R&DBlueprint
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World Health Organization

SOLIDARITY

United in solidarity against filovirus threats
Building research readiness for a future filovirus outbreak
Kampala, Uganda 20-22 February 2024

Community engagement during trials: Overview

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Introduction

- **Community engagement** is a **decision to involve the community in acting together**.

  "***a process of developing relationships that enable stakeholders to work together to address health-related issues and promote well-being to achieve positive health impact and outcomes***" **(WHO, 2020)**

- Community engagement in research, including public health related research, is acknowledged as **an ethical imperative.**

  Aim: Empowerment of communities to engage and take ownership

Speaking impact of CE during trials

Community Engagement

Putting the community at the heart of research, making research accountable

Stakeholder meetings
Exchanging information and ideas about research with all local stakeholders.

Feedback
Sharing views about research between community and study team.

Community outreach
Raising awareness about research and TB.

Psychosocial support
Supporting all patients taking part in the research.

Webinars and cross-site activities
Building a global CAB network and facilitating cross-site learning.

Advocacy and policy change
Influencing program and policy change through meetings with policy makers.

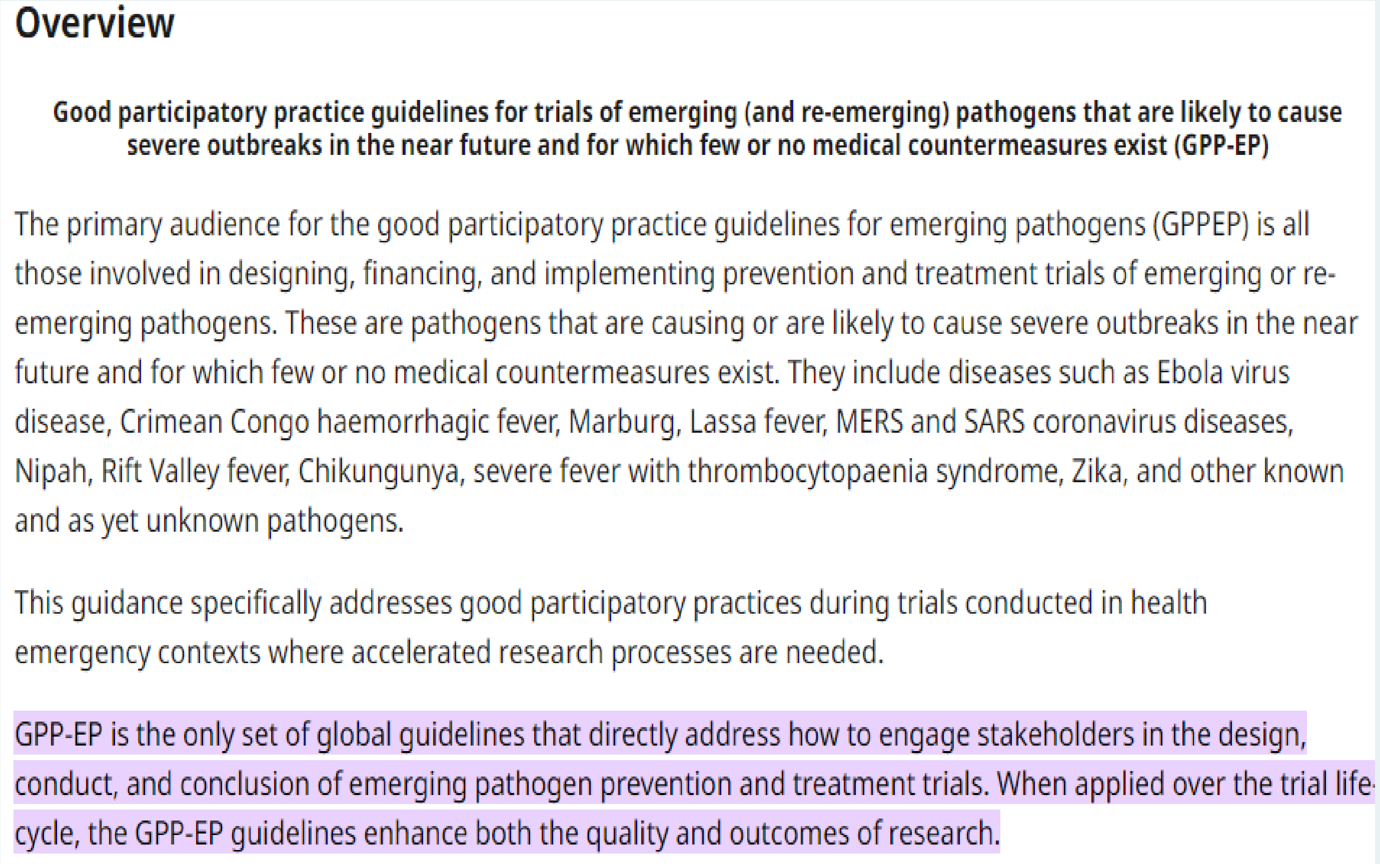
Training
Building capacity of Community Advisory Boards for participation in research.

- ☐ **Be community-led**: Facilitate community-led solutions through the improvement of the quality and consistency of CE approaches
- ☐ **Be data-driven or evidence-based**: Generate, analyse and use evidence about community's context, capacities, perceptions, and behaviours
- ☐ **Reinforce/strengthen local capacity and solutions**
- ☐ **Be collaborative**: Strengthen coordination of stakeholders to increase quality, harmonization and integra

Information & Engagement → **Decision** → **Action**

Introduction

- WHO, 2016 R&D Blue Print



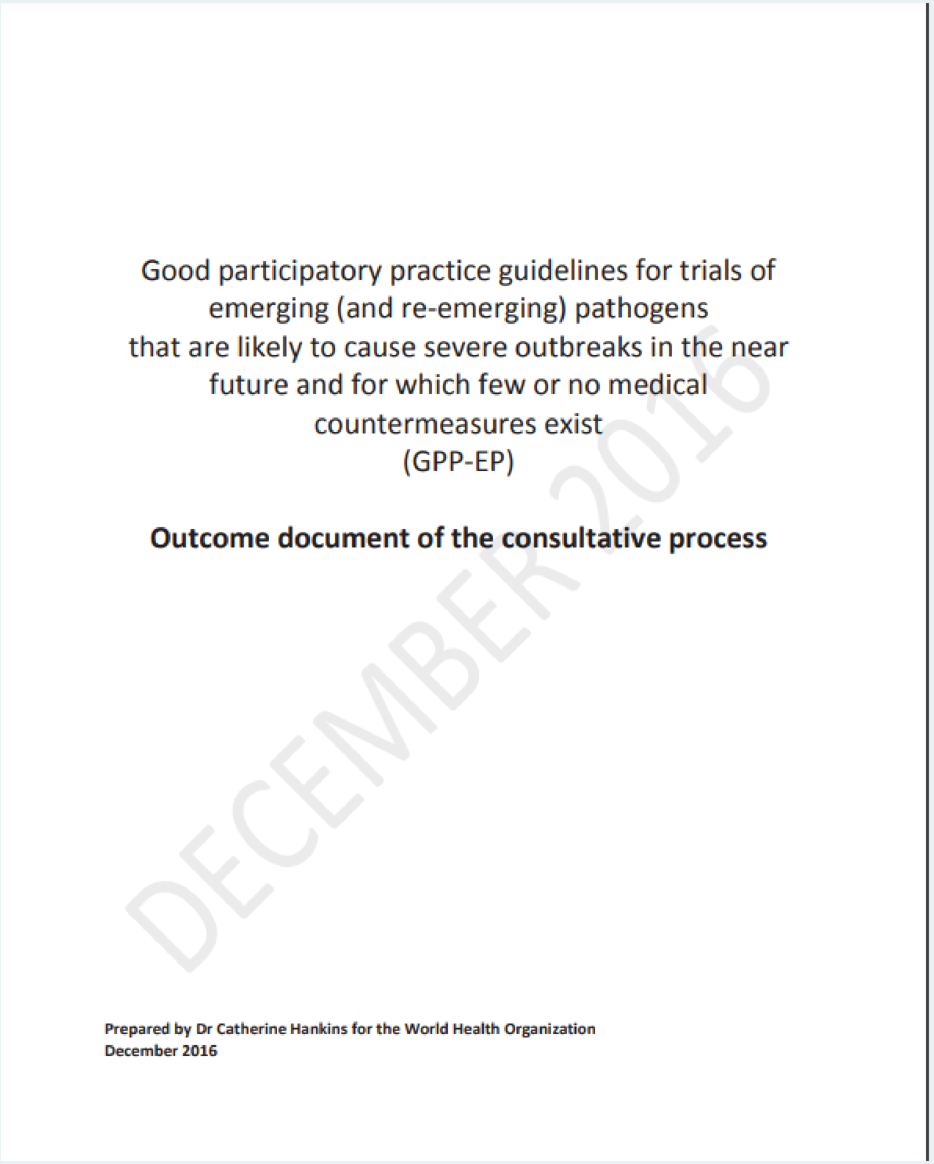
Overview

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)

The primary audience for the good participatory practice guidelines for emerging pathogens (GPPEP) is all those involved in designing, financing, and implementing prevention and treatment trials of emerging or re-emerging pathogens. These are pathogens that are causing or are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist. They include diseases such as Ebola virus disease, Crimean Congo haemorrhagic fever, Marburg, Lassa fever, MERS and SARS coronavirus diseases, Nipah, Rift Valley fever, Chikungunya, severe fever with thrombocytopaenia syndrome, Zika, and other known and as yet unknown pathogens.

This guidance specifically addresses good participatory practices during trials conducted in health emergency contexts where accelerated research processes are needed.

GPP-EP is the only set of global guidelines that directly address how to engage stakeholders in the design, conduct, and conclusion of emerging pathogen prevention and treatment trials. When applied over the trial life-cycle, the GPP-EP guidelines enhance both the quality and outcomes of research.



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

The context of the clinical trial

- Sudden threat, death, fear, denial, social disruption, etc.
- Low risk perceptions
- Low/Inadequate knowledge
- Mistrust, religious beliefs
- Infodemics (Mis-/dis-information, rumours)
- Complacency, anxiety, searching of an escape goat
- Community resistance/reticence?
- Uncertainties & Fear

Community Engagement to

- **Building TRUST**
- **Building confidence**
- **Engaging the audience**
- **Demonstrating respect, humility and empathy**
- **Co-construct the clinical trial**

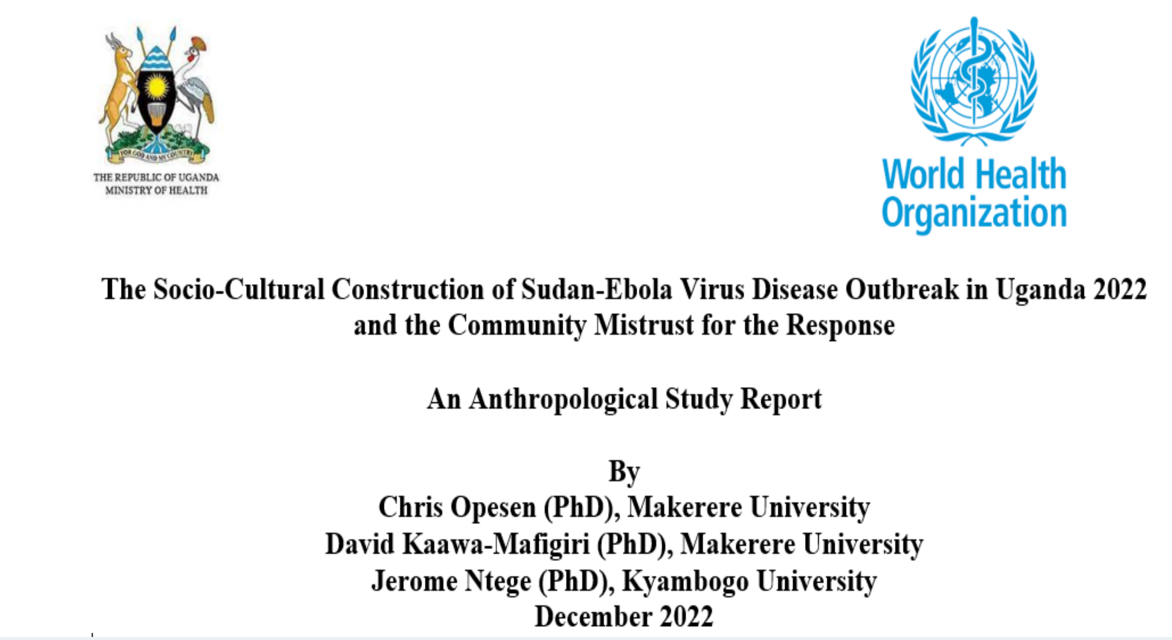
The process to engage communities (co-construction)

Community engagement strategies

Knowing the audience

- **Involve social scientists** at the early stage to facilitate the understanding of the protocols, conduct operational research, and build bridges between communities and trials' **teams**
- **Conduct Rapid Assessment "in-depth and quick studies"** for social and behavioral data, including qualitative research to understand communities' perceptions and beliefs related to the trial, and use this insights to orient CE and the overall trial' strategies
- **Map community engagement partners** (tools available/ Online kobo)

All of this leads to building TRUST



THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

World Health Organization

The Socio-Cultural Construction of Sudan-Ebola Virus Disease Outbreak in Uganda 2022 and the Community Mistrust for the Response

An Anthropological Study Report

By
Chris Opesen (PhD), Makerere University
David Kaawa-Mafigiri (PhD), Makerere University
Jerome Ntege (PhD), Kyambogo University
December 2022

Listen actively: understand and respect community concerns (2-ways)

- **Facilitate community engagement meetings** (Focus Groups discussions, etc.)
- **Community dialogues with experts**: Encourage questions and provide thoughtful responses to enhance audience participation
- Establish **social listening mechanisms** (2-way communication) to manage infodemics (online and offline): feedbacks,
- **Use live polls or surveys to gather audience opinions**, promoting engagement and making sure the audience feel involved
- **Share community feedback & perceptions** with health care workers in the Treatment centers

All of this leads to building TRUST

Plan and implement with the community (co-creation)

- Ensure participation in all levels and in all steps of the trials
- Involve the community in decision-making that affects the trials for ownership & sustainability
- Ensure to communicate and discuss the overall steps of the trials with the communities (beginning to end, including use of results)
- Ensure fairness (EQUITY)
- Ensure fundings to implement CE operational plans
- Ensure accountability with communities
- Ensure feedback and iterative collaboration (sharing and discussion of the results with the communities) from the beginning to the end of the clinical trial

All **communication products and actions aimed at the community** must be adapted to;

- **Settings** in which the population is found e.g., workplace, learning institutions, health facilities, prison, religious institutions
- **Level of education, age, sex, socio-economic status, etc.**
- **Common languages and/or dialects**
- The **most appropriate means of communication** for them (e.g., oral, written, visual, etc.)
- **Trusted and accessible channels and stakeholders.**
- The materials (posters, leaflets, messages…) must also be **pretested before use** and **before mass production**.

All of this leads to building TRUST

Build capacities

- **Inform and train the communities in the clinical trial** (translate scientific knowledge into an easy-to-understand language)

- Hold stakeholders' meetings to listen to and understand the community leaders' concerns and respond

E.g; of worries about the clinical trial

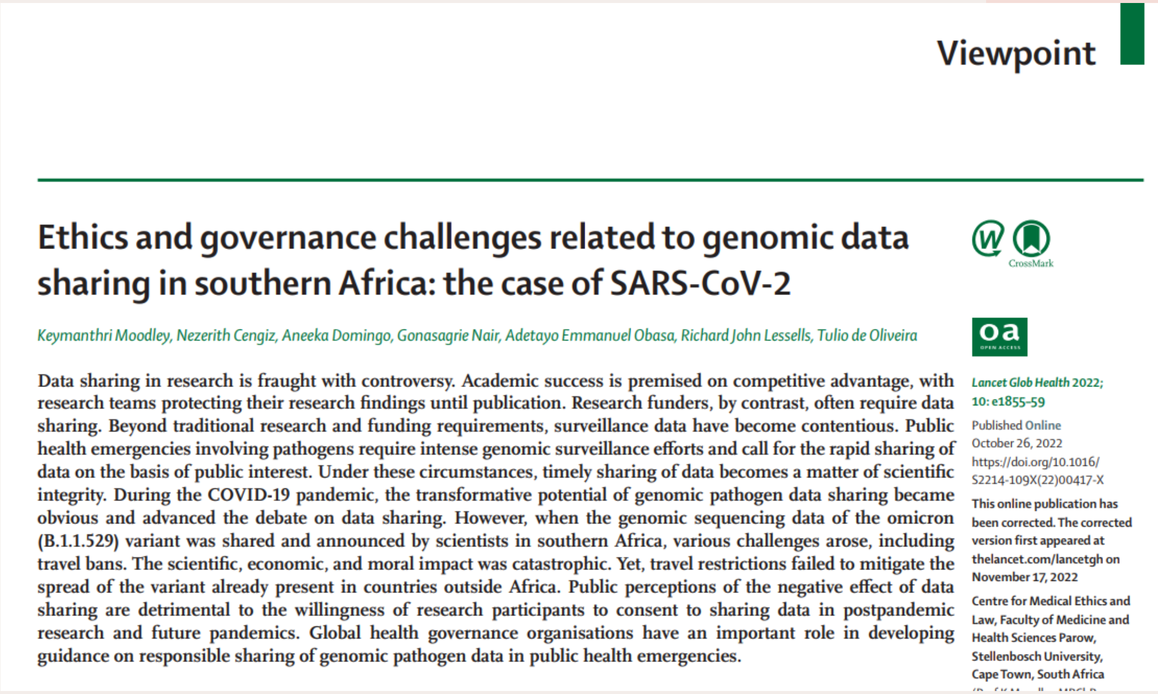
- Level of risk (individual, family and community)
- Benefits
- Payment of the cares
- Post-trial cares/side effects
- The stigma/family trust and social disruption

- Train **community health workers/community volunteers to communicate on the clinical trials** in their communities

All of this leads to building TRUST

M&E, accountability, documentation, and publication

- Hold evaluation and follow-up meetings with the community to give feedback
- Document the process and activities to capture both best practices and challenges/gaps of the engagement of the communities
- Go back to the communities to present the results of the clinical trials
- **Ensure to thank communities for their engagement** in the scientific publication of the results of the trials (if possible, **share a copy of the paper with the communities**/health authorities/health care center/community library)



Viewpoint

Ethics and governance challenges related to genomic data sharing in southern Africa: the case of SARS-CoV-2

Keymanthri Moodley, Nezerith Cengiz, Aneeka Domingo, Gonasagrie Nair, Adetayo Emmanuel Obasa, Richard John Lessells, Tulio de Oliveira

Data sharing in research is fraught with controversy. Academic success is premised on competitive advantage, with research teams protecting their research findings until publication. Research funders, by contrast, often require data sharing. Beyond traditional research and funding requirements, surveillance data have become contentious. Public health emergencies involving pathogens require intense genomic surveillance efforts and call for the rapid sharing of data on the basis of public interest. Under these circumstances, timely sharing of data becomes a matter of scientific integrity. During the COVID-19 pandemic, the transformative potential of genomic pathogen data sharing became obvious and advanced the debate on data sharing. However, when the genomic sequencing data of the omicron (B.1.1.529) variant was shared and announced by scientists in southern Africa, various challenges arose, including travel bans. The scientific, economic, and moral impact was catastrophic. Yet, travel restrictions failed to mitigate the spread of the variant already present in countries outside Africa. Public perceptions of the negative effect of data sharing are detrimental to the willingness of research participants to consent to sharing data in postpandemic research and future pandemics. Global health governance organisations have an important role in developing guidance on responsible sharing of genomic pathogen data in public health emergencies.

Lancet Glob Health 2022; 10: e1855–59

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This online publication has been corrected. The corrected version first appeared at thelancet.com/lancetgh on November 17, 2022

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AFRICANS RISING

"The Lancet" medical journal will no longer accept papers that do not acknowledge African collaborators

After reviewing recent manuscripts with data collected from the continent and recognising a tendency to exclude African contributors, the global medical journal 'The Lancet' will now reject such papers from publication.

Published 2 years agoon July 5, 2022
By **Kylie Kiunguyu**

Challenges

- Insufficient/**inexistence of ethical guidance and regulatory oversight** both at national and community levels
- Lack/insufficient **engagement of local, social, administrative, civil society organizations and political structures in the research during « peace time » for preparation/readiness** for trial enrollment
- Insufficient understanding and implementation of community engagement' timely operational research (during clinical trial)
- Insufficient up to date litterature/guidance/operational frameworks for Community engagement for trials; and/or existing guidance differ across settings
- Ressources/financial
- Insufficient/lack of will to engage communities

Research article | Open access | Published: 06 February 2023

Regulation of community advisory boards during conduct of clinical trials in Uganda: a qualitative study involving stakeholders

Andrew Ojok Mijumbi, Levicatus Mugenyi, Mastula Nanfuka, Collins Agaba & Joseph Ochieng

BMC Health Services Research **23**, Article number: 119 (2023) | Cite this article

1012 Accesses | Metrics

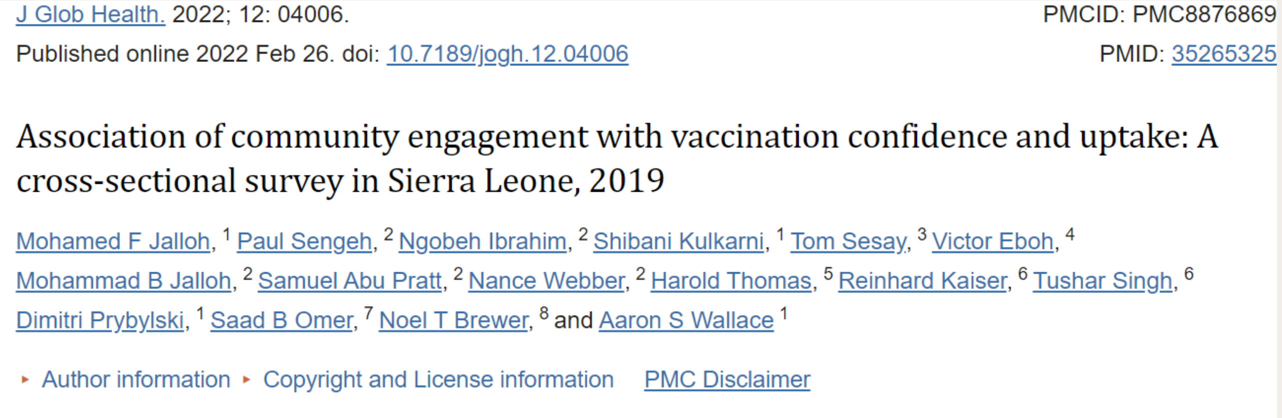
The Global Health Network Conference Proceeding **Published on** Jun 16, 2023 **DOI** 10.21428/3d48c34a.59f3074e

Mapping of Clinical Trials and Their Community Engagement Approaches in Uganda; A Situational Analysis

by Andrew Mijumbi Ojok, Levicatus Mugenyi, Mastula Nanfuka, Collins Agaba, Winfred Badanga Nazziwa, and Joseph Ochieng

Build on experience, and existing litterature

- Ebola vaccine introduction in West Africa (2014-2016)
- COVID-19 related clinical’ trials



J Glob Health. 2022; 12: 04006. PMCID: PMC8876869

Published online 2022 Feb 26. doi: 10.7189/jogh.12.04006 PMID: 35265325

Association of community engagement with vaccination confidence and uptake: A cross-sectional survey in Sierra Leone, 2019

Mohamed F Jalloh,[1] Paul Sengeh,[2] Ngobeh Ibrahim,[2] Shibani Kulkarni,[1] Tom Sesay,[3] Victor Eboh,[4] Mohammad B Jalloh,[2] Samuel Abu Pratt,[2] Nance Webber,[2] Harold Thomas,[5] Reinhard Kaiser,[6] Tushar Singh,[6] Dimitri Prybylski,[1] Saad B Omer,[7] Noel T Brewer,[8] and Aaron S Wallace[1]

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ORIGINAL ARTICLE

developing world bioethics WILEY

Considerations for stakeholder engagement and COVID-19 related clinical trials’ conduct in sub-Saharan Africa

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ABSTRACT

The aim of this study is to determine how stakeholder engagement can be adapted for the conduct of COVID-19-related clinical trials in sub-Saharan Africa. Nine essential stakeholder engagement practices were reviewed: formative research; stakeholder engagement plan; communications and issues management plan; protocol development; informed consent process; standard of prevention for vaccine research and standard of care for treatment research; policies on trial-related physical, psychological, financial, and/or social harms; trial accrual, follow-up, exit trial closure and results dissemination; and post-trial access to trial products or procedures. The norms, values, and practices of collectivist societies in Sub-Saharan Africa and the low research literacy pose challenges to the conduct of clinical trials. Civil-society organizations, members of community advisory boards and ethics committees, young persons, COVID-19 survivors, researchers, government, and the private sector are assets for the implementation and translation of COVID-19 related clinical trials. Adapting ethics guidelines to the socio-cultural context of the region can facilitate achieving the aim of stakeholder engagement.

Final tips & takeaways

TRUST

PERCEPTION

EMPATHY

EMPOWERMENT

SUCCESS OF A CLINICAL TRIAL

Ressources

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THANK YOU