

Chapter 5:
Incorporating Ethics

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In organizing the health care treatment of participants in clinical trials aimed at preventing HIV/AIDS, trial planners and staff must consider various ethical obligations. The preceding chapters touch on some of these obligations, particularly through examples, such as keeping in mind constraints created by cultural norms. Of particular note, the practices described here are closely aligned with principles of justice and fairness. They both seek to meet the needs of the participants and to minimize creating new disparities in health care access based on research participation. Wherever possible, they attempt to raise standards for the community as a whole. This chapter outlines further ethical issues and how to assess them.

Much of the ethical challenge lies around ancillary care, or care that is provided even when it is not part of the study. As noted by participants in the *2006 Georgetown University Workshop on the Ancillary-Care Obligations of Medical Researchers Working in Developing Countries*, “[w]hichever arguments supporting researchers’ ancillary-care obligations are accepted, it is clear that these obligations extend to diseases and conditions unrelated to what is under study. The implications of justice are not restricted to the target disease alone; neither are the implications of due concern for welfare, rescue, or what is effectively entrusted to researchers by consenting to participate in certain procedures.” The participants outlined four guidance points (“The Four Ps”) that should be considered in ethical discussions of ancillary care obligations: positive duty, planning, partnership, and practical provision. (See box titled “The Four Ps.”)

The Four Ps: Guidance Points on Ancillary Care Obligations

The participants in the *2006 Georgetown University Workshop on the Ancillary-Care Obligations of Medical Researchers Working in Developing Countries* identified the following points as basic to ethical guidance on ancillary-care obligations.

Positive duty: Researchers and research sponsors, especially those working in developing countries, have some positive moral obligation to provide some ancillary care to their study participants (or to see to it that their participants receive such care).

Planning: Researchers and research sponsors, especially those working in developing countries, should develop plans, both in general and for each protocol, for meeting the ancillary care obligations that may be expected to arise. They should also take account of the unpredictable nature of ancillary care needs and plan accordingly.

Partnership: These ancillary care plans should be developed in dialogue and partnership with the host community, in ways that maintain respectful interaction; avoid displacing or disrupting local health care structures; and represent the population of potential study participants, community advisory boards, and the local medical community.

Practical provisions: Where they have foreseeable ancillary care obligations, researchers and research sponsors should take definite practical steps toward meeting these obligations. This might mean hiring a physician with certain competencies as part of the local study team, setting aside a certain line item or percentage of the budget, or forming partnerships with those who can provide drugs or with development agencies that can aid in improving the local infrastructure.

Unfortunately, the qualitative nature of these factors means that no simple formula answers the question: Should the trial staff provide a specific form of ancillary care in a particular circumstance? Like many of the topics discussed in this chapter, trial leadership must weigh various factors — sometimes, on a case-by-case basis — to determine when ancillary care will or will not be provided. The qualitative nature of the decision also underscores the importance of community engagement and participation, as described in the UNAIDS/AVAC document on *Good Participatory Practices in Biomedical HIV Prevention Trials*.

The health care package for trial participants should also include discussions of potential benefits and risks. Every clinical trial carries some medical risk, and an HIV prevention trial can generate additional risks, including:

- Anxiety
- Depression
- Potential public discrimination or stigma
- Stress on the participant and possibly the family

Where possible, counseling and care should be available for participants who experience side effects. In addition, clinical trial staff should counsel participants on methods of reducing risk during and after the trial.

Given some of the potential risks — particularly public discrimination or stigma — participants should also be assured that all information and data will remain confidential. For example, in *Guidelines on Protecting the Confidentiality and Security of HIV Information: Proceedings from a Workshop*, UNAIDS writes, “Confidentiality relates to the right of individuals to protection of their data during storage, transfer, and use, in order to prevent unauthorized disclosure of that information to third parties.” Any trial plan should include a written confidentiality policy that describes how information and data will be collected, stored, transferred, and released. Typically, a confidentiality and security officer oversees such tasks, but the entire trial staff must also be aware of the procedures and know how to implement them. Otherwise, the collection of

information on testing and treatment cannot be kept secure, which could cause damage in the lives of participants.

Confidentiality needs to be explicitly considered when developing a referral plan, especially for HIV-positive research participants. In fact, participant concerns about confidentiality can be a significant barrier to effective referrals for those newly discovered to be infected.

Additional challenges emerge when prevention trials are implemented across multiple sites in multiple countries. The UNAIDS/AVAC document, *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials*, notes that local ministries of health, ethics committees, and regulatory bodies might have divergent requirements. Trial sponsors, in turn, might try to establish uniform standards for participating research sites. At one site, for instance, the sponsor's requirements might provide a minimal baseline, while at another site, the sponsor requirements might fall below the baseline required by local research governance. Negotiating such differences and arriving at solutions that are feasible and equitable will likely remain a challenge for some time to come. The Seven Steps outline a strategy for navigating these ethical challenges.