World Health Organization

WHO R&D Blueprint

novel Coronavirus

Good Participatory Practice for COVID-19 clinical trials: a toolbox

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R&DBlueprint

Powering research
to prevent epidemics

Table of Contents

This toolbox was developed for the World Health Organisation COVID-19 Research Roadmap as a joint initiative between the social science and ethics working groups.

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Background

Good Participatory Practice Guidelines for Emerging Pathogens (GPP-EP) help ensure respectful community engagement and strengthen trust through collaborative partnerships. GPP-EP applies across research types and settings, and at all stages of research. This document is based on GPP-EP guidelines that were prepared by Dr Catherine Hankins for the World Health Organization in December 2016, and is a synthesis of key action points. This "how to" guide, overview, tips and resources will be updated as new resources are completed and approved.

Benefits of GPP-EP include the following:

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

The COVID-19 Research & 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. This Task Force is a joint initiative between the Social Science and Ethics Working groups.

The **aim of this document** is to inform processes for rapid engagement with stakeholders involved in implementing clinical research relevant to COVID-19 and to provide user-friendly tools for rapid multi-stakeholder engagement, in alignment with actions from "Good Participatory Practice Guidelines for trials of Emerging Pathogens (GPP-EP) 2016."

Overview table

1. DURING STUDY DESIGN SELECTION & PROTOCOL WRITING	2. BEFORE THE STUDY STARTS	3. DURING STUDY IMPLEMENTATION	4. AFTER THE STUDY
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 & meet with local & national authorities Seek permissions at national and local levels Harmonise the study with local response plans Agree on standards of care and set up optimal trial conduct Understand community concerns, resistance, & rumors Develop clear and locally appropriate study information for public/community engagement and informed consent forms using local languages	Monitor study implementation and impact in the community Apply and continuously amend stakeholder engagement plan Engage potential participants in honest informed consent and wider information-sharing processes Include local expertise in research data collection and analysis	Maintain relationships to support future research engagement through: ▪ Managing closure & exit ▪ Ensuring access & implementation of study findings ▪ Share results through targeted and broad dissemination strategies
Use a variety of channels to communicate and engage effectively using 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. 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.			

Process

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 lock-down and self-isolation?

Harmonise trials with 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 RCT) will likely require different forms of engagement.

Use GPP to support realistic, locally acceptable clinical research design and implementation:

- to fulfil 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 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.

STUDY CLOSURE

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.

Tip sheet for rapid Good Participatory Practice

BEFORE THE STUDY STARTS

1. **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, act as a dialogue facilitator, and create a simple, clear, informative overview of the study by including graphics, finding or creating educational videos, engaging champions…
- 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.

2. **Rapid consultation with key groups in 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 socio-cultural practice.
  - Create a Community Advisory Board (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 bio-samples 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
  - to help identify appropriate methods to bring people together for consultation, e.g. (online) focus groups, citizen forums...
  - to 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.
- Focus community consultations on gathering feedback in key areas, such as:
  - General research literacy and information needs
  - Appropriate practices for recruitment and informed consent

- Best ways to keep populations/communities informed through the trial process, and to feedback trial outcomes when the study is complete
- Anticipate obstacles (e.g. potential stigma for participants) and issues that could undermine trial success.

3. **Feedback focused recommendations to trial team**.

- Establish mechanisms for doing this – formal and informal, document recommendations (e.g. recommendations tracker) and follow up, collect and share Top tips….
- Incorporate stakeholder insights into trial design and adapt designs to be nimble in response
- Plan best approach for restitution of findings

Note: ideally this is an iterative process with ongoing engagement to continuously identify and address emerging challenges related to trial operations.

DURING THE STUDY

1. **Monitor, and seek ongoing feedback from participants. Tools: "how to" guide, recommendation tracker**

- Stay in touch with CAB & other advisors – 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 (SAE) & 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.

2. **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.

3. **Ongoing documentation of lessons learned. Tools: "lessons log"**

- Use virtual (physical distancing) or live public meetings and workshops to share and learn;
- Communicate, Evaluate, Record.

STUDY CLOSURE

1. **Prepare and communicate closure and exit strategies in advance**

- Discuss possible study closure scenarios in 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?

2. **Meet with survivor groups, and offer ongoing on-line information and summaries of findings in local lay language**

- Communicate trial results, using different approaches (1-way, 2-way communication, different communications channels, etc.).

3. **Establish continued communication channels with collaborators so that they can be involved in authorship, presentations, Intellectual Property, etc**.

Additional resources for GPP-EP

Afsana, K., D. Habte, J. Hatfield, J. Murphy, and V. Neufeld. 2009. *Partnership Assessment Toolkit*. Canadian Coalition for Global Health Research. https://www.ccghr.ca/wp-content/uploads/2013/05/PAT_Interactive_e-1.pdf.

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World Health Organization (2016) *Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens that are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist (GPP-EP). Outcome document of the consultative process.* Prepared by Dr Catherine Hankins for the World Health Organization December 2016. https://www.who.int/blueprint/what/norms-standards/GPP-EPP-December2016.pdf?ua=1