3.13 Policies on trial-related harms

3.13.A. Definition

Policies on trial-related harms describe how research teams will treat and compensate trial participants should they experience physical or social harms that are determined to be associated with trial participation, as well as how such harms will be addressed and mitigated.

3.13.B. Relevance to good participatory practice

A key ethical obligation of research teams is to maximise benefits and minimise harms for trial participants. Relevant stakeholders can provide valuable input about possible social harms of trial participation. These are of particular concern for individuals or groups who may be vulnerable, marginalised, stigmatised, or who have less power in society. Relevant stakeholders can also provide advice about local expectations of research team obligations to address trial-related physical and social harms. Discussing with stakeholders before a trial starts and clearly explaining how trial-related harms will be addressed and mitigated can significantly influence community stakeholder perceptions of the trial and of how well community stakeholder concerns will be addressed.

3.13.C. Special considerations

Sponsors typically give specific and binding guidance to research teams on how to determine and report physical harms as adverse events. It is good practice to define similarly stringent procedures for the determination, documentation, reporting, and management of social harms that trial participants may experience. Examples of social harms due to trial participation include stigma, discrimination, and verbal, emotional, physical, or sexual abuse.

3.13.D. Good participatory practices for policies on trial-related harms

1. Research teams and relevant stakeholders list anticipated physical and social harms that might occur due to trial participation.

2. Research teams and relevant stakeholders discuss and develop policies on trial-related physical and social harms, considering the following issues:
    a. Strategies to prevent or reduce the risk of trial-related harms.
    b. Procedures to encourage and facilitate reporting of social harms.
    c. Procedures to investigate events that have been reported indirectly, such as through a third party, taking confidentiality issues into account.
    d. Procedures for reporting social harms and whether these are to be reported to sponsors, ethics committees, and regulatory bodies, even if not specifically required by them.
    e. Procedures for ensuring optimal referrals to appropriate services for trial-related harms.
    f. Strategies to inform trial participants of the potential risks of engaging with media.
    g. Compensation or insurance policies, when applicable, for specific trial-related harms, coverage provided by the policies, how claims are made, and how participants are informed of their rights in relation to the policies.
3. Research teams and relevant stakeholders review follow-up strategies to reduce trial-related physical and social harms over the course of the trial.
4. Research teams maintain clear written records of discussions and agreements. This includes recommendations, actions taken by the research team, and any unresolved issues that require follow-up.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to ensure the effective management of physical and social harms related to participation in a trial.

3.13.E. Additional guidance

1. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 11, page 40, Potential Harms).[1]