



Engagement and Ethics Review

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What do ethics guidelines see as core features and practices?

‘Broad and inclusive’

‘Early and sustained’

‘Dynamic and responsive’

‘Based on evaluation of context’

‘Planned in writing’

‘Resourced/funded’

REVIEW ARTICLE

Strengthening stakeholder engagement through ethics review in biomedical HIV prevention trials: opportunities and complexities

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Abstract

Introduction: Clinical trials of biomedical HIV prevention modalities require the cooperation of multiple stakeholders. Key stakeholders, such as community members, may have stark vulnerabilities. Consequently, calls for HIV prevention researchers to implement “stakeholder engagement” are increasingly common. Such engagement is held to benefit inter-stakeholder relations, stakeholders themselves and the research itself. The ethics review process presents a unique opportunity to strengthen stakeholder engagement practices in HIV prevention trials. However, this is not necessarily straightforward. In this article, we consider several complexities. First, is stakeholder engagement a legitimate component of what Research Ethics Committees (RECs) should review for HIV prevention trials? Second, what are the core features of engagement that should be under ethics review? Third, what are the key practices that should be highlighted in ethics review?

Methods: To address these questions, we examined the international ethics guidelines specialized for such trials (UNAIDS 2012, UNAIDS-AVAC GPP 2011) and directly applicable to such trials (CIOMS 2016; WHO 2011). Thematic analysis was used to code and analyse these guidelines.

Results and discussion: Ethics guidelines support REC review of engagement. Guidance recommends that engagement be broad and inclusive; early and sustained; and dynamic and responsive. Broad engagement practices include evaluating the context, planning in writing, and resourcing. RECs should assess engagement as part of a comprehensive review, and recommend revisions where necessary. Researchers should profile key elements of engagement valued in ethics guidance, when they draft ethics submissions. Importantly, the ethics review process should not undermine the “dynamic responsiveness” required for excellent engagement in this field.

Conclusion: As evidence-informed engagement strategies emerge, these should inform the ethics submission and review process. Priorities in the review process should strive to avoid a superficial, check-list type approach that caricatures what a thorough, nuanced ethics review of a rich, responsive engagement process.

Keywords: stakeholder engagement; community engagement; ethics review; Research Ethics Committee; Institutional Review Board; biomedical HIV prevention trials

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1. Ethics guidelines for such trials (UNAIDS 2012, UNAIDS-AVAC GPP 2011) and directly applicable to such trials (CIOMS 2016; WHO 2011).

recognize that when sponsors and researchers engage relevant stakeholders, potential risks and harms can be mitigated.

Ethics guidelines recognize several potential benefits of engagement. First, there are beneficial outcomes of engagement for inter-stakeholder relations – that is, relations between researchers and stakeholders that are more trusting, “collaborative,” involve “partnership,” are “mutually beneficial” and “equitable” so that power imbalances are reduced [2]. Second,

1 Broad and Inclusive

Adapted from Slack et al., 2018

CIOMS (2016)

"Stakeholders are individuals, groups, organizations, government bodies, or any others who can influence or are affected by the conduct or outcome of the research project. The process must be fully collaborative and transparent, involving a wide variety of participants, including patients and consumer organizations, community leaders and representatives, relevant NGOs and advocacy groups, regulatory authorities, government agencies and community advisory boards" (p. 25)

UNAIDS-AVAC GPP HIV (2011)

"any individual or collection of individuals who have a stake in a biomedical HIV prevention trial" (p. 14)

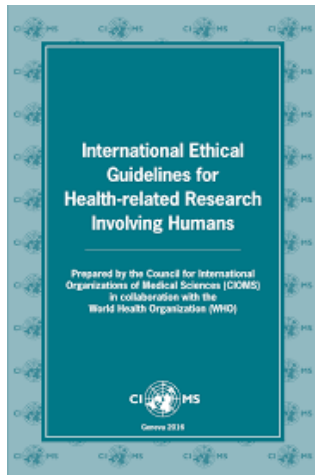
UNAIDS HIV (2012)

"the concept [of community] needs to be broadened to civil society so as to include advocates, media, human rights organizations, national institutions and governments, as well as researchers and community representatives from the trial site" (p. 18)

WHO GPP Emerging Pathogens (2016)

"Stakeholders are all individuals or collections of individuals who can influence or are affected by the conduct or outcome of a trial, i.e. all those who have a stake in an emerging pathogen prevention or treatment trial." (p.10)

CIOMS
2016
GP 7, p25



- **Include** a *description of the plan for community engagement in the protocol or other documents submitted to REC*
- **Identify** *resources allocated for proposed activities in protocol or other documents submitted to REC*
- **Specify** *what has been and will be done, when and by whom*



REC review of engagement should -

- **Preserve ability of researchers to implement timeous and responsive engagement in the field**
- **Be flexible about which documents contain engagement plans and resources, and about level of detail**

1. See <https://engage.avac.org/>
2. Register
3. Select “learn”
4. Select “Strengthening Engagement Through Ethics Review” online course



Stakeholder Engagement Online Course

Strengthening engagement through ethics review:
 Focused on HIV prevention trials
 Applicable to other infectious diseases

Receive a certificate and downloadable resource!

Link with colleagues via ENGAGE host platform!

Who should enrol?

- ✓ Research Ethics Committees (RECs) or IRBs – especially community, lay or non-institutional REC members.
- ✓ Researchers and others interested in engagement.

What you will learn in each module

Engage in 6 self-paced interactive modules 30-40 minutes each.

1	2	3	4	5	6
Learn how engagement helps navigate ethical complexities in trials	Understand the ethical underpinnings of stakeholder engagement	Hear how guidance encourages RECs/IRBs to review engagement	Learn about key features of engaged trials	Review key practices of engaged trials	Interact with a real clinical protocol

What have others said?

"Great job on stakeholder engagement through ethics review, reviewers should take these into consideration when reviewing protocols."

"The course is good and helped highlight the importance of SE in REC review. The various national and international guidelines was most useful"

"I liked the way the course is tailored. The protocol review practical part of the course made it very interesting and enriching to me."

"A very important topic for researchers and would wish that all be familiar with the contents of the course to enrich and strengthen research involving human subjects."

"Great course structure. The combination of audio, graphics and quiet reading sessions made it great!"

"Since am part of researcher staff, I felt it was very helpful to know more about such things and how to engage with other committees."

"This was a well structured course with easy navigation and excellent interactive content."

To join the course, please visit:

<https://engage.avac.org/> to take the course

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U.S. President's Emergency Plan for AIDS Relief



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2 Early and Sustained

Adapted from Slack et al., 2018

CIOMS (2016)	"Researchers, sponsors, health authorities and relevant institutions should engage potential participants and communities in a meaningful participatory process that involves them in an early and sustained manner in the design, development, implementation, design of the informed consent process and monitoring of research, and in the dissemination of its results" (p. 25)
UNAIDS-AVAC HIV GPP (2011)	"activities required for the development, planning, implementation, and conclusion of a trial, including dissemination of trial results" (p. 5); "a long-term process that extends throughout and beyond the life-cycle of any single clinical trial" (p. 66)
UNAIDS HIV (2012)	"engage in consultations with communities who will participate in the trial from the beginning of the research concept, in an open, iterative, collaborative process" (p. 17)
WHO GPP Emerging Pathogens (2016)	"Early engagement of relevant stakeholders in an honest, transparent manner that respects all parties is key to finding common ground and addressing any opposition or disagreement among stakeholders from the outset and over the course of a trial." (p.12); "Identification of potential stakeholders is a process that is ongoing over the life of a trial, given that stakeholders' interests, priorities, perspectives, and cultures may change." (p.11)

3 Responsive and Dynamic

Adapted from Slack et al., 2018

CIOMS (2016)

"In the design and conduct of the research[...] the researchers and the sponsors must be responsive to the concerns of the community" (p. 63)

UNAIDS-AVAC GPP HIV (2011)

"The application of each practice or set of practices will vary by location, the type of trial being conducted, and trial site experience" (p. 26), "stakeholders interests, priorities, perspectives, and culture may change over time" (p.16), "Stakeholder identification and inclusion considers the dynamic stakeholder landscape" (p. 31)

UNAIDS HIV (2012)

"engage in consultations with communities [...] in an open, iterative, collaborative process" (p. 17) "find solutions to unexpected issues that may emerge once the trial is underway" (p. 17)
"Defining the relevant community for consultation and partnership is a complex and evolving process" (p. 18)

WHO GPP Emerging Pathogens (2016)

"Respect is demonstrated when stakeholders communicate and act in ways that value and honour each other's perspectives and realities and are responsive to each other's interests." (p.19)

A Based on evaluation of context

Adapted from Slack et al., 2018

CIOMS (2016)

"Active community involvement [...] helps the research team to understand and appreciate the research context" (p.5)

UNAIDS-AVAC GPP HIV (2011)

"Successful stakeholder engagement requires a broad, inclusive, and multifaceted understanding of the context in which a biomedical HIV prevention trial is conducted" (p.16)

"Formative research activities can be conducted informally to gather information about local populations and research areas or formally as a part of approved, funded protocols." (p.27)

UNAIDS HIV (2012)

"A social and political analysis should be carried out early on in planning the research process, to assess determinants of vulnerability, such as poverty, gender, age, ethnicity, sexuality, health, employment, education, and legal conditions in potential participating communities" (p.32)

WHO GPP Emerging Pathogens
(2016)

"Successful stakeholder engagement requires a broad, inclusive, and multifaceted understanding of the context in which an emerging pathogen prevention or treatment trial is conducted." (p.11); "Informed by information gathering and formative research, a comprehensive and effective stakeholder engagement plan describes strategies and mechanisms" (pp24-25)

B Planned in Writing

Adapted from Slack et al., 2018

CIOMS (2016)	"The research protocol or other documents submitted to the research ethics committee should include a description of the plan for community engagement, and identify resources allocated for the proposed activities. This documentation must specify what has been and will be done, when and by whom" (p.25)
UNAIDS-AVAC HIV GPP (2011)	"A comprehensive stakeholder engagement plan enables research teams to collaborate with stakeholders and facilitate a more participatory approach to biomedical HIV prevention research" (p. 35)
UNAIDS HIV (2012)	"Scientific and ethical review prior to approval of a trial protocol should take into consideration these issues [...] community participation and involvement" (p. 24)
WHO GPP Emerging Pathogens (2016)	"...a comprehensive and effective stakeholder engagement plan describes strategies and mechanisms for building relationships and constructively engaging with a broad range of local, national, and international stakeholders" (pp24-25)

C Resourced

Adapted from Slack et al., 2018

CIOMS (2016)	"The research protocol or documents sent to the research ethics committee should [...] present resources allocated for the community engagement activities" (p.102)
UNAIDS-AVAC HIV GPP (2011)	"Trial sponsors ensure sufficient funding and research teams allocate resources and time to support stakeholder engagement" (p.45), "Research teams designate trial site staff responsible for [engagement]" (p. 28)
UNAIDS HIV (2012)	"The principal investigator and site research staff should work with representatives of affected communities to identify needs related to their participation, including logistical requirements such as transportation to the meeting site" (p.19)
WHO GPP Emerging Pathogens (2016)	"This means that trial sponsors provide adequate human resources and sufficient funds in research budgets to implement the activities of Section 4 of the GPP guidelines." (p.8)
