

Appendices

Appendix 1:

Abbreviations Used in this Manual

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AIDS: acquired immunodeficiency syndrome

ART: antiretroviral therapy

ARV: antiretroviral

AVAC: AIDS Vaccine Advocacy Coalition

CAB: community advisory board

GCM: Global Campaign for Microbicides

FHI: Family Health International

HIV: human immunodeficiency virus

HIVNET: HIV Network for Prevention Trials

HPTN: HIV Prevention Trials Network

HVTN: HIV Vaccine Trials Network

MRC: Medical Research Council, Durban, South Africa

MTCT: mother-to-child transmission

MU–JHU: Makerere University–Johns Hopkins University

NARI: National AIDS Research Institute, Pune, India

NIH: U.S. National Institutes of Health

PEPFAR: U.S. President's Emergency Plan for AIDS Relief

STI: sexually transmitted infection

UNAIDS: Joint United Nations Programme on HIV/AIDS

UNC: University of North Carolina

USAID: U.S. Agency for International Development

UZ-UCSF: University of Zimbabwe–University of California, San Francisco

WHO: World Health Organization

Appendix 2: Site Descriptions

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This appendix provides an overview of each of the seven sites participating in the case studies for the Partnering for Care project. For more details, see *Partnering for Care in the HIV Prevention Trials Network. Part II: Case Studies*.

Fiocruz, Rio de Janeiro, Brazil

The Brazilian government plays a fundamental role in health care through its universal health system. This includes treating HIV/AIDS in Rio de Janeiro. For example, in 2006, more than 80 percent of Brazilians who needed ART received it, according to UNAIDS. In addition, the government provides ART for free.

The Brazilian government also sponsors Rio's HPTN clinical trial site. It participated in two HPTN trials that studied serodiscordant couples, as well as many clinical studies directed by other organizations. This site consists of an on-site clinic at Fiocruz, called the Evandro Chagas Clinical Research Institute, and two off-site locations at hospitals: Nova Iguacu General Hospital (Nova Iguacu) and Servidores do Estado Hospital (Servidores). Fiocruz and Servidores lie inside Rio, and Nova Iguacu lies about an hour (by bus) outside the city. Nova Iguacu includes extremely poor areas, and this hospital's emergency room receives an average of 1,500 visits per day.

The Evandro Chagas Clinical Research Institute in Fiocruz manages this three-location site. All data and laboratory management come from Fiocruz.

**Makerere University–Johns Hopkins University (MU–JHU)
Research House, Kampala, Uganda**

Kampala is Uganda’s capital and is home to more than one million people. In 2005, according to UNAIDS, HIV infected nearly 7 percent of the adults in the country. Of those who needed ART, about 50 percent received it. ART is freely available from several sources, including government hospitals and various treatment centers with public and private support.

This HPTN site has been active for 20 years. This university-based site has participated in various clinical trials, including those for preventing mother-to-child transmission of HIV, tests of an HIV vaccine, and other research. It provides services from the study’s clinic and Mulago Hospital, which is at the same location as the HPTN site. The staff at this site spends about 30 percent of its time providing care.

This HPTN site has also participated in various treatment programs, including the MTCT Plus Program, which is funded by Columbia University. MTCT Plus provides care, treatment, and ARVs for families with an HIV-positive member.

Medical Research Council (MRC), Durban, South Africa

Durban is the second-largest city in South Africa and home to more than three million people. In 2005, nearly 20 percent of the people ages 15–49 were infected with HIV. Although government hospitals and the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) provide ART for free in South Africa, fewer than 20 percent of the people who need ART get it. In part, that low treatment rate could come from the small fee required to access the care at government hospitals and local clinics.

The MRC site in Durban started in 1969. This government-sponsored site focuses on research and has run various clinical trials, including studies of HIV prevention in women and serodiscordant couples. These studies included tests of microbicides.

The MRC also works with RK Khan Hospital, which is about 20 minutes outside of Durban. MRC and RK Khan Hospital have worked together on several clinical trials.

National AIDS Research Institute (NARI), Pune, India

Pune lies east of Mumbai (Bombay) in India's western state of Maharashtra, and was home to more than four million people in 2001. According to UNAIDS, less than 1 percent of the Indian population was HIV positive in 2005. Although the National AIDS Control Organization provides ART free of cost at governmental hospitals in six high-prevalence states, including Maharashtra, only 10 percent of the people who need ART get it.

The government-sponsored NARI study site was established in 1992, and it includes one on-site clinic and laboratory, and six off-site clinics around the city. Four of those sites are at hospitals, and one is at the National Institute of Virology. The other clinic is in Pune's red-light district.

The NARI site focuses on both care and research programs. For example, NARI has participated in several HPTN trials, primarily ones for serodiscordant couples.

**University of North Carolina Project (UNC Project),
Tidziwe Centre, Lilongwe, Malawi**

Lilongwe is Malawi's capital and is home to more than half a million people, according to the 2003 census. In 2005, the HIV prevalence for adults ages 15–49 was just over 14 percent. This country provides free health care.

In 1999, the University of North Carolina and Kamuzu Central Hospital collaborated to form the UNC Project, which is located at the Tidziwe Center. This two-story building provides 20,000 square feet — including a conference room, exam rooms, a laboratory, a lecture hall, a library with online access, and a pharmacy — on the Kamuzu Central Hospital grounds. The laboratory can run a range of tests, including HIV testing, serum and cell separation and storage, and HIV viral-load testing.

The UNC Project has run several HPTN clinical trials, including tests of microbicides to prevent HIV infection and studies of ART. This site also works on non-HPTN studies, such as the Breastfeeding Antiretroviral and Nutrition study.

University of Pennsylvania, Philadelphia, Pennsylvania, USA

According to the 2000 census, more than 1.5 million people live in Philadelphia. The HIV prevalence rate in the United States was 0.6 percent in 2005. ART is available through many sources, including hospitals and various treatment centers with public and private funding. Several programs — including the Ryan White CARE Act and the Pennsylvania Drug Assistance Program — assist HIV-positive patients with the cost of care and treatment. Patients can also seek free care at health care centers run by the city of Philadelphia.

In 1989, the HIV Prevention Research Unit at the University of Pennsylvania Center for Addiction Studies started as an HIV Network for Prevention Trials (HIVNET) site, and now it is an HPTN and HIV Vaccine Trials Network (HVTN) site. This site focuses on HIV risk related to drug use and sexual practices.

The University of Pennsylvania site has participated in several HPTN clinical trials. These include trials on populations that include women at risk for HIV, intravenous drug users and members of their sex and drug networks, and serodiscordant couples.

University of Zimbabwe–University of California, San Francisco (UZ–UCSF) Collaborative Research Programme, Harare, Zimbabwe

Harare is the capital of Zimbabwe and home to more than 1.5 million residents, nearly 3 million in the overall metropolitan area. The HIV prevalence rate in Zimbabwe was just over 20 percent in 2005. Of those who need ART, only about 7 percent receive it. Zimbabwe is not a PEPFAR country, and it receives no Global Funds.

This university-based site — a collaboration between the University of Zimbabwe and the University of California, San Francisco — focuses on research. It includes one on-site clinic and works with other off-site clinics. Given the limited access to ART in Zimbabwe, the HPTN site often tries to make referrals for treatment for participants who screen out as HIV-positive during recruiting for a trial.

The UZ–UCSF site has participated in many HPTN clinical trials. These include various study populations, including high-risk but HIV-negative participants, men who have sex with men, women at risk for HIV, serodiscordant couples, and pregnant HIV-positive women.

Appendix 3: References

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Appendix 4: Checklist — Local Obstacles and Issues

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In creating a health care system for participants in a clinical trial for HIV prevention, planners — as well as trial sponsors, funders, and others — should understand local cultural norms. To assess these norms, planners can consider the topics listed in the checklist below. In addition, this checklist encourages clinical trial planners to evaluate specific obstacles and issues, as well as seek ways to overcome or resolve such constraints.

Checklist Guidelines

Public Health Goals: For the study population or local community, list the key public health goals, how these goals could affect the clinical trial, and possible approaches to getting the most from the trial in conjunction with the local population goals.

Views on HIV/AIDS: List the most common points of view in the local population regarding HIV/AIDS (e.g., fear, discrimination, etc.), potential impacts on the trial (e.g., causing potential participants to fear association with an HIV/AIDS study) or the participants (e.g., being shunned by other community members for participating), and possible solutions to related obstacles.

Health Care Views: List the most common perspectives on health care in general among community members (e.g., Are they inclined more toward traditional remedies or modern medicine? Are they open to public health education?), how this could affect the trial (e.g., influencing local opinions about the value of a given trial), and what tools might be used to work with local health care views.

Treatment Concerns: List any treatments or forms of health care (e.g., contraception) that are unacceptable, restricted, or stigmatized locally, potential impacts (e.g., participants not practicing “safe” sex), and how trial leaders or staff might handle such obstacles.

Social Constraints: List any local economic or political issues that could affect the trial or its participants, the possible impacts (e.g., a reduction in local health care facilities), and how trial planners or sponsors could resolve these issues.

Checklist — Local Obstacles and Issues

Public Health Goals	Top Goals	Potential Impacts on the Trial	Possible Solutions
Views on HIV/AIDS	Common Viewpoints	Potential Impacts	Possible Solutions
Health Care Views	Key Perspectives	Top Impacts	Possible Solutions
Treatment Concerns	Treatments	Potential Impacts	Possible Solutions
Social Constraints	Top Constraints	Top Impacts	Possible Solutions

Appendix 5: Checklist — Public Health System Constraints

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The health care that can be provided with any clinical trial depends on a range of constraints in the surrounding system of public health. To assess challenges and opportunities related to a specific clinical trial in a particular location, consider the items listed below. In addition, fill in the blanks to provide a framework in which to develop a trial's health care system.

Checklist Guidelines

Basic Needs: List basic needs that may be lacking in the trial's area (e.g., nutrition, housing, clean water), the likely impact of these basic needs on the participants and the trial, and potential partnerships or other ways to improve these conditions.

Common Medical Needs: List the most common medical diseases or conditions in the trial area, the top likely impacts of these medical needs on the participants and the trial itself, and potential solutions to any negative impacts.

Local Medical Resources: List the available facilities (e.g., clinics, pharmacies, etc.), the impacts that these facilities could generate for trial participants or the services that trial staff might need to cover, and how to resolve any related problems.

Local Service Limitations: List the key shortcomings in local health care services (e.g., limited available testing or treatments, particularly at specific sites), how these shortcomings will affect trial participants (e.g., traveling for some health care or not receiving it), and ways to improve these situations.

Likely Treatments Needed: List the top treatments that trial participants (and family members) will probably need, how this could affect the participants or the trial (e.g., requiring extra funding), and how to provide these treatments.

Economic Constraints: Note the top economic constraints (e.g., lack of health insurance) faced by trial participants, the crucial impacts on participants (e.g., not receiving some needed care), and what efforts could improve this situation.

Political Constraints: Determine any government changes that might affect health care for trial participants (e.g., dissolution of health care programs), the potential impact on the participants, and possible solutions.

Funding Opportunities: List potential sources (e.g., nonprofit health care organizations, government bodies, PEPFAR, Global Fund, etc.) of additional funding for health care for trial participants, what funds or resources to request, and how to approach these sources.

Checklist — Public Health System Constraints

Medical Issues			
Basic Medical Need	Top Needs	Top Impacts on the Trial	Possible Solutions
Common Medical Needs	Top Diseases/ Conditions	Top Impacts	Possible Solutions
Local Medical Resources	Available Facilities	Top Impacts	Possible Solutions
Local Service Limitations	Key Shortcomings	Top Impacts	Possible Solutions
Likely Treatments Needed	Top Treatments	Top Impacts	Possible Solutions

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Checklist — Public Health System Constraints, *continued from previous page*

Socioeconomic Issues			
Economic Constraints	Top Constraints	Top Impacts	Possible Solutions
Political Constraints	Key Issues	Top Impacts	Possible Solutions
Funding Opportunities	Possible Resources	Possible Funds	Steps for Contact

Appendix 6: Checklist — Engaging the Community

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The success of any clinical trial for an HIV prevention strategy depends on a strong working relationship with the local community. This relationship can attract participants to the trial, reveal possible referral partnerships, and improve the long-term health care of trial participants and others in the community.

The steps outlined in the checklist below can help trial planners to incorporate community involvement from the start.

Checklist Guidelines

Target Population: List the eligibility criteria for the research project(s) to be implemented in the community and the numbers of men, women, and children (minors) to be enrolled.

Community Involvement Plans: List the goals of engaging the community (e.g., desired interactions), how a trial hopes to reach those goals, and the expected benefits (e.g., enrolling participants, increasing referral partnerships).

Community Involvement Funding: List items related to community involvement (e.g., developing a community advisory council), provide a budget for each item, and note the intended source of the funding.

Community Involvement Staff: Name the position — usually one person who works as a liaison between a clinical trial and the local community — and list expected duties or obligations.

Community Advisory Board (CAB): List the desired categories of members (e.g., diverse community members, local government leaders), note contacts who might put clinical trial leaders in touch with members in each category, and list the actual members of the council as they are added. For guidance on establishing community advisory mechanisms such as a CAB, see the UNAIDS/AVAC document *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials*.

Review: Note the frequencies and forms of reviews between the clinical trial leaders and the local community (e.g., monthly meetings with the community advisory board or biannual “town meetings”).

Checklist — Engaging the Community

Target Population	Eligibility Criteria		Enrollment Targets
			Men Women Children (Minors)
Community Involvement Plans	Goals	Techniques	Desired Outcome
Community Involvement Funding	Item	Funding	Source
Community Involvement Staff	Position	Obligations	
Community Advisory Board	Desired Members	Contacts for Members	Actual Members
Review	Frequency	Form	

Appendix 7: Checklist — Care and Treatment Package

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In the planning stage of a clinical trial for the prevention of HIV, leaders should develop a health care package for participants. Using this form, planners can create a checklist of treatments to provide, as well as specific details related to the treatment.

Checklist Guidelines

Treatment: List each treatment that will be provided as part of a clinical trial's health care package.

Recipients: Who will receive the treatment? Is it only for trial participants? Will it be available to others (e.g., those who screen out or family members of participants)?

Source: Who will provide this treatment? Will it come from trial staff (i.e., direct treatment) or from a referral group (i.e., indirect treatment)?

Duration: Determine how long a treatment will be provided. Will it only be available during the clinical trial? Will the treatment or care also be available for a prescribed period after the trial?

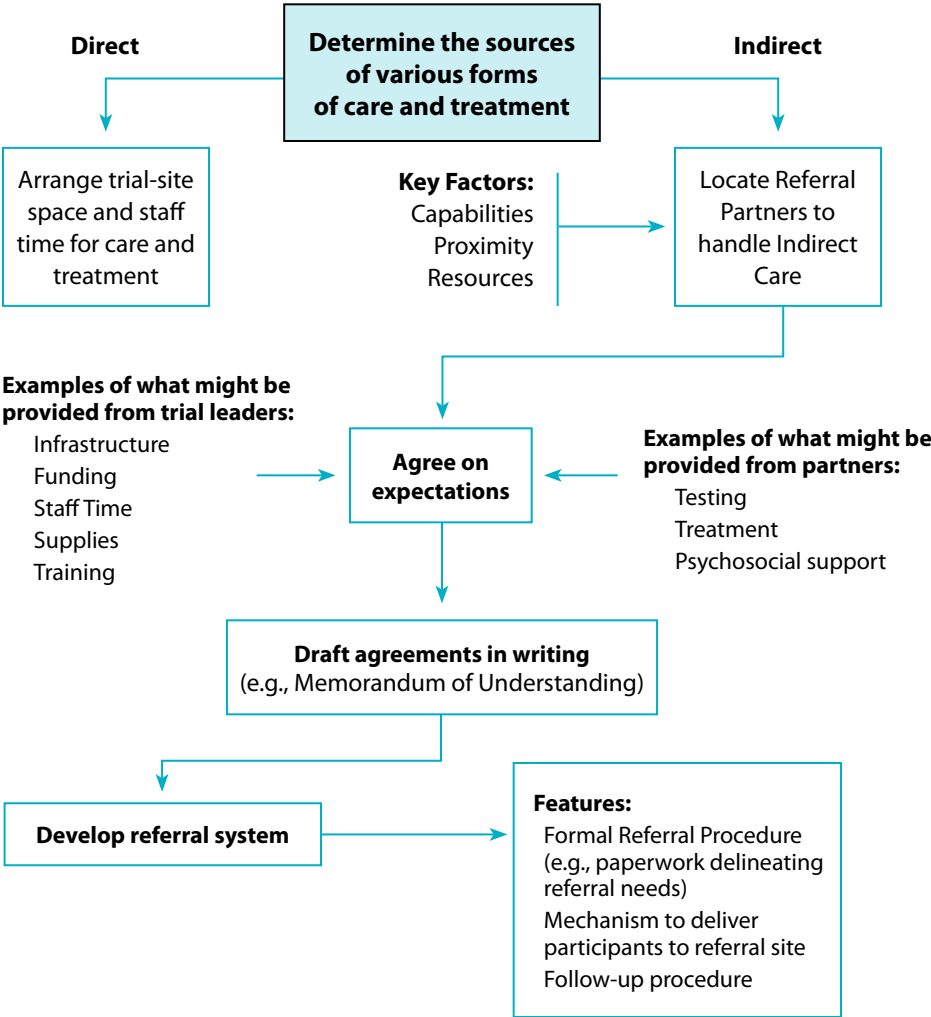
Funding: Note how the care and treatment will be funded. Will the clinical trial include a budget item for this care and treatment? Will the trial planners arrange with another group to fund this health care?

Checklist — Care and Treatment Package

Treatment	Recipients	Source	Duration	Funding

Appendix 8: Checklist — Creating a Referral System

To develop a referral system, use the following checklist for general guidance.



Appendix 9: Checklist — Resources to Implement

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The following is a list of the kinds of resources that are likely to be needed to implement the seven steps.

Step	Resource Mechanism	Who	Timeframe
1: Build a public health attitude among research leaders and staff	Formal and informal communication; trainings; incentives	Principal investigator as primary lead with active involvement of other staff	Ongoing
2: Assess the local community's values, attitudes, and priorities	Community assessment or formative research prior to trial implementation	Social scientist plus additional team members as needed	3 months (excluding any required approvals)
3: Assess the assets and constraints of the public health system	Community assessment or formative research prior to trial implementation	Public health evaluator, community health evaluator, or social scientist with community/public health experience plus additional team members as needed	4–6 weeks (excluding any required approvals)

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Checklist — Resources to Implement, *continued from previous page*

Step	Resource Mechanism	Who	Timeframe
4: Engage the community	Community advisory board or other formally constituted group plus information-sharing events (such as meetings, newsletters, or radio spots) as appropriate	Community liaison officer and principal investigator plus other staff as needed	Ongoing
5: Determine the extent of care to provide	Systematic review of protocol combined with results of previous steps	Principal investigator, clinical research staff, community advisory board with input from research governance bodies	2–4 weeks
6: Build relationships with nearby resources	Formal meetings with leadership at clinics, hospitals, service organizations, etc.; information-sharing; resource-sharing; and volunteering	Principal investigator, study coordinator, community liaison officer plus other staff as appropriate	Ongoing
7: Develop a referral system	Memoranda of agreement or understanding with referral organizations; monitoring of effectiveness	Health counselor(s), principal investigator, plus other staff as appropriate	Ongoing



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