Good Participatory Practice (GPP) for COVID-19 clinical trials: A toolbox
Introduction

This document draws on the World Health Organization’s Good Participatory Practice Guidelines for Emerging Pathogens (GPP-EP) (2016) which were adapted in 2020 specifically for COVID-19. It will be updated as new resources are completed and approved.

Good Participatory Practice (GPP) can help ensure respectful community engagement and strengthen trust through collaborative partnerships.¹

Aims

The aims of this document are to:

- inform rapid engagement processes and activities with key stakeholders involved in implementing clinical research relevant to COVID-19
- provide user-friendly tools for rapid multi-stakeholder engagement

Benefits

GPP applies across research types and settings and at all stages of research.

The benefits of delivering effective GPP:

- It strengthens the design, acceptability and quality of research, including the feasibility assessment for site selection.
- It strengthens recruitment and informed consent processes by incorporating local views and through dissemination of information.
- It identifies and minimizes physical or social risks (e.g. community or individual stigma) that may result from enrolment.
- It strengthens alignment of research approach and outcomes with the collaborating population’s priorities.
- It can empower communities and demonstrate respect, both goals in themselves, and strengthen mutual understanding, trust and credibility of researchers with implications for current and future research.

¹The COVID-19 Research and Development Roadmap 2019 Novel Coronavirus Global Research and Innovation forum (11-12 February 2020) identified GPP-EP as a cross-cutting priority in clinical research to rapidly and ethically involve communities in the design, delivery, and dissemination of clinical research.
Some key themes of GPP for clinical trials

1. Use a variety of channels to communicate and engage effectively

Use local languages and clear wording; all stakeholders should have an opportunity to learn, raise concerns, and provide input into study planning and implementation. Lockdown may necessitate the increased use of social media.

2. Keep track of community priorities and concerns raised

Keep track of community priorities and concerns raised, how and where these were raised, and if and how they have been responded to by the research team.

Concerns may be about the study itself, other studies being conducted in the area, or broader health care provision.

3. Engage with and build local capacity

Do this by carefully planning and following through with collaborator agreements, and enabling their contributions.
GOOD PARTICIPATORY PRACTICE FOR COVID-19 CLINICAL TRIALS: A TOOLBOX

GPP for COVID-19 clinical trials toolbox an overview

Before the study starts

- Carefully select and understand context – work with local experts as equal or leading partners.
- Plan adequate budgeting for GPP and designate a team member to be GPP lead.
- Identify and engage with stakeholder populations to assess study appropriateness and acceptability.
- Think about the end of the study as you prepare, and include stakeholders’ involvement in shared outputs.
- Develop a stakeholder engagement plan.
- Engage with stakeholders and meet with local and national authorities.
- Seek permissions at national and local levels.
- Harmonize the study with local response plans.
- Agree on standards of care and set up optimal trial conduct.
- Understand community concerns, resistance and rumours.
- Develop clear and locally appropriate study information for public/community engagement and informed consent forms.

During the study

- Monitor study implementation and impact in the community.
- Apply and continuously amend the stakeholder engagement plan.
- Engage potential participants in honest informed consent and wider information-sharing processes.
- Include local expertise in research data collection and analysis.
- Keep track of community priorities and concerns raised, how and where these were raised, and if and how they have been responded to by the research team. Concerns may be about the study itself, other studies being conducted in the area, or broader health care provision.
- Engage with and build local capacity. Carefully plan and follow through with collaborator agreements, and enable their contributions.

After the study

- Maintain relationships to support future research engagement:
  - Managing closure and exit
  - Ensuring access and implementation of study findings
  - Sharing results through targeted and broad dissemination strategies

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Before the study starts

→ Carefully consider the contexts in which to do the research – is this the right time and place? Can it be done in conditions of lockdown and self-isolation? Harmonize trials with the local response plan.

→ Understand the scope and breadth of other planned research activities. Aim to harmonize across trials by accounting for co-enrolment and minimizing participant and family burden.

→ Identify, engage, and partner with local expertise wherever possible, including in public engagement and study leadership.

→ Recognize that different types of research (e.g. hospital-based phase 1 vaccine trial vs a multi-facility, multi-country randomized controlled trial (RCT)) will likely require different forms of engagement.

→ Use GPP to support realistic, locally acceptable clinical research design and implementation:
  - to fulfill a need for rapid health systems and social science research that enable preparedness and response
  - to inform community/public
  - to inform the research design

During the study

→ Keep in touch and keep track of study issues through your Community Advisory Board (CAB) and stakeholder engagement.

→ Identify and prepare to respond to relevant shifts and impacts on the community and new knowledge about the context or emerging pathogen.

→ Be truthful with participants and communities to maintain trust in recruitment and support valid informed consent.

→ Engage local partners and other relevant expertise in data analysis.

After the study

→ Manage closure and exit respectfully, and ensure continued access to study updates, successful discoveries, and feedback findings for stakeholder communities.

→ Continue respectful collaboration with local investigators. What you do now will be the foundation of trusting, collaborative research in the future.
Before the study starts

Nominate a person who will be responsible for GPP activities
→ This person should be a member of the research team who:
  - ideally is based in or from the country or region where the study is to be implemented. Consider working with local anthropologists or fieldworkers who understand local cultures, priorities and concerns
  - takes responsibility for conducting rapid engagement activities, acts as a dialogue facilitator, and creates a simple, clear, informative overview of the study by including graphics, finding or creating educational videos, engaging champions etc.
  - keeps clear records of the research, and also of engagement activities
  - takes responsibility for bringing practical recommendations to the research team and communicating specific needs/challenges relevant to the context where the trial is being implemented

Rapid consultation with key groups in the population or community where the study is to be implemented
→ Identify groups and individuals (such as elected or informal spokespersons) who can represent them. This will be influenced by context and sociocultural practice:
  - create a CAB or access existing ones, whenever possible, even if during the implementation of the trial
  - connect with survivors and affected families to help inform your study if a CAB is not feasible
→ Learn how to best set up data and materials storage or transfer agreements, including for biosamples and biometric data collection and ownership.
→ Connect with local researchers, outbreak teams, and research ethics committees, and create collaborators agreements.
→ Perform formative research to inform/refine research questions and procedures.
→ Work with local community engagement implementers/educators to:
  - plan consultations and mapping with different groups
  - help identify appropriate methods to bring people together for consultation, e.g. (online) focus groups, citizen forums etc.
  - gather feedback from population and community groups on what they want trial teams to know about their contexts and communities that is relevant to implementing a clinical trial
  - consider language, translation needs (link with Translators Without Borders), community entry points, social mobilizers, etc.

Feedback focused recommendations to trial team
→ Establish mechanisms to give focused recommendations as part of feedback to the team, both formal and informal.
→ While multi-country trial designs may be centralized, especially during pandemics, it is good practice to consider stakeholder insights for trial design where appropriate. Mechanisms to facilitate stakeholder input into the feasibility early in the process is good practice.
→ Incorporate stakeholder insights into trial design and adapt designs to be nimble in response.
→ Plan best approach for sharing findings. Note: Ideally this will be an iterative process with ongoing engagement to continuously identify and address emerging challenges related to trial operations.

During the study

Monitor and seek ongoing feedback from participants
→ Use tools such as a “how-to” guide and recommendation tracker to assist.
→ Stay in touch with CAB and other advisers.
→ Share lessons learned immediately.
→ Be attentive to emerging community tensions, manage rumours, and keep track of current and evolving social climate – and respond.
→ Establish approaches for: communication of protocol alterations, serious adverse events (SAEs) and critical incident review procedures; establish policies related to harms and compensation.
→ Anticipate and keep track of how research interacts with prioritization guidance for scarce resources such as hospital beds, ventilators, or medicines.
Ongoing communication with stakeholder groups

- Ensure team members engage in fair recruitment strategies, understanding the importance of showing respect and communicating truthfully.
- Informed consent must be supported by sensitivity to power imbalances and locally appropriate materials (e.g. methods of confirming consent beyond conventional signature - verbal, thumbprint options to signed forms, local definition of 'minor', capacity, etc.) that ensure valid, free and voluntary consent while avoiding false hope and therapeutic misconception.
- Explain what will not be offered and why.
- Plan how co-enrolment will be tracked across studies.
- Plan how participants will access the research team for emerging questions and concerns throughout the trial process.

Ongoing documentation of lessons learned

- Create evaluation tools such as a log of lessons learned.
- Use virtual (physical distancing) or live public meetings and workshops to share and learn.
- Communicate, evaluate and record.

After the study

Prepare and communicate closure and exit strategies in advance

- Discuss possible study closure scenarios in the case study closes early.
- Consult CAB and local champions for communication strategies to help manage expectations related to study outcomes, follow-up, recommendations and implementation of trial findings, continued access to successful interventions, related resources (e.g. clinical, training).
- Consult national governments re: follow-up and access strategies for continued, rapid and affordable access of successful resulting products, as well as other resources introduced for the study (e.g. labs).
- Review data and specimen management: Where will they be stored? Who will have future use?

Meet with survivor groups and offer ongoing online information and summaries of findings in local lay language

- Communicate trial results, using different approaches (one-way, two-way communication, different communications channels, etc.).

Establish continued communication channels with collaborators

- Keep communicating so that collaborators can be acknowledged or involved in authorship, presentations, negotiation of intellectual property (IP) etc.
Additional GPP resources


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