3.11.E. Additional guidance

1. *The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*.[5]
2. *Ethical considerations in biomedical HIV prevention trials* (Guidance Point 14, page 48, Care and Treatment).[1]
3. *Ethical considerations in biomedical HIV prevention trials* (page 13, selected circumstances in which biomedical HIV prevention trials should not be conducted).[1]
4. *Mapping the Standards of Care at Microbicide Clinical Trial Sites*.[35]

3.12 Non HIV-related care

3.12.A. Definition

Non HIV-related care refers to health and social care services provided or made available to trial participants that are not directly related to HIV prevention, HIV care and treatment, or trial-related harm. The non HIV-related care services appropriate for trial participants will depend on the trial population and local health priorities. Examples could include provision of female or male sexual and reproductive health care, management of infectious diseases, nutritional health, psychiatric care, and psychosocial services.

3.12.B. Relevance to good participatory practice

Access to non HIV-related care can provide benefits for participants, contribute to their welfare, and improve clinical trial outcomes. Negotiating the range of non HIV-related services available to participants at the trial site or via referral will assist in ensuring that relevant stakeholders clearly understand the breadth of services available and reasons for inclusion and exclusion of certain services.

3.12.C. Special considerations

Non HIV-related care packages may vary from site to site, depending on local health priorities and local standards of care.

3.12.D. Good participatory practices for non HIV-related care

1. Research teams identify the existence and capacity of local social care and primary health-care services and of secondary and tertiary diagnostic and treatment services. This enables the provision of appropriate referrals and linkages, should the need arise.
2. Research teams and relevant stakeholders discuss access to non HIV-related care services during the trial's protocol development phase.
3. Research teams and relevant stakeholders discuss non HIV-related care services to be offered to participants and consult with local social and health-care service providers when appropriate. Discussions take account of the following:
   a. Non HIV-related care services required by the trial protocol.
   b. Additional non HIV-related care services that community stakeholders would like to see the trial site offer to participants.
   c. Services that will be offered through referral.
   d. Whether any non HIV-related services will be available to partners of trial participants.
   e. The impact on local service delivery of any services offered or referred to by the trial.
4. Research teams maintain clear written records of discussions and agreements. This includes relevant stakeholder recommendations, actions taken by the research team, and any unresolved issues.
5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds to ensure provision of the locally discussed, non HIV-related care package.

3.12.E. Additional guidance

See *Mapping the Standards of Care at Microbicide Clinical Trial Sites*.[35]

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]

2. *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Guideline 19, page 78 right of injured subjects to treatment and compensation).[7]

3.14 Trial accrual, follow-up, and exit

3.14.A. Definition

Trial accrual, follow-up, and exit activities include the recruitment, screening, enrolment, follow-up, and exit of trial participants in biomedical HIV prevention trials.

3.14.B. Relevance to good participatory practice

Community stakeholders can provide the best information on how to design socially and culturally acceptable strategies for recruitment, screening, enrolment, follow-up, and exit. Community stakeholders included in the process of developing these strategies can play an important role in identifying and mitigating trial-related stigma, misconceptions, or miscommunication.

3.14.C. Special considerations

1. Follow-up of participants after missed visits must respect agreements between the participant and research team about how to contact the participant.
2. Exiting a trial may present changes in what participants have become accustomed to with regard to clinical care and the impact of the trial on their social relationships. Anticipation and discussion of these issues between research teams and community stakeholders will help in the development of appropriate strategies to support participants upon trial exit.

3.14.D. Good participatory practices for trial accrual, follow-up, and exit

1. Research teams consult with relevant stakeholders about accrual, follow-up, and exit processes, taking account of the following: