

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

### 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:

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- a. Strategies and messages that are socially and culturally appropriate, meet the needs of specific stakeholders in terms of language and literacy, and draw on a range of communication modes, including written, oral, and visual.
  - b. Procedures to anticipate, monitor, and mitigate trial-related stigma resulting from ineligibility to enrol or from enrolment itself.
  - c. Procedures for training and supervising trial site staff on creating respectful relationships with participants and fostering an environment that is nonjudgmental and welcoming.
  - d. Strategies to ensure the confidentiality of participants during trial visits, while following up participants outside of the trial clinic, and after trial exit.
  - e. Procedures for informing participants about trial results and trial product assignment, when available.
  - f. Procedures for transfer of care at the end of follow-up or trial closure, such as providing participants with referrals to HIV counselling and testing and to other supportive services.
2. Research teams provide relevant stakeholders with ongoing updates on trial accrual, follow-up, and trial exit.
  3. Research teams seek advice from relevant stakeholders on how to improve accrual, follow-up and exit processes, and messages.
  4. Research teams maintain clear written records of discussions and agreements, as well as ongoing discussions about ways to modify strategies.
  5. Trial sponsors ensure sufficient funding and research teams create a budget and allocate funds and staff time to support stakeholder engagement in the development of locally acceptable trial procedures.

### 3.15 Trial closure and results dissemination

#### 3.15.A. Definition

Trial closure occurs when all participants have exited from the trial and all trial procedures are completed. Results dissemination