder input on the policy and subsequent changes is necessary and should be filed below.

Trial Site Name:

Purpose:
To describe how the research team will treat and compensate participants should they experience any trial-related physical or social harms, as well as how such harms will be addressed.

Responsibilities:
(Insert name of trial staff job title) is responsible for day-to-day oversight of the policy as well as the policy components.

Part A: Stakeholders
List key stakeholders who can act as advisors in anticipating social harms, providing advice to the research team on how to mitigate such social harms, and provide overall advice on the trial-related harms policy.

Part B: Anticipated Harms
List social and physical harms that the research team and stakeholders anticipate trial participants might experience.

Part C: Prevention Strategies
Describe main strategies to prevent or reduce risk of trial-related harms.

Part D: Reporting Procedures
Describe procedures for investigating and reporting trial-related physical and social harms experienced by participants.

Part E: Referral Procedures
Describe procedures for referring participants to appropriate services, if they experience trial-related harms.

Part E: Compensation of Participants
Describe procedures for compensating participants, if they experience trial-related harms.

History:

Version Number	Date Plan Becomes Effective	Supercedes *(e.g. the version and date of the previous plan)*	Review Date	Key Changes Between Versions
1.0				Initial Release

Approval

Principal Investigator Signature

Date

Section 14: Trial Accrual, Follow-up, and Exit

Trial accrual, follow-up, and exit activities include the recruitment, screening, enrolment, follow-up, and exit of trial participants in biomedical HIV prevention trials. Use this section to file any information related to stakeholder discussions or consultations on these processes.

KEY STEPS
» Determine the key stakeholders who you can consult to discuss strategies for trial accrual, follow-up, and exit activities of trial participants. » Conduct meetings and consultations to discuss trial procedures, such as recruitment, screening, enrolment, follow-up, and exit of trial participants. » Integrate comments and suggestions into relevant trial procedures. » Document outcomes of stakeholder consultations and ongoing information about trial accrual, follow-up and exit processes in this section of the GPP Trial Site Binder.

Consultations on Trial Accrual, Follow-up, and Exit Procedures			
Name of Stakeholder and Contact Details	**Trial Procedure Discussed**	**Suggested Ideas or Comments**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

1.
2.
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4.
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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 15: Trial Closure and Results Dissemination

Trial closure occurs when all participants have exited from the trial and all trial procedures are completed. Results dissemination involves dissemination of trial results to participants, community stakeholders, and the public at large, as well as the unblinding of participants to trial group or arm assignment. Use this section to file information about stakeholder discussions or consultations around such processes and your trial closure and results dissemination plan.

KEY STEPS

- Determine the key stakeholders with whom to discuss strategies for trial closure and results dissemination.
- Well in advance of the end of your trial, conduct meetings and consultations to discuss a clear plan for communicating this information and to pilot draft messages that will be used to minimize any misunderstandings.
- Create a written plan for trial closure and results dissemination.
- Document outcomes of stakeholder consultations and ongoing information about trial closure and results dissemination in this section of the GPP Trial Site Binder.

Trial Closure and Results Dissemination Plan

Trial Site Name:

Purpose:
To describe procedures for trial closure and dissemination of results to participants, community stakeholders, and the public at large.

Responsibilities:
(Insert name of trial staff job title) is responsible for day-to-day oversight of the plan as well as activities stipulated in the plan.

Part A: Plan for Trial Results
Describe your strategies to manage expectations about trial closure scenarios and trial results, including preparing participants and relevant stakeholders for all possible outcomes.

Part B: Key Messages
List potential messages to use in different trial closure scenarios as well as different results scenarios.

Part C: Results Dissemination
Describe your procedures for contacting and informing trial participants of research results before they are announced publicly as well procedures for public announcement.

Part D: Results Consultation
Describe how community stakeholder responses to the results will be systematically collected and documented.

History:

Version Number	Date Plan Becomes Effective	Supercedes *(e.g. the version and date of the previous plan)*	Review Date	Key Changes Between Versions
1.0				Initial Release

Approval

Principal Investigator Signature _____ Date _____

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

1.
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Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**

Section 16: Post-Trial Access to Trial Products and Procedures

The term "post-trial access to trial products or procedures" refers to making the prevention product or procedure tested in the trial available to trial participants and local community stakeholders (1) should the new product or procedure be scientifically validated or approved by relevant authorities, and (2) in the form of follow-on, open label, or other such studies before product licensure or approval, should an efficacy or effectiveness trial have a compelling positive finding, with no safety concerns. Use this section to file information related to stakeholder discussions and consultations on this issue.

KEY STEPS

- Determine the key stakeholders with whom you can consult to discuss how trial participants and others might have access to the product or procedure you are testing and the processes for licensure and roll-out, should the product be safe and effective.
- Conduct meetings and consultations to discuss potential options for post-trial access.
- Create a written plan with stakeholders given different trial outcomes.
- Document outcomes of stakeholder consultations and ongoing information about post-trial access to trial products or procedures in this section of the GPP Trial Site Binder.

Summary of Stakeholder Comments on Post-Trial Access to Trial Products and Procedures				
Name of Stakeholder and Contact Details	**Suggestions or Comments from Stakeholder**	**Action Agreed Upon**	**Person/Party Responsible**	**Comments**

Meeting Minutes

Use this section to document minutes from relevant meetings conducted with stakeholders regarding this Topic Area. You may also insert or attach separate meeting reports, or if creating a physical binder, file them in this section.

Meeting Title	
Meeting Date	
Meeting Attendees	

Note Taker	
Purpose of Meeting	

Agenda Topics

1.
2.
3.
4.
5.

Meeting Notes:

Meeting Outcomes		
GPP Action Items	**Person Responsible**	**Deadline**