



Formative Research Activities Job Aid

Important note: The scope of GPP does not include the actual conduct of formative research; rather, it includes the engagement of stakeholders in the process of formative research activities, as well as how they can help lay a foundation for stakeholder engagement in a forthcoming clinical trial. This outline is meant to provide guidance around the process of outlining formative research activities, with a focus on identifying stakeholders' roles and key areas of input.

Steps	Key points and questions to consider
<p>Develop a plan for formative research activities:</p> <ul style="list-style-type: none">• What do we need to know?• How should we collect this information?• Who should collect it?• Approval and notification processes• Plan for implementing <p>Involve stakeholders in the development and/or review of the plan (see section below)</p>	<p>What do we need to know?</p> <ul style="list-style-type: none">• What key information needs to be gathered?• What similar information has already been collected by us or others? If by others, do we have access to that data?• Is extensive mapping of the research context necessary, or can the formative process focus on just a few priority areas?• What might we be overlooking due to assumptions about the target population or the context? <p>How should we collect this information?</p> <ul style="list-style-type: none">• What methods will most effectively reach the populations we need to hear from and allow them to share information openly and honestly (e.g. focus groups, community workshops, interviews)?• Are there factors that may keep certain individuals from speaking up? How can those be mitigated? <p>Who should collect it?</p> <ul style="list-style-type: none">• Who is most likely to make those we are consulting feel at ease and be honest in their responses?• Who can commit the time to collecting this information? <p>Approval and notification processes:</p> <ul style="list-style-type: none">• Who has the final authority to approve changes and who needs to be included in the approval process?• Is review from a research ethics committee required? If not, how will researchers ensure that the activities are being conducted ethically?• Who wants to be notified, and in what level of detail, about the progress of formative research activities? <p>Timeline and resources:</p> <ul style="list-style-type: none">• What is the timeline for implementing? What resources are needed?• What factors could potentially affect the timeline or availability of resources?• How flexible is the timeline, and what back-up resources may be available? <p>Resource: Stakeholder Engagement Toolkit (FHI 360) - Step 4</p>



Steps	Describe Key Features of the Research Context
Create a budget and allocate funds and staff time; ensure sufficient funding from the trial sponsor	<ul style="list-style-type: none">• Adequate funding and staff time are essential for conducting formative research activities.• If your trial site has limited resources, think about doing research, which is less formal but still structured, using members of your research team.
Identify key informants and relevant stakeholders that can assist with formative research activities	<ul style="list-style-type: none">• Formative research will produce better results when done in collaboration with stakeholders.• Who are the key stakeholders or groups able to give insight on the information you wish to collect?• Who are the key stakeholders that are likely to support your research? Who will likely oppose it?• If stakeholders will be involved in the actual formative research activities, what are the steps to ensure their participation and understanding of the process?• Stakeholders may have interest but lack time.• Work with each stakeholder to determine what role is of most interest and most practical.• Resource: GPP participatory community mapping tool
Designate trial site staff responsible for managing these activities	<ul style="list-style-type: none">• Staff must have adequate time dedicated to formative research and stakeholder engagement activities.• Outreach staff and clinical staff should be involved.
Conduct formative research studies and activities	<ul style="list-style-type: none">• The GPP guidelines do not specify how to conduct formative research, but they discuss the potential benefits and outline specific steps of stakeholder involvement in activities.
Discuss the findings and their implications	<ul style="list-style-type: none">• If findings are contradictory to each other or to what is understood about the community or context, what is the best way to resolve the incongruities?• What changes are necessary based on the findings?• It's important to manage expectations of stakeholders. Ensure stakeholders have realistic expectations about what will happen with formative research findings. Remember that undergoing formative research without acting on results can be damaging to relationships with stakeholders.
Document formative research activities and findings	<ul style="list-style-type: none">• Stakeholders should review documentation of findings to ensure that a common understanding exists.• Resource: GPP Binder Section 1