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Strengthening Engagement Through Ethics Review

- Ethics guidelines recommend that researchers implement stakeholder engagement in clinical trials *for HIV* (UNAIDS, 2021; UNAIDS & AVAC, 2011), *for TB* (AERAS GPP TB-Vax, 2017; CPTR GPP TB-Drug, 2012) and for *emerging pathogens* (WHO GPP EP, 2016) as well as in *health studies more generally* (CIOMS, 2016).
- Ethics guidelines also recommend that Research Ethics Committees (RECs) review engagement in all these contexts (UNAIDS, 2021; UNAIDS & AVAC, 2011; AERAS, 2017; CPTR, 2012; CIOMS, 2016; WHO, 2011).
  - CIOMS (2016) states that the *"research protocol or other documents submitted to the Research Ethics Committee should include a description of the plan for community engagement" (p.25).*
- Empirical research (SETER study: UKZN BREC BE 38/19) indicates that many stakeholders value engagement highly and perceive ethics review of engagement as valuable. Interviewees noted 3 complexities with engagement processes - namely tokenism, toxicity and tailoring – which we have termed the "Three T's".

About this resource

- This resource aims to summarize these empirically identified complexities, highlight current ethics guidance, and set out implications for critical stakeholders.
- This resource is aimed at researchers, RECs and advocates working in trials of HIV prevention.

Minimizing Token Engagement for Trials

HAVEG interview research found that token engagement is recognized in various ways – including: when engagement has the main goal of recruitment; when it is not early or sustained; when it narrowly focuses on certain stakeholders (namely institutional gatekeepers or Community Advisory Boards (CABs)); when gender inclusivity is ignored; when engagement staff and practices become 'stale' over time; when inputs from stakeholders are inadequately solicited or impactful; when socio-economic, political, racial and cultural contexts are ignored; when engagement mechanisms do not address stakeholder bias; and when engagement is poorly resourced or evaluated. Also, HAVEG interview research found that several interviewees perceived engagement to be somewhat neglected in the ethics review process, that REC members may be disconnected from community realities and that community representatives are inadequately represented or empowered on RECs, and that community representatives are inadequately represented or empowered on RECs.

Ethics guidance says

- *"Research teams ensure that representation of stakeholders is comprehensive, including representatives of populations that will be recruited into trials, and that interactions with stakeholders are meaningful and responsive for all parties." (UNAIDS & AVAC GPP 2011).*

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- *"Following good participatory practices through the entire research life-cycle helps facilitate local ownership of research, enables more equitable relationships, and increases the likelihood of successful research conduct, trial completion and application of research results." (UNAIDS & AVAC GPP 2011).*
- *"Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support establishment, ongoing capacity-building, maintenance, and activities of stakeholder advisory mechanisms." (UNAIDS & AVAC GPP 2011).*

- **Implications for Researchers** – Researchers should ask community experts how 'token' engagement could best be avoided at their site. Researchers should aspire to inclusive, sustained and responsive engagement that is well resourced, and highlight these features in ethics submissions.
- **Implications for RECs** –RECs should counter token engagement in trials by asking insightful questions e.g. about diversity of stakeholders, about the 'sustainedness' of engagement across the trial life-span, about its funding, amongst others. REC Application Forms should prompt applicants to describe their engagement plans. RECs should strengthen the role of community/lay representatives on RECs, which may support review of engagement, as well as other important goals.
- **Implications for Advocates** - Advocates should ask questions of researchers designed to support high-quality engagement in the field including how diverse and sustained engagement will be maintained, as well as funding (*to be developed*).

Minimizing Toxic Engagement for Trials

HAVEG interview research found that certain interviewees raised concerns that engagement practices might (inadvertently) have potential harmful consequences. This included for *participants* when, for example, engagement of community leaders might inadvertently pressure potential participants to take part in research. Also, for *community stakeholders* when, for example, outreach to a stigmatised group compounds stigma, or reinforces gender biases or negative stereotypes, or perpetuates inequalities between researchers and communities. Also for *scientific progress* if engaged parties implement disruptive practices. Also, HAVEG interview research found some interviewees viewed that poor review of engagement might exacerbate tensions or undermine flexible responsiveness in the field.

Ethics guidance says

- *"Underlying determinants of the HIV epidemic can be entrenched in the social, cultural, legal, institutional, or economic fabric of society. Examples of these determinants include gender and other power inequalities, gender-based violence, economic instability (...) discriminatory practices, HIV-related stigma, social marginalization, and criminalization of HIV transmission. Recognition of these factors is the first step in developing practices that avoid inadvertently replicating or reinforcing them in the design and conduct of biomedical HIV prevention trials." (UNAIDS & AVAC GPP 2011).*
- *"Power inequalities between research teams and community stakeholders can include imbalances in literacy, education, and economic resources, as well as those inherent in patient–provider relationships. National, racial,*

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ethnic, and linguistic differences between members of research teams and community stakeholders can also exacerbate inequalities. In order to achieve meaningful community stakeholder participation and partnership, it is essential to recognise these various power inequalities and address them." (UNAIDS & AVAC GPP 2011).

- *"Stakeholder collaboration can help (…) avoid reinforcing existing inequalities and increase sensitivity to the needs of vulnerable populations." (UNAIDS & AVAC GPP 2011).*

- **Implications for Researchers** – Researchers should ask: Have potential risks of engagement (e.g. undue pressure from community leaders to take part/not to take part) to participants been minimized? Have potential risks (e.g. increased stigma? reinforced stereotypes? misinformation?) to community stakeholders been minimized?
- **Implications for RECs** – RECs should carefully consider whether engagement practices for studies might carry potential for harm and whether this risk has been mitigated. RECs should encourage 'reflexivity' rather than 'compliance' when reviewing engagement where REC queries encourage thoughtful reflection and responsiveness in practices and strive for a collaborative relationship with researchers (Jennings, 2010).
- **Implications for Advocates** – Advocates should ask researchers whether engagement activities carry the potential for harm and how to mitigate such harm (*to be developed*)

Maximizing Tailored Engagement ("Intensity") for all studies

HAVEG interview research found that interviewees perceived that studies might need different 'levels' or 'intensity' of engagement. Several factors were viewed as affecting intensity – including the level of study risk; the level of vulnerability of participants; the type of study (e.g., interventional versus non-interventional); the novelty/innovativeness of the study; the phase of the study; the study duration and the disease under investigation. Interviewees recognized that this issue of tailoring the level of engagement to the study at hand required more guidance, thought and work.
Also, interviewees recognised that REC review of engagement across various studies should likely vary and volunteered factors mirroring those affecting intensity of engagement itself.

Ethics guidance says

- *"The extent of community engagement should be tailored to the type, stage, length of the proposed research, and the potential risks to participants; less extensive community engagement may be justified for small studies of short duration and minimal risk" (HPTN 2020).*
- *(...) when conducting research with extremely disadvantaged or stigmatized populations/communities, such as men who have sex with men (MSM) in countries where same sex activity is criminalized, and people who inject drugs (PWID) in countries where drug use and harm reduction is criminalized, the ethical obligation to engage deeply with these communities increases because of the very real potential for serious social harms" (HPTN 2020)*

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- **Implications for Researchers** – Researchers should consider whether planned engagement activities are 'dosed' appropriately depending on the study risks, the vulnerability of the study population, study design complexities and other relevant factors.
- **Implications for RECs** – RECs should assess if the level/intensity of engagement is appropriate given the above factors (e.g. clinical trial vs observational study). RECs should become aware of the factors they intuitively rely on when recommending more intense engagement.
- **Implications for Advocates** – Advocates should ask researchers about the level of engagement to be implemented for observational studies versus clinical trials (*To be developed*).

Ensuring sound decision-making practices

HAVEG interview research suggested that interviewees valued authentic engagement of stakeholders when making key decisions. For example, that relevant stakeholders be consulted, that robust discussions occur, and that stakeholder views be addressed.

Ethics guidance says

- *"In equal partnerships, there is a shared understanding that the voices of all partners are equally important and essential, and that differences in approaches, expertise and preferences are to be respected (...) The nature of community involvement should be one of continuous mutual education and respect, partnership and consensus- building around all aspects of the testing of potential HIV prevention products". (UNAIDS 2021)*
- *"Research teams maintain clear written records of discussions and agreements with relevant stakeholders, including requests, concerns, recommendations, actions taken by the research team, and any unresolved issues that require follow-up" (UNAIDS & AVAC GPP 2011).*

A framework for decision-making called Deliberative Democracy (Gutmann & Thompson, 2009; Parker, 2006) states that:

- *Deliberation, persuasion and debate are needed to reach democratic decisions*
- *The views of all those who have a stake should be accounted for*

This framework recommends that:

- *Decisions should be justified - that is, have a reason, and justifications should be accessible to all whom the decisions affect*
- *Decisions should be expressive, that is express what is important for those affected; OR decisions should be instrumental - that is lead to better/improved outcomes, OR both*
- *Decisions can be substantive – where decisions are argued and based on substance – OR procedural where decisions are based on for example voting, OR both*
- *Decisions can be consensual, that is made through group consensus, OR pluralist, that is inclusive of all recommendations and views*

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- ***Implications for researchers –*** Researchers should consider how to best elicit and address stakeholder views, and to best communicate substantive decisions taken about the research *(to be developed).*

- ***Implications for RECs –***RECs should ask researchers to describe efforts to engage all relevant stakeholders in key decisions about the research and to achieve consensus on key concerns *(to be developed).*

- ***Implications for Advocates -*** Advocates should amplify the voices and views of community stakeholders to ensure these voices are addressed in decision-making processes. Advocates should argue/deliberate for those stakeholders who are not represented in key decision-making processes *(to be developed).*

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COMMENTS

Send any comments/ feedback to Abigail Wilkinson at HAVEG, UKZN wilkinsona@ukzn.ac.za

Useful Resources

AERAS GPP TB-Vax. (2017). *Good Participatory Practice Guidelines for TB Vaccine Research*. Retrieved from https://www.avac.org/sites/default/files/resource-files/Aeras_GPP-TB%20VAC%202017_FINAL_Low%20res%5B1%5D.pdf

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