

## Volunteers in Research and Ethics

### VoREthics Initiative

Sub-Saharan Africa Workshop, May 24, 2022

### Meeting report

**Meeting agenda:** Focus on the risks of exploitation of healthy volunteers in biomedical research

#### Introduction (11:00 – 11:15)

Meeting chairpersons : Esperança Sevene (*Eduardo Mondlane University*) & Elizabeth Allen (University of Cape Town & The Global Health Network)

#### How to protect HVs from exploitation: African perspectives. (11:15 – 11:45)

- Primus Che Chi (*KEMRI-Wellcome Trust Research Programme, Kenya*)

- Juliet Mwanga (*Epicentre's Uganda Research Centre*)

#### Lessons learned from the February UNESCO meeting (11:45 – 11:55)

François Bompert (*DNDi, Switzerland*)

#### Open discussion with the audience: identified risks of exploitation, field experiences, recommendations (11:55 – 13:00)

Moderators: Elizabeth Allen and Esperança Sevene

#### Next steps (13:00)

François Hirsch (*Inserm, France*)

**Attendees:** a total of 78 persons, from 21 countries, including 3 healthy volunteers from Uganda, registered to attend the meeting.

**Prior to the meeting,** questionnaires sent to attendees enabled collecting insights from African colleagues regarding cases of exploitation they may have witnessed, and solutions they could propose to limit risks of exploitation. They are summarised below:

#### Examples of possible exploitation reported by 9 of 39 persons who answered the questionnaires included:

- Lack of **community engagement**, including communication of risk
- Issues of **informed consent**; complete lack (e.g. debate around WHO malaria vaccine), insufficient information for informed choice, vulnerable groups (e.g. during labour)
- Specific concern about using **food as an incentive in poor populations**
- Lack of participant awareness of **injury compensation** processes (insurance), including where AEs have been determined as not related to study
- Specific to genetic research: lack of **robust mechanism for privacy**
- Specific to malaria: lack of follow up of houses to be sprayed with an approved insecticide
- Lack of **feedback of results** (including where participants were assured otherwise)
- Lack of **guidance on/compensation for secondary use of data**

#### Examples of possible solutions proposed: education & dialogue

- **Invest in education** in biomedical research and bioethics to strengthen competence and open ways to develop and deploy solutions to prevent or mitigate risks

- Ensure **research protocols align with ethical standards**
  - **Innovative and collaborative learning initiatives** tailored to key audiences (higher education, researcher teams, research-relevant bodies, potential participants), e.g. long-term train the trainer programmes, videos showing reality of complex studies like first-in-human
  - **Constant dialogue between stakeholders** to strengthen understanding of the research process, roles within an interconnected framework
- ➡ Help maintain robust safeguards, increased access to evidence through improved education-communication

### Examples of possible solutions proposed: Health authority & ethics committee oversight

- **Acts of legislation** (e.g. for a national health research ethics committee)
- Capacity for **strong, competent, and independent ethics committees** with effective continuing oversight
  - **Robust and comprehensive ethical review** of research protocols
  - **Assessment of the information/consent form**
  - Ensuring they are informed about **breaches of ethics**
  - **Field site visits** to monitor processes, perhaps de-briefing of HV to make sure they understood the study before participation

### Examples of possible solutions proposed: Community engagement & informed consent

- Comprehensive, meaningful **community-partnered engagement to empower** communities about their rights in research, to ask questions and to be able to say NO
  - Establish platforms through which elected community representatives have **input into development/design, implementation and completion of research studies**
- ➡ Questions are asked/answered, clarity is achieved, trust in research process is built
- Clearly written **informed consent form in local language, emphasising voluntariness**
    - Procedural document for compensating HV taking part in research so that informed consent is **without inducement**

**During the meeting,** discussions led to clarify and expand on some ideas, in particular:

- Healthy volunteers' motivations to participate in research studies: the 3 healthy volunteers who spoke during the meeting said that they did not feel they were being exploited, and that they felt "in control" throughout the studies. They said that their questions and concerns were properly addressed, and that they were treated well throughout the studies. Money was not their primary incentive, although good indemnification of transportation expenses was important. Their primary motivations were to contribute to the common good. Of note, their educational levels were high (two were health professionals), and the studies they enrolled into were not very lengthy or demanding, therefore compensation levels were not very high. They all acknowledged that they could perceive risks of exploitation of people with lower educational levels and more economically vulnerable.
- The right of withdrawal of volunteers involved in infectious challenge studies may be difficult to respect / ensure once infection has been initiated.
- Communities and, ideally, former healthy volunteers, should be involved in the design and wording of information and informed consent documents to ensure they can be properly

understood, to ensure that language/educational/cultural barrier prevent proper understanding. These concern scientific and medical terms for which simple, easily understandable local language translations may not exist. They also concern legal terms (e.g. to explain rights of volunteers) or insurance terms that may be difficult to understand.

- An attendee said that all externally sponsored or designed research in Africa is exploitative, and that until relevant research questions are generated from within Africa, with African design and conduct of research, this will not be resolved. Local norms should be in place to improve the collaborative research.
- Appropriate housing conditions during the study, and more generally the well-being of volunteers, should be ensured
- Multiple time consenting, as well as checking of understanding of key information items provided for informed consent were highlighted as good practices.
- Compensation: the dilemma between giving too low a compensation (risk of exploiting people) vs. giving too much (risk of undue inducement) was raised by several speakers. It was said that compensating for tangible costs (e.g. transportation costs) is much easier than compensating for time spent because of study requirements. Some countries have national guidelines on appropriate level of compensation. Uganda provides such guidelines, setting minimum rates, but not maximum ones.
- Several speakers alluded to the importance of helping IRBs ensure the quality and risk/benefit ratio of studies. It was suggested that sub-committees, specifically designed and trained to review studies involving healthy volunteers could be considered as good practice.