

A Model Designed to Enhance Informed Consent: Experiences From the HIV Prevention Trials Network

Cynthia Woodsong, PhD, and Quarraisha Abdool Karim, PhD

HIV prevention research in developing countries has resulted in increased attention to and discussion of ethical issues, particularly the issue of the quality of informed consent. We present a conceptual framework for an enhanced informed consent process, drawing on experiences garnered from domestic and international studies conducted by the HIV Prevention Trials Network, funded by the National Institutes of Health.

This framework guides the development of an informed consent process designed to help ensure initial and continued comprehension of research participation, with an emphasis on HIV prevention research. Attention is focused at the individual and community levels and on 3 study phases: preenrollment, enrollment, and postenrollment. (*Am J Public Health*. 2005;95:412–419. doi:10.2105/AJPH.2004.041624)

Informed consent is the bedrock of bioethics, the tangible evidence of respect for individuals and for autonomous decisionmaking. The increasingly litigious environment in many countries in which research studies originate (especially industrialized countries) frequently has the effect of reducing “informed consent” to a participant’s signature on a form obtained before study enrollment.^{1–3} In contrast, in research conducted in international settings, concerns about cultural differences and the vulnerability of some groups of research participants stemming from gender, age, or circumstances that restrict voluntary consent have created a set of provisions in ethics guidance documents that some perceive as overprotectionist.^{3–6} The growing body of literature on the conduct and evaluation of informed consent^{7–9} serves as testimony to the efforts of individual scientists to achieve respect for individuals and autonomous decisionmaking. However, ensuring that consent is truly voluntary and fully informed remains challenging.

In addressing the challenges posed by the HIV pandemic, the US government, and the National Institutes of Health in particular, has increasingly provided infrastructure and financial and training support for the conduct of HIV research in developing settings, especially sub-Saharan Africa. This support is

justified by the magnitude of the epidemic and the disproportionate burden of infection in these countries. As multinational prevention studies increase in prevalence, a particular challenge is how best to obtain informed consent in culturally diverse settings where understandings of diseases may differ, decisionmaking may be both collective and individual, the social costs of HIV-related stigma and discrimination can be severe, and limited access to health services can undermine the voluntary nature of consent. In addition to the ethical imperative of achieving informed consent, researchers are finding that failure to do so can have negative consequences in regard to study accrual, retention, and scientific validity. This situation, in turn, has further ethical implications.¹⁰

Over the past 3 years, researchers participating in the HIV/AIDS Prevention Trials Network (HPTN) have encountered an array of ethical and scientific challenges in the process of preparing for and implementing studies. (The HPTN is a worldwide collaborative clinical trial network that develops and tests the safety and efficacy of primarily nonvaccine interventions designed to prevent the transmission of HIV.) The diverse geographic distribution of sites with a common purpose has provided a unique opportunity to achieve a better understanding of

issues and local solutions. Given the context within which this research has taken place, HPTN researchers have found it necessary to look for ways to enhance the process through which informed consent is obtained, yet meet sponsor and local regulatory requirements. The structure of the network has facilitated sharing of experiences during site preparedness activities and at site visits, workgroup meetings, and annual meetings that, in 2004, brought together more than 600 individuals working within the network. Training in the protection of research participants and in good clinical practices¹¹ has particularly facilitated the exchange of experiences involving ethical dilemmas and the variety of approaches that sites have developed to resolve them.

We present a framework for the informed consent process that has evolved at HPTN sites to ensure initial and continued comprehension of research participation. The framework focuses attention on the individual and community levels. It is grounded in the experiences of HPTN, and our discussion includes examples from the network. We also describe how the framework is currently being used to implement the informed consent process in a randomized control clinical trial of microbicides. We argue that this approach can improve both the ethical and scientific aspects of research endeavors.

ETHICAL CHALLENGES FACING NETWORK SITES

One aspect of HPTN research that has proven essential in addressing ethical challenges has been the adoption of a principled approach to working in partnership with communities, as described by Lo and Bayer.¹² This has helped facilitate the 2-way communication required to achieve mutual understanding of research endeavors. Others have presented detailed conceptualizations of

“community.”^{13–15} According to the HPTN, community is “the group of people who will participate in research, as well as those who are likely to be affected by or have an influence on the conduct of the research,”¹⁶ and thus a geographic focus provides a foundation for identifying HPTN communities.

Although there are a number of approaches to community collaboration, HPTN sites work with community advisory boards, or analogous groups, that represent interests of the community and potential participants and facilitate the collaborative process.^{16–19} Community advisory board members may be formal or informal community leaders, may represent groups in the community (e.g., women’s or youth groups), and may serve in an advisory capacity for single or multiple research studies conducted by single or multiple research entities. Community involvement has proven essential in the success of HPTN research, and we consider it a prerequisite to achieving high-quality informed consent, especially in contexts in which the cultural norms of the researchers and participants are vastly different.

For example, cultural differences in the decisionmaking process have illustrated fundamental differences in a basic premise of informed consent: respect for individuals and the assumption of autonomy. Concerns about individual autonomy have been expressed in a larger debate about the “universal validity” of the Western conceptualization of autonomy as embodied in informed consent.^{4,20–25} In many communal societies, it is traditional for community representatives to influence decisions regarding a range of activities in which community members should engage, including participation in research projects.^{14,21,26} This tradition is potentially at odds with the concept of autonomous voluntariness and may create coercion, subtle or otherwise.^{9,27}

The requirements of some of the HPTN study protocols have conflicted with cultural norms. For example, research on microbicides requires discontinuation of certain traditional sexual practices (e.g., the use of drying agents in the vagina) and introduction of a new sexual practice (e.g., condom use among married partners). In some cases, expected disruption of such cultural norms has led research-

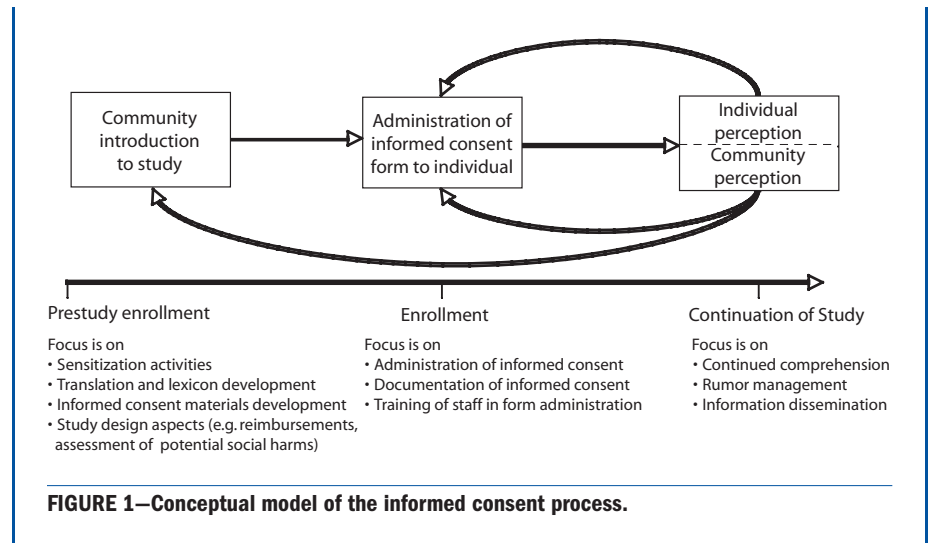


FIGURE 1—Conceptual model of the informed consent process.

ers and community members to fear that social harms might result. In addition, it has been recognized that the validity of data on self-reported behaviors will probably be compromised when study protocols require behaviors that conflict with norms.

As the array of issues has grown, it has become increasingly clear that solutions for protecting both research participants and the research endeavor itself require paying more attention to the larger informed consent process. On one hand, individual participants need to be well introduced to a study before enrollment, and the larger community within which they reside needs to be aware of and support the research endeavor. On the other hand, the study design must incorporate aspects that reflect the realities of participants’ social and cultural contexts. In such settings, the informed consent process occurs not just at enrollment but, rather, during 3 phases of the research period (preenrollment, enrollment, and postenrollment/continuation of study) and at 2 levels (individual and community), as illustrated by the framework presented in Figure 1.

PREENROLLMENT STAGE

The preenrollment phase includes activities conducted to determine how to convey research protocol concepts, recognize community concerns about HIV, and respect community norms and expectations for individual versus group decisionmaking. (There

is increasing interest in active partnering with communities to determine research priorities and design. Although HPTN studies are designed through close collaboration of principal investigators based in the United States and those in other, primarily developing countries, the structure of the network is not amenable to community-generated research designs. We refer the reader to the literature on this topic.²⁸) Researchers often seek to involve community leaders and stakeholders in informational meetings that introduce the proposed research.^{24,29} In the early stages of study implementation, HPTN researchers found that both formal and informal community leaders serve as sources of information about a study, whether or not they are officially involved. Research teams benefited from discussing upcoming plans and ideas for studies as early as possible to learn about community concerns and potential interest in supporting the studies. Community representatives and advisory board members are now encouraged to inform the research staff as to what community members think about a study before it begins enrolling participants and to engage in dialogue to resolve problems.

Involvement of community representatives in pilot activities and the review of pilot results has facilitated appropriate adjustments to aspects of study designs. This practice improves potential participants’ understanding of a study as well as the extent to which the community embraces the endeavor. Research

sponsors frequently require studies to follow a set template for informed consent forms. However, researchers are increasingly concerned that the lengthy and detailed information contained in such forms is incomprehensible to most participants.^{15,29} HPTN has sought input from community members that can be incorporated into draft consent forms and a range of supportive materials, including informational and recruitment activities. In 1 instance, when some community leaders suggested that the consent of male partners be added to the process of enrolling women in a study, research staff explained that this would not be acceptable according to international ethics guidelines. Instead, they worked to develop supportive materials that could be provided to male partners, as well as community leaders, to address concerns regarding male involvement.³⁰ Since a study's pilot activities also require informed consent, this provides an important opportunity to test different options for the form and the process for administering it.

The questions that potential research participants ask in the consent process have reflected issues that surface "on the street" in the community; staff can benefit from knowing about these issues and having answers ready. At 1 HPTN site, staff maintain a list of frequently asked questions and use them to create staff information sheets. These information sheets, in turn, are used to provide consistent responses to such questions. When some of these questions were found to be common to sites in other countries, the sheets were circulated to facilitate thinking and discussion within the larger network. Such documentation of participant perspectives has thus aided in the larger context of the informed consent process.

DEVELOPMENT OF INFORMED CONSENT MATERIALS

International ethics guidelines are not clear about the potential array of materials (e.g., "advertisements") that should be considered part of the informed consent process and reviewed by ethics committees (usually labeled "institutional review boards" in the United States). Drama scripts, songs, partner letters, fact sheets, and similar project information

materials are all part of the informed consent process, requiring careful development and review for content as well as appropriateness for target groups. We found that decisions about what materials to develop and their content benefited from collaboration with community members and research staff charged with taking the perspectives of potential participants. Piloting of these materials helped identify problems and provided suggestions for revisions.

Community outreach is facilitated by adult learning approaches to developing materials, such as illustrated booklets, videos, and drama skits, for use with illiterate populations.^{31,32} HPTN researchers work in partnership with community advisory boards and clinic staff to develop activities such as dramatic performances that convey social dimensions of problems to be addressed in a research project. The drama's content surfaces a health problem (e.g., unintended pregnancy) in an open, public setting. Following a general discussion, members of the audience are encouraged to talk to clinic staff to learn more about the associated research project. This approach has helped improve broader community recognition of the need for such research.

A number of studies have documented the difficulties involved in attempting to adequately convey basic research concepts in settings where the scientific paradigm is not widely known or accepted.^{33,34} Comprehension of the basic concept of "experiment" may be lacking, and related research concepts such as "randomization," "blinding," and "placebo" have been problematic to communicate.³⁵⁻³⁷ It can be difficult to achieve a proper balance between too much and too little information in informed consent. Certainly, the informed consent process must convey to participants the host of responsibilities and behaviors that will be expected of them during the research period, but HPTN researchers have found it challenging to not exceed an individual's absorptive capacity on any given occasion.³⁸ Furthermore, since the indigenous knowledge systems for disease and illness among some cultural groups are incongruent with the biomedical model,³⁴ explanations of study design may require more time and effort. In these situations, care

has been taken not to undermine individual and community belief systems, which serve important functions for cultural groups.

Once the format and content of informed consent materials were thought through and an appropriate approach agreed upon, translation and literacy issues needed to be addressed. As have others,^{9,24} HPTN researchers found that in all cases translation of informational materials benefited greatly from involvement of those who know the community well. This has helped ensure that translations are appropriate and at the correct level of understanding, involving salient concepts and metaphors. Some HPTN sites have benefited from developing a lexicon that includes slang and metaphors for sexually transmitted infections, reproductive health disorders, sexual practices, and types of sex partners. Lexicons reflect different uses of such terms and metaphors among community subgroups who are expected to participate in the study. For example, adolescents often use different terms for sexual activities than those used by adults, and recruitment efforts may be more successful if staff demonstrate their comfort and familiarity with these terms. Such a lexicon has proven most useful if regularly updated and consulted by research staff. Lexicons can become a tool for the larger research community working in similar settings in the country if they are well documented and made available.

Explanations of medical procedures can be difficult to convey and may require the use of supplementary materials to ensure that participants understand what they are being asked to do. For example, at 1 HPTN site, previous research pointed to participant concerns about the volume of blood taken for HIV testing (the 5 "vials" were rumored to be Coke bottles). In the microbicide part of the trial, staff who administer informed consent now show actual empty vials to prospective participants during administration of informed consent, demonstrating, with a teaspoon of water, the volume each vial holds. An informed consent booklet given to participants includes a scale drawing of a vial to further reinforce this point.

While guidelines often specify that informed consent materials should not be

written above an 8th-grade reading level, this is inappropriately high for many developing countries, and it is usually in fact exceeded.^{39,40} However, achieving lower levels of literacy in consent forms does not ensure increased comprehension,^{41,42} especially in cases in which the vocabulary (e.g., “randomization” or “placebo”) does not exist in the local language. Similarly, some ethics principles (e.g., confidentiality and voluntary) can be difficult to translate at lower literacy levels.^{37,43} Researchers who have experienced these difficulties appreciate the utility of good back-translation procedures. For example, staff at 1 HPTN site observed that the concept of voluntariness and freedom to withdraw without penalty translated, in effect, to “the researchers don’t care if you quit the study.” This prompted an additional round of revision and back-translation to help make the point more clear that continued participation was valued.

Procedures used for translation, back-translation, testing of reading levels, and revision of informed consent forms and related materials are variable, and intentions to pretest and pilot test can easily be waylaid by concerns about the lengthy approval processes of some ethics committees.⁴⁴ Such revision and review requires allowances for revision of informed consent materials in the study timeline. In the case of the HPTN microbicide trial, supportive informed consent materials were pilot tested efficiently and effectively with past research participants.

ENROLLMENT STAGE

The primary ethics focal point for many researchers is enrollment. This is the moment of truth when, ideally, an informed individual makes a reasoned decision and signs (or thumbprints) on the dotted line. As Figure 1 illustrates, the focus at the enrollment stage is primarily on an individual rather than the community. Although researchers generally consider individual consent as primary, there is also an emergent trend toward making appropriate information available to significant others (e.g., partners and family members) at the expressed request of individual participants.^{9,20,21,27} As others have observed,¹⁵ a phased approach to consent at the individual

level can allow potential participants time for further consideration and discussion with others at their discretion.

Depending on the nature of the research, there may be waiting periods between initial recruitment, screening consent, and enrollment consent. For example, if selection criteria require laboratory results, some time will pass between consent to be tested for biospecimens and enrollment in the study. In contexts in which decisionmaking is shared, this time may allow participants to discuss the study with their spouse, family members, or others in the community. In response to community requests at HPTN microbicide trial sites, materials were developed to facilitate these discussions, and staff were prepared to meet with family members if so requested by potential participants. Staff were trained to be sensitive to the possibility that family or community members could exert undue influence on an individual to join the study. For example, when staff at 1 HPTN site learned that a participant’s husband insisted she join a study against her will, staff provided several counseling sessions to help her withdraw from the study without incurring her husband’s disapproval.

In HIV prevention research, autonomy issues regarding gender and age require special care, since much of this research is conducted among women from deeply patriarchal societies.⁴⁵⁻⁴⁸ Although many women do not have agency to negotiate how and when to have sex, research protocols may require women to change their sexual activities, such as by discontinuing traditional practices for douching or use of vaginal drying agents.⁴⁹⁻⁵¹ In preparation for microbicide trials, HPTN researchers recognized the need to respect cultural norms, yet they were committed to not reinforce gender inequalities that oppress women. Research was seen as an opportunity to involve men and other community members and advise them on HIV risk reduction. At 1 site, male partners were provided with condom promotion counseling services.⁵² Research staff then had grounded information to assist them in developing a consent approach that respected participants’ desires to involve their partner or family members while also raising awareness of women’s rights to make their own decisions.

ADMINISTERING THE CONSENT FORM

The HPTN experience underscores the importance of the environment where informed consent forms are administered and documented. It is essential to have well-trained, knowledgeable staff administer a fully comprehensible consent form in a private and comfortable setting that facilitates questioning from the potential participant. Participants need time for discussions regarding components that are difficult to grasp, and they often need to be encouraged to ask questions.⁵³ Here staff benefit from familiarity with project lexicons and advice on how to respond to expected questions. As mentioned, some HPTN sites document typical questions, draft appropriate responses to them, and make this information available to their staff.

It is important to provide a private and comfortable setting within which to administer informed consent. Participants need to feel sufficiently comfortable about asking questions, not feel rushed, and be confident that others waiting outside cannot hear what is being discussed. This is especially important if enrollment is taking place at a facility where other services are being provided. The setting should allow a participant to enter and emerge without observers learning the outcome of his or her decision about participation. For example, all of the individuals who were screened for participation at 1 HPTN site were provided with a similar bag to take away from the consent room regardless of their enrollment status so that casual observers could not discern who did and did not enroll. This practice helped mitigate against the potential for social harm, a risk especially salient in HIV prevention studies wherein HIV-positive status is an exclusion criterion.⁵⁴

It is becoming common for participants to be expected to demonstrate comprehension of consent elements before enrollment.⁵⁵⁻⁵⁷ HPTN microbicide trial participants are administered a brief, quizlike interview before their enrollment. If they cannot satisfactorily demonstrate comprehension, they are asked to return another day to repeat the consent and quiz process. If they cannot demonstrate comprehension at that session, they are deter-

mined to be unable to provide consent and are not enrolled. This process strengthens participants' comprehension of the consent information and highlights areas that need additional attention in the process. For example, if initial comprehension problems are observed to cluster around a particular element of informed consent (e.g., confidentiality), staff can take care to explain this element more carefully in subsequent consent sessions with new participants.

Many researchers have adopted the practice of reading each required section of the informed consent form and then inviting questions and discussion of the section before moving on to the next, rather than reading the form in its entirety and asking the participant whether she or he has any questions at the end. Experienced research staff may effectively use a more conversational approach as opposed to a verbatim reading, but such an approach must be piloted before study enrollment and monitored throughout the study so that the consent content does not drift over the course of enrollment. Increasingly, research sponsors require staff to complete a certified course on human research participant protection. However, most currently available courses do not include practical training in administration of informed consent. To supplement ethics training already in place at some of the HPTN sites, Family Health International's Research Ethics Training Curriculum was adapted for use, and training sessions were conducted at the network's annual meetings as well as on-site.^{58,59} Also, staff responsible for conducting training in good clinical practices for HPTN sites expanded the ethics components of such training. Pharmaceutical Product Development (PPD) provides training in good clinical practices for HPTN. Pharmaceutical Product Development staff member Barbara Pennington and C.W. collaborated to incorporate the informed consent model presented in this article into the training provided to HPTN staff.

As illustrated in Figure 1, although the primary focus during the brief period of study enrollment is on the individual, this period is preceded and followed by influences from the larger contexts of family and community. If the consent process has been thoughtfully planned, these influences will, at the moment

of consent, positively reinforce an individual's decision to voluntarily join a study from a fully informed position.

POSTENROLLMENT AND CONTINUATION OF STUDY

Comprehension of informed consent should be maintained throughout the study period, especially if the research requires repeated interactions or continues for several months or years.^{60,61} Here the interplay between the individual and community levels is again of concern as participants go about their daily lives as members of a community (Figure 1). As indicated by the feedback loop in Figure 1, in the case of studies with a lengthy accrual period, the postenrollment experiences of early enrollees may influence the decisions of others who join the study. Since not all reactions to study procedures can be anticipated, if the staff and community are prepared to monitor issues that arise early in the informed consent process, adjustments can be made to improve the process for subsequent enrollees. For example, although women participating in a Population Council clinical trial were informed that pelvic examinations would be required during the study, they were shocked to learn, after consenting and presenting for their examination, that they would have to get undressed.⁶² This situation prompted the Population Council staff to engage in more explicit discussions in subsequent studies, and both discussion and illustration of this issue was included in the Population Council and HPTN microbicide trial materials.

At its best, informed consent is still a potentially bewildering process that involves presentation of information that is often difficult for individuals to grasp.^{7,47,53} In longitudinal studies, participants may not be able to remember concepts and procedures for study visits discussed at enrollment over the course of the investigation. Individuals taking part in HIV/AIDS studies may not adequately anticipate others' reactions to their participation, particularly in settings where the stigma associated with HIV/AIDS is high. Furthermore, the implications of clinical procedures (e.g., colposcopy) and expectations for behavior in some studies simply cannot be fully under-

stood until after participants undergo the first several study visits. Thus, comprehension in the HPTN microbicide trial is evaluated quarterly through the use of an interview similar to the one administered at enrollment.

A number of studies have shown that participants may not recall the risks and benefits that might accrue throughout the study duration. Particularly disturbing for HIV prevention research is the potential that participants (or their partners) may mistakenly believe that they are receiving a therapeutic intervention.^{63,64} For example, some male partners of women enrolled in early microbicide trials refused to use condoms, assuming that the product they were using was providing protection and not acknowledging that there was an equal chance that the product was a placebo.^{65,66} This example demonstrates the importance of providing reminders of study purposes and requirements so as to ensure both participant protection and study integrity.

In the postenrollment period, community-level misunderstandings can influence continued participation and undermine adherence to the study protocol. Negative rumors and misinformation may originate from study participants or members of the larger community, and, once begun, they may require community-level resolution before individuals are once again properly informed and confident in their role as research participants. In all studies, and especially in those involving extended accrual periods, HPTN staff are alerted to be sensitive to emerging misunderstandings and rumors. Community advisory boards are asked to provide advice on community reactions during the period of time after enrollment begins so that adjustments can be made as necessary to the consent process and misinformation can be corrected.

For example, at several HPTN sites, researchers have encountered persistent rumors about the use of blood samples taken from research participants. At 1 site, it was rumored that the blood was sold to Satanists and the proceeds were used to purchase project vehicles; the money received was therefore "blood money." This situation required a coordinated response from the community advisory board as well as the research staff. Since vehicles were a symbolic focus for rumors, outreach

workers stopped using them to conduct follow-up visits. Community advisory board members visited local churches and women's groups to dispel the myths. Similar rumors appeared in different communities at different times, requiring continued diligence from staff and community advisory board members to dispel them.

Research has demonstrated that participants in randomized control trials often believe they are in the arm involving an active and proven drug or device.^{63,64,67} If participants provide consent believing that participation will protect them from infection, they may withdraw from treatment or the study after realizing that other participants are becoming infected. Certainly they are free to withdraw, but withdrawal attributable to misunderstanding of the benefits of study participation requires amelioration at the study level, in addition to the level of individual participants. It also may require outreach to the community to clarify the study design and the importance of continued participation. As have other HIV prevention scientists, HPTN researchers have keenly felt the need to regularly remind participants about proven effective means of prevention, and risk reduction counseling is included in the care provided to HPTN participants.

A related issue encompasses the concept of mutual responsibility between participant and community. The consent materials that explain basic scientific concepts can be used to inform participants and the community that the success of the project depends on sufficient numbers of participants remaining in the study for its duration. For example, during the process of designing the HPTN microbicide trial, concerns were raised that women randomized to the condom-only arm might discontinue at higher rates than those in the study product arms, thus jeopardizing the scientific merit of the study. The informed consent materials thus stressed the importance of making a commitment to remain in the study regardless of randomization assignment, emphasizing that participants in the condom-only arm were just as important to the study as those using products. Women were assured of their right to withdraw but also were made aware of the value of their continued participation.

Perhaps the most widely acknowledged postenrollment aspect of informed consent is the requirement that researchers inform participants about new information learned regarding aspects of a study (e.g., study drugs or procedures) during the study itself.^{10,20} Such information potentially changes the risks and benefits of study participation, but researchers may not anticipate how new information might influence participants' willingness to remain enrolled in a study. New information can be easily conveyed to participants at subsequent study visits, but information also is needed at the community level. Again, if new information (or misinformation) becomes known through popular media, community reactions could either positively or negatively influence participants. Dialogue with community members can help determine how best to convey information to study participants. An illustrated "community fact sheet" was developed to serve 2 purposes in the HPTN microbicide trial: first, to serve as a general introduction to the trial and, second, to serve as a vehicle of communication throughout the trial as needed.

CONCLUSIONS

While the informed consent process described here is most applicable to longitudinal studies, the preenrollment and enrollment process is applicable to any study requiring informed consent. Even the most basic pretest and posttest designs benefit from monitoring of individual and community perceptions between initial enrollment and study completion. This is often accomplished with a study monitoring and evaluation component, and the activities we specify for the study continuation phase could supplement these data. Even studies involving a 1-time interaction with participants can benefit from this approach, since attention to the tasks and issues associated with preenrollment and enrollment can result in an improved consent process as well as yield better screening-enrollment ratios.

The responsibility for achieving this enhanced approach to informed consent will rest largely with investigators and community representatives. Much of what is included in our framework will potentially be reviewed

by ethics committees, and we would encourage these committees to ask for documentation of the processes described, including community engagement. We recognize that busy ethics committees usually review a host of studies at each sitting, which limits the amount of time that can be devoted to each individual study.^{15,29,45} Furthermore, the regulatory environment does not clearly specify scrutiny of the range of materials and processes that support informed consent.

A number of informed consent issues can be addressed within the framework we have described. We argue that attention to both individual and community contexts, over time, is necessary to achieve the spirit of informed consent: a reflection of respect for individuals and autonomy. Working with community members can aid in the creation of a consent form that is comprehensible to potential participants and an informed consent process that remains active throughout the study. In addition, it can contribute to a process that addresses potential issues such as undue inducement, psychological risks, lack of awareness of the Western scientific model, and differences in concepts of autonomy and rational decisionmaking. Finally, it can strengthen the research effort through recruitment and retention of participants who better understand their roles and responsibilities in the study and can thus better adhere to the study protocol. Thus, improved informed consent will benefit all who are involved in public health. ■

About the Authors

Cynthia Woodsong is with Family Health International, Research Triangle Park, NC. Quarraisha Abdool Karim is with the Centre for the AIDS Programme of Research in South Africa and the Division of Epidemiology, Mailman School of Public Health, Columbia University, New York, NY.

Requests for reprints should be sent to Cynthia Woodsong, PhD, Family Health International, PO Box 13905, Research Triangle Park, NC, 27709 (e-mail: cwoodsong@fhi.org).

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Contributors

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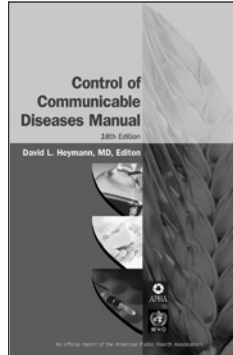
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