Strategies for Protecting Human Research Subjects Globally

Roadmap for Success in International Research: Strategies for Protecting Human Research Subjects Globally

Summary Report of Conference

Held August 2-3, 2004
in Chapel Hill, North Carolina, USA

Prepared by

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Table of Contents

Section | Page
---|---
1. Introduction | 1
2. Development of the Conference Agenda | 1
3. Report Organization | 1
4. Summary of the Plenary Sessions—Day 1 | 2
   Plenary Address—Thinking Globally: The Promises and Challenges of International Research | 2
   Panel Discussion I—Global Perspectives on Human Subject Research Protections | 3
   Panel Discussion II—Regulations and Guidelines in International Research | 4
5. Summary of the Plenary Sessions—Day 2 | 5
   Plenary Address—International Forums for Research Ethics Committees | 5
   Panel Discussion III—Cross-Cultural Concepts: Perception of Research, Consent, Tribal or Gatekeeper Permission | 6
   Panel Discussion IV—Setting Up and Maintaining Communication and Partnerships with International Institutional Review Boards (IRBs) | 7
6. Summary of the Breakout Sessions | 8
   A1—Building Knowledge about the Research Subjects and their Communities | 8
   A2—Identifying Risks and Benefits in Communities with Diverse Populations | 9
   A3—Target Community Involvement in Research | 9
   A4—Cultural Sensitivity and Cultural Competence vs. Cultural Relativism | 10
   B1—Protection of Human Subjects—Nuts and Bolts | 10
   B2—Capacity Building: Obtaining Federalwide Assurances (FWAs) and Setting Up Institutional Review Boards (IRBs) Outside of the United States | 11
   B3—Informed Consent Issues | 11
   B4—Reporting Adverse Events and Unanticipated Consequences to Subjects and Others and Handling Complaints | 12
   C1—Informed Consent Issues | 12
   C2—Subject Recruitment Abroad: Cultural Issues | 12
   C3—Biospecimens and Personal Data—Perceptions by Diverse Cultures | 13
   C4—Biomedical Research: International and Domestic Standards of Care and Providing Resources for Research Subjects | 13
   D1—Working with Vulnerable Populations in Other Cultures | 14
   D2—Lessons Learned from Unexpected Findings | 15
   D3—Behavioral and Social Science Research: What Are the Risks | 15
   D4—Protecting Research Subjects’ Confidentiality and Privacy | 16
7. Conclusions and Recommendations | 17

Appendices
A Conference Planning Committee
B Speaker Biographies
C List of Additional Resources
<table>
<thead>
<tr>
<th>Acronyms</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIDS</td>
<td>Acquired immune deficiency syndrome</td>
</tr>
<tr>
<td>ARENA</td>
<td>Applied Research Ethics National Association</td>
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<td>CAB</td>
<td>Community Advisory Board</td>
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<td>CFR</td>
<td>Code of Federal Regulations</td>
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<td>CIOMS</td>
<td>Council for International Organizations of Medical Sciences</td>
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<td>DHHS</td>
<td>Department of Health &amp; Human Services</td>
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<td>DNA</td>
<td>Deoxyribonucleic acid</td>
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<td>Data Safety and Monitoring Board</td>
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<td>European Union</td>
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<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>FHI</td>
<td>Family Health International</td>
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<td>FECCIS</td>
<td>Forum for Ethics Committees in the Confederation of Independent States</td>
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<td>FERCAP</td>
<td>Forum for Ethical Review Committees in Asia and the Western Pacific</td>
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<tr>
<td>FLACEIS</td>
<td>Foro Latinoamericano de Comités de Ética en Investigación en Salud (Latin American Forum for Ethics Committees in Health Research)</td>
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<td>FOCUS</td>
<td>Forum for Institutional Review Boards/Research Ethics Boards in Canada and the United States</td>
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<td>Federalwide Assurance</td>
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<td>Good Clinical Practice</td>
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<td>Harvard School of Public Health</td>
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<td>International Conference on Harmonization</td>
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<td>Indian Council of Medical Research</td>
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<td>Institutional Review Board</td>
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<td>PABIN</td>
<td>Pan-African Bioethics Initiative</td>
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<td>Public Responsibility in Medicine and Research</td>
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<td>SOP</td>
<td>Standard operating procedure</td>
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<td>U.S. Agency for International Development</td>
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<td>World Health Organization</td>
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1. Introduction

This report summarizes the key points, issues, and recommendations presented at the conference “Roadmap for Success in International Research: Strategies for Protecting Human Research Subjects Globally,” held in Chapel Hill, North Carolina, on August 2-3, 2004. The conference was conducted with support in part from a grant to RTI International (RTI) from the National Institutes of Health (NIH) as part of their Human Subjects Research Enhancements Program (NIH 2 S07 RR018257-02).

RTI organized this conference in collaboration with several cosponsors: Family Health International (FHI), the U.S. Department of Health & Human Services’ (DHHS) Office for Human Research Protections (OHRP), North Carolina State University (NCSU), the Department of Social Medicine at the University of North Carolina (UNC) School of Medicine, and the Applied Research Ethics National Association (ARENA).

The conference goal was to address the recognized need for training in international human subjects issues. Its aim was to provide information and tools to help researchers, regulators, and Institutional Review Board (IRB) members implement the very best procedures to protect study participants globally.

2. Development of the Conference Agenda

RTI worked closely with the cosponsors to assemble initial lists of both possible topics and speakers. Potential international speakers included researchers with whom we have collaborated on current or past international studies, contacts we have in various countries who have special expertise in the human subjects area, or advocates for research subjects in different countries. We also identified potential U.S. speakers with experience in global research or knowledge of the regulations that apply to such research. Through an intensive, iterative process of substantive discussions and follow-up, members of the conference planning committee (see Appendix A) matched the lists of topics and speakers to develop the preliminary program.

Candidate speakers were contacted to determine their availability and interest in participating in the conference. This planning process ultimately produced our final conference agenda. To ensure that the conference presentations addressed the agenda topics selected, conference organizers and session moderators worked closely with speakers to focus their presentations on their area(s) of expertise and specific points and issues anticipated to be of most interest to attendees.

The conference agenda was designed to be both useful and stimulating—a true learning experience. The speakers had noteworthy credentials and experience, both in conducting research and in developing or implementing regulations and ethical guidelines (see Appendix B). The speakers presented a broad international perspective, representing Belgium, Ghana, Guatemala, India, Malawi, Mexico, Uruguay, and the United States. Likewise, the approximately 250 conference attendees were from quite diverse backgrounds, coming from or having conducted research in countries all over the world.

The two-day conference comprised a combination of plenary sessions featuring keynote addresses and panel discussions for all attendees each morning, followed by concurrent breakout sessions each afternoon that included presentations and opportunities for more open discussions. All participants received a notebook of materials that consisted primarily of all speakers’ slides supplemented by brief faculty biographies, selected documents to promote discussion, and a list of links for resources about protection of human subjects and international research (see Appendix C).

3. Report Organization

The remaining sections of this report summarize the conference sessions. A summary of each day’s plenary address is followed by summaries of the plenary panel discussions. These are then followed by summaries of each breakout session, all drawing from speakers’ slides and our note-takers’ reports. Conference note-takers reported on key points covered at the session,
any issues of particular interest to the audience, and any controversial issues that were discussed. Finally, the conclusions briefly summarize recurring themes that arose during the conference.

### 4. Summary of the Plenary Sessions – Day 1

#### Plenary Address

**Thinking Globally: The Promises and Challenges of International Research**  
Ward Cates, Family Health International (FHI)

Dr. Cates began his address with a description of the global context in which research takes place in resource-poor countries. People in these nations face intensification of poverty, degradation of the basic health care infrastructure (especially in the countries most affected by AIDS), severely limited access to basic health care, inadequate nutrition and water, and very low annual per capita health expenditures. Some feel that resource-rich nations have a moral imperative to conduct research in these resource-poor settings. Researchers who undertake investigations in these countries must confront these challenges and develop feasible interventions to improve the lives of the study participants.

Dr. Cates discussed how Good Clinical Practices (GCPs) serve as a cornerstone of medical research quality. GCPs provide researchers with benchmarks for ensuring ethical and data integrity and standard practices for clinical trials, whether conducted in the United States or outside. GCPs address research ethics by specifying that IRB guidelines must be followed, that the informed consent process should be effective, and that assurances of confidentiality made to subjects must be genuine. These guidelines also specify that research processes need to be driven by a well-planned protocol and include specifics for adverse event reporting and drug accountability.

Dr. Cates described three essential cornerstones of research studies: accrual, adherence, and retention. All three of these have ethical components. For example, during accrual, researchers must ensure that subjects are empowered to make decisions about their participation. Adherence to the study product by the study participants is critical to estimating the true impact of an intervention. To ensure reasonable subject retention, researchers must sustain enthusiasm and interest among participants, while respecting their right to withdraw from the study at any time. Research quality depends heavily upon appropriate ethical review and approval of these processes.

Informed consent is a process that extends throughout the life of the study. It is essential to include locally used terms in consent documents so they can be understood by the participants. Beliefs about disease causality and variability in literacy levels and language can also present formidable challenges to achieving comprehensible informed consent. It is important to provide an adequate explanation of the research model for populations who may be unfamiliar with this concept. Since cross-cultural variability exists in the ways people make decisions about participating in research studies, obtaining consent from gatekeepers or community leaders as well as from the individual subject may be necessary. Researchers also need to find ways to avoid any undue inducement that might affect a subject’s decision to participate and to minimize any possible social harm that may result from the study or associating with the researchers.

Global research ethics must include the interests of whole communities as well as the interests of individuals living in the community. Community input should be obtained for protocol development, the informed consent process, and cohort recruitment and participant retention procedures. At the site level, community participation often consists of establishing an advisory process and an education plan. The involvement of a community advisory board (CAB) during all phases of a study can be very helpful. CABs serve as an important bridge between researchers and communities, and may take part in early discussions about the appropriateness of a proposed study in the local community. The CAB can also help researchers with rumor management. To provide true community involvement, researchers must provide sufficient resources to support local participation and strive to achieve adequate community involvement on protocol and study teams. Researchers should consider using a diverse range of methods to reach out to research participants, such as drama, quizzes, pictorial comics, role-playing, and focus groups.
In addition, community-specific research goals should be linked to scientific outcomes.

Finally, it is imperative that international researchers promote leadership of in-country scientists and involvement of the community in all stages of the research process. It is also essential for researchers to have a plan for translating the research results into practice in the local community health system and for building in-country infrastructure and capacity. This plan should be developed in partnership with the local researchers before research begins. Researchers need to incorporate strong ethical safeguards when working in resource-poor settings and effective training in research ethics is crucial for local investigators.

Panel Discussion I
Global Perspectives on Human Subject Research Protections
Vasantha Muthuswamy, Indian Council of Medical Research (ICMR), India
Dafna Feinholz-Klip, Latin American Forum for Ethics Committees in Health Research (Foro Latinoamericano de Comités de Ética en Investigación en Salud, FLACEIS), Mexico
Joseph Mfutso-Bengo, Malawi Bioethics Research Unit, College of Medicine, Malawi
Francis P. Crawley, European Forum for Good Clinical Practice, Belgium
Moderator: Roberto Rivera, Family Health International (FHI)

Panel members presented insights about how research ethics are viewed and practiced in their countries and globally. Although unique issues related to research in India, Latin America, Africa, and Europe were discussed, several common themes also emerged during the session. These themes were related to diversity, vulnerability, informed consent, lack of health services, building ethics capacity including the advent of regional ethics forums, regulations and guidelines, and partnerships between international researchers.

Population members within a single country can be quite diverse in terms of language, poverty, literacy, access to medical care, religion, social structure, and medical beliefs and practices. This diversity makes it difficult to design and implement studies that take this diversity into account. For example, it may not be feasible to translate a consent form into all the possible languages spoken by study subjects. In countries where the only way that some people can get medical care is to enroll in a clinical study, researchers must guard against over-emphasizing the benefit-risk ratio of a study at the expense of not fully disclosing risks. In countries where doctors are regarded as individuals of high authority, researchers must be careful that patients are empowered to make their own decisions about participating in a study being done by the doctor who also provides their treatment.

The speakers emphasized that ethical research must:

♦ Respond to the health priorities of the host country
♦ Contribute to the ongoing development of its health care capacity
♦ Promote in-country systems so that in-country researchers can make their own decisions about research priorities and provide oversight for studies in their countries.

To build capacity, it is important to involve the local community in the research process. This demonstrates respect for local researchers and also helps to ensure that the research targets the health priorities of the countries. Mutual learning and respect between international researchers will build trust and foster full partnerships between the researchers, not only in the design and conduct of a study, but also in publishing and disseminating the results. The key is to do good research while promoting public trust in research.

A lack of awareness about ethics can occur at all levels—some subjects may not understand their rights and some investigators may not understand their obligations. This underscores the need for more ethics training for investigators, sponsors, and ethics committee members. The ethical review system needs to continue to evolve and could be improved by building infrastructure in the host countries, increasing knowledge of ethical guidelines and regulations, and involving more people from more countries in international ethical debates. The emergence of regional ethics forums has been a critical first step in opening this dialogue between researchers in specific regions and around the world. Some issues currently under debate around the world revolve around confidentiality
and privacy protection, intellectual property risks, access to medicines and vaccines, involvement of children in clinical research, use of stem cells, and research with biological weapons.

Issues related to the review of international human subjects research were also discussed. Both initial review and ongoing monitoring of a study are critical to protecting its participants. However, sometimes IRBs and ethics committees focus more on the initial review of a study, and do not give enough attention to monitoring of the study for unexpected risks or for unanticipated consequences after it begins. More guidance is needed about how to facilitate the review of studies by multiple IRBs in terms of local versus remote decision-making and how jurisdiction is determined.

The recognition that informed consent is a process, rather than a one-time event, was also discussed as a crucial element in protecting research subjects. Not only must study subjects understand the information presented to them at enrollment, but they must be given information throughout the study so they can decide if they want to continue.

In summary, ethical research—in any country—must involve the community, undergo ongoing independent review, have social value for the community, be scientifically sound, offer fair benefit to the subjects, and assure truly informed consent. If the research has these attributes, then the study community will be both protected and respected. The panelists stressed that the protection of research subjects globally is a shared responsibility.

Panel Discussion II
Regulations and Guidelines in International Research
Shirley J. Hicks, DHHS Office for Human Research Protections (OHRP)
Jim Shelton, U.S. Agency for International Development (USAID)
Vasantha Muthuswamy, Indian Council of Medical Research (ICMR), India
Francis P. Crawley, European Forum for Good Clinical Practice, Belgium
Moderator: Wendy Visscher, RTI International

The session began with a summary of the U.S. federal regulations for the protection of human subjects: 45 CFR 46 for DHHS, and 21 CFR 50 and 56, for the Food and Drug Administration (FDA). 45 CFR 46 Subpart A is the guiding policy for protection of human subjects, and additional protections are given for vulnerable subjects in Subparts B-D. Subpart A is known as the “Common Rule” and it has been adopted by 17 U.S. government departments and agencies.

USAID also implements the Common Rule for research it sponsors in international settings. In general, USAID will accept the use of one “competent and cognizant” IRB for each research project, although they hold all participating institutions responsible. USAID also encourages the establishment of local IRBs. Much of USAID’s work is covered by the exemption category that is allowed for the evaluation of public benefit or service programs.

OHRP issues Federalwide Assurances (FWAs) to institutions that conduct human research funded by the U.S. government. An FWA is the institution’s commitment that they will comply with U.S. regulations or with international procedures that offer at least equivalent protections and are accepted by OHRP. Close to 1600 institutions worldwide currently hold FWAs.

ICMR established its “Ethical Guidelines for Biomedical Research on Human Subjects” in 2000. These guidelines cover general principles, such as voluntariness, informed consent, privacy and confidentiality, minimizing risk, non-exploitation, community agreement, and institutional arrangements, as well as general ethical issues. Unfortunately, research projects that violated ethical norms have taken place in India during and after release of the guidelines. In recognition of the need to obtain legal status for these guidelines, they are being drafted for legislation to be placed before the Indian Parliament.

The role of regulations and guidelines in international research is crucial for two reasons:

♦ Regulations and guidelines provide roadmaps for researchers engaged in international research. They provide general guidance about what is not permitted and what might be acceptable.

♦ Regulations and guidelines provide a focal point for the international community of researchers, health-care professionals,
governments, and advocacy groups to focus debate and appreciation of current issues in international health research.

European regulations for protecting human subjects in biomedical research have been shaped by GCP guidelines, the development of the International Conference on Harmonization (ICH) process, and the drive toward a single regulatory dossier for submitting applications for drug registration in Europe, the United States, and Japan. This included the development of the GCP component of the ICH. Since 1995, efforts have focused on developing the European Union (EU) Directive on Implementing GCP (published in April 2001) and its subsequent implementation into European national legislation.

Another important debate for Europe has centered on revisions to the Declaration of Helsinki and how these will influence both perspectives and practices in Europe. Nearly every European country is currently debating either regulations or guidelines related to human subjects protections. Europeans are examining how international research and human subjects protections will be regulated at both the national (within each European nation) and European levels, as well as how Europe will engage other countries in the discussions about international guidelines.

5. Summary of the Plenary Sessions – Day 2

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<td>International Forums for Research Ethics Committees</td>
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<tr>
<td>Dafna Feinholz-Klip, Latin American Forum for Ethics Committees in Health Research (Foro Latinoamericano de Comités de Ética en Investigación en Salud, FLACEIS), Mexico</td>
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Dr. Feinholz-Klip, Chairperson of FLACEIS, a regional ethics forum that is part of an international endeavor that includes other regional forums, presented information about the role of these forums and how they can facilitate ethical research in each individual region and around the world. She noted that the expansion of health research abroad has increased the need to focus attention on the growing disparity in health care resources and access among nations, and the lack of resources for health research. There is an absence of voices from resource-poor countries in international debates about research ethics even though much research is conducted in such countries. These voices can play a key role in setting priorities for research, the conditions for international research collaboration, and the ethical paradigms used to review research.

Recently, there has been a growing awareness of the importance of protecting human subjects in research, strengthening regional ethics dialogue and decision-making, and increasing the active participation of international groups in setting ethical review parameters. These factors, coupled with the need to be sensitive to regional realities, led to the formation of several regional ethics forums including FERCAP (Asia-Pacific), FLACEIS (Latin America), FECCIS (Russia and the Commonwealth of Independent States), PABIN (Africa), and FOCUS (North America). The shared objectives of these forums are to promote:

♦ Scientifically sound and ethically reviewed research
♦ Independent, transparent, and competent ethical review
♦ Adequate resources for infrastructure in diverse regions of the world
♦ Similar standards and procedures for enhancing respect and capacity for local decision-making.

Dr. Feinholz-Klip described the composition, objectives, and activities of FLACEIS in detail. Eighteen Latin American countries and over 100 individuals are members of this forum, which formed in 2000. This forum was begun in response to the growing need for improved infrastructure, training, and capacity for ethical review of research in the region. FLACEIS’ mission is to “foster a better understanding and implementation of health research ethics evaluation in Latin America.” This mission is accomplished through various objectives, including:

♦ Improving communication between ethics committees in the region
♦ Organizing international symposia
♦ Orienting sites to standardized procedures for ethics evaluation
♦ Making educational materials on research ethics available to members
♦ Participating in the development of an international standard for ethical review.

FLACEIS has been involved in many activities to support these objectives. For example, they have translated the World Health Organization (WHO) Operational Guidelines for Ethics Committees that Review Biomedical Research into Spanish, members have written reports and papers on topics related to human subjects protection, and the forum has organized regional workshops and offered ethics training.

Dr. Feinholz-Klip discussed challenges FLACEIS and the other regional forums face. These challenges occur at all levels of the research endeavor: government (creating political will to support research and national systems for protecting subjects), society (enhancing public awareness about ethical review and empowering potential research participants), ethics committees (building infrastructure, educating), and researchers (training, quality improvement, standard procedures, and ethical methods including informed consent).

Obtaining appropriate informed consent in some non-Westernized cultures may require a developmental phase, input from multiple sources (e.g., community leaders, prospective participants, and multidisciplinary researchers), and customized and creative methodologies (e.g., pictorial consent forms). In addition, in some cultures, permission from multiple gatekeepers will be required to conduct a study in their community. However, even if gatekeeper permission is granted, there is evidence that individual participants still view their participation as voluntary. Another interesting finding was that many participants who could not read expressed interest in being given a copy of the written consent form.

Researchers’ perceptions of fairness in the conduct of clinical trials may not match the perceptions of participants. Researchers must take into account differing cultural concepts related to benefits and risks of research. For example, some cultures may assume that participation in a research study will bring personal benefit and therefore researchers must take care to fully disclose possible risks. However, in other cultures, subjects may believe that even discussion of possible negative consequences will result in their occurrence.

The discussion identified several issues for ongoing consideration. For example, the use of simplified and customized consent processes can be applied to research in any geographic location including the United States. Concerns about translation issues, such as how to ensure that different translations of the same consent form convey the same information, and about how many translations should be done when multiple languages are spoken by participants in the same study, were also noted. Another concern centered on how to ensure that oral consent explanations are consistent with the information conveyed on a written consent form.

Unique aspects of international research studies that underscore the need for cultural sensitivity and customizing informed consent processes and research methods to fit the study population were discussed during this session. The panelists described:

♦ A pictorial consent process that was used in a study of community nutrition in rural Guatemala
♦ A method used to develop and test an informed consent process for a research-naïve population in Tibet whose language has no terms to describe some research concepts
♦ How to obtain multiple levels of permission within a community to conduct research in northern rural Ghana
♦ Results from a study that obtained information directly from HIV clinical trial participants about their perceptions of fairness of medical treatment received as trial participants.
Panel Discussion IV
Setting Up and Maintaining Communication and Partnerships with International Institutional Review Boards (IRBs)

Joseph Mfutso-Bengo, Malawi Bioethics Research Unit, College of Medicine, Malawi
David Borasky, Family Health International (FHI)
Sarah B. Putney, Harvard School of Public Health (HSPH)
Helen McGough, University of Washington

Moderator: Debra Paxton, North Carolina State University

This panel focused on issues related to forming and maintaining partnerships between U.S. and international IRBs—and lessons learned from such collaborative experiences.

The session opened with a discussion of how to obtain informed consent and IRB approval in a multicenter study in an international setting. Globalization has led to a variety of changes in cultural identity that sometimes seem contradictory: convergence of cultures, divergence of cultures, competition of cultures, and reciprocity of cultures. The problem of ethical jurisdiction is superimposed on this backdrop of globalization, and questions arise about which IRB should make the final decision, the role of arbitration, and which principles are malleable and which are not.

Informed consent is a major element of a study that must be approved by the IRB. By examining differing philosophies of informed consent, the required elements of consent in the U.S. regulations, and some dilemmas posed by obtaining consent in international settings under the auspices of U.S. (remote) and local IRBs (in-country), some overall conclusions were drawn:

♦ Local ethics committees (constituted and conducting deliberations according to appropriate international standards) should, under most circumstances, be allowed to adjudicate conflicts between remote and local committees.
♦ When committees are at an impasse, it may be helpful for them to consider whether the issue is a nonarguable, universal principle or a more relative or circumstantial principle.
♦ In general, the local committee is better suited for making a judgment about what is appropriate in a community.

Next, the panelists described three examples of partnerships between U.S. and international IRBs.

A mentoring project in which a U.S. institution partnered with two African IRBs proved to be beneficial to both partners. The African IRBs received resources to help them meet appropriate international standards and the U.S. institution realized a greater understanding of the review of foreign research. Communication between the partnering IRBs was key to the success of this effort, and multiple site visits and meetings were held between representatives of the collaborating institutions. Lessons learned included the following:

♦ African IRBs are dedicated to protecting human subjects, but despite their best efforts, they may not meet international standards.
♦ Funding for international IRBs can be very challenging.
♦ More guidance and support for international IRBs in developing nations are needed.
♦ U.S. IRBs have much to learn from their foreign counterparts.

Key factors to the success of research partnerships between a U.S. university and institutions in Africa, Asia, Europe, and Latin America were communication and mutual understanding. Communication and understanding can be enhanced by conducting site visits, knowing the local research setting, helping to build the capacity of the local IRBs, and developing good methods for handling participant concerns. Site visits can serve multiple purposes including quality monitoring, training, and mutual knowledge exchange. Findings from site visits should be shared with IRB members and the collaborating institutions. Photographs can be used to help IRB members from developed countries understand the local research settings. It was recommended that complaints from participants be handled by both the remote and local IRBs, with the local IRB handling any direct meetings or intervention in solutions.

Implementing a non-study-related adverse event reporting system can also be helpful. This type of system not only can monitor these types of events, but can also educate IRB members about the local research setting and set the stage for improving local standards of care.
Activities undertaken through a partnership between another U.S. university and institutions in Kenya were described. First, these collaborators organized a conference featuring an equal number of speakers from Kenya and the United States. Researchers, IRB members, administrators, government officials, and students attended the conference. Next, representatives from two institutions in Kenya were invited to attend the annual conference of Public Responsibility in Medicine and Research (PRIM&R) and Applied Research Ethics National Association (ARENA) in the United States and to attend a summer workshop that focused on developing ethics committee review forms and a database.

Finally, a second conference was held in Kenya with a shift in having most of the presenters being from Kenya. Future plans for the partnership include expanding the curriculum to include Responsible Conduct of Research and providing workshops on IRB infrastructure. From this experience, the following successful strategies were delineated:

- Local researchers and IRB members should be involved in curriculum development.
- The presentation of the curriculum should include some local presenters.
- Learning sessions should be interactive.
- Local examples of protocols should be used for exercises.
- The U.S. collaborators should meet face-to-face with local IRB members, researchers, and institution administrators.

The panelists noted that a variety of mechanisms exist for establishing partnerships between international IRBs. These include mentoring, oversight and monitoring, and collaborations on conferences and curriculum development. There should be face-to-face contact between partners, frequent communication, and an understanding that change may occur slowly despite the best efforts of both partners. It is clear that learning occurs in both directions. Issues to be addressed in the future include capacity building and efforts to secure funding to form these partnerships.

6. Summary of the Breakout Sessions

<table>
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<tr>
<th>Breakout Session A1</th>
<th>Building Knowledge about the Research Subjects and their Communities</th>
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<tbody>
<tr>
<td>Cynthia Woodsong, Family Health International (FHI)</td>
<td>Robert Ssengonzi, RTI International</td>
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<td>Moderator: Norman Goco, RTI International</td>
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The speakers in this session addressed formative research methods that can be used to build knowledge about research subjects and their communities. They stressed the importance of preparedness work that can help researchers recognize the uniqueness of specific study sites and develop appropriate study methods. This work should be a two-way learning process that prepares the community for the research and prepares the research to fit the community. Approaches to obtaining this information about the study community and potential study subjects can include structured and semi-structured interviews and focus groups.

Many lessons can be learned from preparedness work. For example, the idea that risk may be difficult to communicate, that disseminating study findings to community members can reduce "research fatigue," and that different approaches for documenting informed consent may be needed in some settings (e.g., some populations are reluctant to sign documents).

Preparedness should be an ongoing process. Learning about the community must occur before, during, and even after a study ends.
The speakers in this session focused on how to identify risks and benefits for participants in different study locations. They noted that these may be unique for persons from different cultures and may include issues that are not immediately evident to researchers who come from outside that culture. Risks and benefits that affect the study subject directly (e.g., physical, psychological, legal) were distinguished from those that affect the community groups to which the subjects belong. It was noted that something that is good or bad for an individual subject may or may not be good or bad for their community group.

How to best explain risks and benefits in the consent form was discussed. The use of ethnographic methods to learn about how subjects (and health care providers) view risks can be very helpful in developing culturally appropriate consent language and procedures. It is important not to overstate the possible direct benefits of the research. Subjects need to understand that they are participating in research rather than getting treatment, commonly known as therapeutic misconception. Some subjects may have little exposure to clinical research, so researchers must be careful to describe the study in terms that the subjects understand and that are not frightening to them.

IRBs need to be flexible about how risks and benefits are described to participants. All the IRBs (U.S. and local) that review a study must have an understanding of what is appropriate in the community in which the study is being conducted. One question raised by the audience was how to handle the tension that can arise between reviewing IRBs about the best way to obtain informed consent.

The concept of “fair benefits” was also discussed. It is important for researchers to consider how the individual communities can benefit from the rich scientific knowledge that is gained from their global research. A good first step in ensuring fair benefits is giving local researchers a primary role in the research planning so that local priorities can be considered when research is introduced and conducted in a community.

This session began with a review of the diverse meanings of the word “community,” such as persons with the same disease, profession, geographic location, or lifestyle. Researchers must ensure that they truly include the community of possible participants in a study’s planning and conduct.

Participation of the community in international research helps build a bridge between the community and the researchers.

Community involvement needs to start at the very beginning and continue through each stage of the research. Community involvement should include advocacy, education, and ongoing meaningful involvement by the study subjects to realize true partnerships between the participant communities and the researchers. Indeed, it was argued that community involvement is an essential component, not a luxury, for the conduct of ethical research.

CABs are often chosen to represent the interests of study participants and provide participants with a way to voice local questions and concerns. CABs can provide valuable knowledge about international research settings to investigators and can assist them in developing alternative methods to obtain truly informed consent. It is important for researchers to develop strategies to make meetings with the CABs productive and to provide ongoing formal and informal training to CAB members to address any knowledge disparities. CABs themselves can also provide communities with leadership training and organizational tools.
The speakers in this session discussed the concepts of cultural sensitivity, cultural competence, and cultural relativism. They then presented examples of how these concepts were applied in a study in Guatemala.

Cultural relativism, a method of examining cultural phenomena without prejudice, can be used as a tool to gain an understanding of cultural diversity. A related concept, cultural sensitivity, refers to the nonjudgmental awareness that there are differences and similarities among cultures. Applying knowledge about cultural groups into practice is referred to as cultural competence. For a study to be fully successful, researchers must display both cultural sensitivity and cultural competence in relation to the target population.

Cultural sensitivity and cultural competence were demonstrated in the conduct of a nutritional study in Guatemala. By challenging some ethnocentrically biased assumptions that are often held by U.S. researchers, the study methods and procedures were adapted to be culturally appropriate for the local study population. For example:

♦ A pictorial flip chart was used to obtain informed consent rather than a written form.
♦ Vocabulary was adapted to remove technical terms and explain the study concepts in lay language that could be best understood by the local population.
♦ Study questionnaires were adapted to characteristics of the local study population and were pretested and validated at each site.
♦ Surrogate variables were assessed for obtaining demographic information that the local population considered highly sensitive (e.g., asking about occupation and assets rather than about income).

◊ The potential impact that the study might have on the community milieu was considered in designing the study.

The assumption that study procedures and measures developed in one culture are generalizable to other cultures is false. Using cultural sensitivity and cultural competence to adapt study procedures and methods is an important step to ensure a viable research endeavor in an international setting.

This presentation began with a summary of the ethical principles for the protection of human subjects in research that are outlined in the Belmont Report—respect for persons, beneficence, and justice. The applicable U.S. regulations (45 CFR 46 for DHHS and 21 CFR 50 and 56 for the FDA) were then reviewed. Subpart A of 45 CFR 46 is called the “Common Rule” and is used by many U.S. funding agencies.

A researcher must either have direct contact (interaction or intervention) with a human being, or access to “private identifiable information” for the activity to qualify as research with human subjects under the regulations. IRB review is required for all research with human subjects, although some may be deemed exempt. In addition, any institution whose researchers are engaged in human subjects research must obtain an assurance of compliance with the DHHS Office for Human Research Protections (OHRP).

The regulations cover various aspects of IRB review requirements including the level of review needed for specific kinds of research activities, specifications for IRB membership, and the criteria for IRB approval. Requirements for informed consent are covered in the regulations along with conditions under which some or all of the elements of informed consent may be waived. Subparts B, C, and D of 45 CFR 46 address additional requirements for specific vulnerable populations: pregnant women, prisoners, and children.
OHRP regulations and guidance documents are available through its official website: http://ohrp.osophs.dhhs.gov.

Breakout Session B2
Capacity Building: Obtaining Federalwide Assurances (FWAs) and Setting Up Institutional Review Boards (IRBs) Outside of the United States

Dan-My T. Chu, DHHS Office for Human Research Protections (OHRP)
Sarah B. Putney, Harvard School of Public Health
Dafna Feinholz-Klip, Latin American Forum for Ethics Committees in Health Research (Foro Latinoamericano de Comités de Ética en Investigación en Salud, FLACEIS), Mexico
Moderator: Debra Paxton, North Carolina State University

In this session, the speakers addressed issues related to obtaining an FWA, registering IRBs with OHRP, and building the capacity of IRBs outside the United States. FWAs are needed when institutions are “engaged” in human subjects research, but confusion exists about what constitutes human subjects research. It was clarified that a single FWA covers an entire institution and that separate FWAs are not needed for individual research studies.

The FWA requirement does not have to be presented as simply a regulatory hoop. Instead, approaching non-U.S. researchers about applying for an FWA can be used as a touchstone to reinforce that we are all part of a common endeavor—the social contract between the researchers and participants to do good. U.S. researchers working with non-U.S. researchers should engage them as equal partners when obtaining the FWA for their site(s) by providing them with the rationale for the assurance mechanism and gaining their buy-in. This process can include personal visits, regular and ongoing communication, identifying the local IRBs that will be involved, and developing solutions as a team.

Some challenges faced by non-U.S. researchers during the FWA application process include:

- The need for an English-speaking person to be involved in the process
- The resources needed to complete the required training
- How to inform researchers, IRB members, and high-level officials about their responsibilities under the FWA.

The FWA process permits different types of arrangements between U.S. and non-U.S. researchers for the protection of human subjects in the studies they conduct jointly. This flexibility allows researchers to be sensitive to cultural differences in their study designs.

Audience discussion raised issues about monitoring compliance with the FWA. The need for more guidance about the FWA process was noted, particularly for non-English-speaking researchers.

Breakout Session B3
Informed Consent Issues

Edward E. Bartlett, DHHS Office for Human Research Protections (OHRP)
Cynthia Woodsong, Family Health International (FHI)
Paulina Tindana, Navrongo Health Research Centre, Ghana
Moderator: Diana Sparrow, RTI International

The speakers in this session reviewed U.S. and international regulations and guidelines related to informed consent, the consent process itself, and obtaining multilevel consent in some communities. The Common Rule, International Conference on Harmonization–Good Clinical Practices (ICH-GCP), and the Council for International Organizations of Medical Sciences (CIOMS) all emphasize the importance of informed consent, and address the overall process, content, and documentation of consent, but they differ in the circumstances under which a waiver is allowed. However, all the regulations and guidelines do accommodate culturally appropriate approaches for obtaining informed consent.

The concepts of informed consent as an ongoing process and an agreement between the researcher and the participant were discussed. Researchers can obtain more meaningful informed consent by using innovative tools such as booklets, community partnerships, and ongoing monitoring to ensure subjects’ comprehension of research requirements.

Successfully accomplishing all research is contingent on how well those conducting a study can support the values and practices of a
culture in the design of their study. Evidence exists that the majority of communities use some process or technique to protect their members from being exploited. Thus, those conducting research should study the mechanisms that already exist and appropriately develop and plan their process to obtain consent. It is important to learn from existing customs and incorporate them into a study design, rather than forcing a process that may not be ideal in that community.

Breakout Session B4
Reporting Adverse Events and Unanticipated Consequences to Subjects and Others and Handling Complaints
Glen Drew, DHHS Office for Human Research Protections (OHRP)
Janet Robinson, Family Health International (FHI)
Deborah McFadden, RTI International
Moderator: Evelyn Studer, RTI International

This session began with a review of the definition of “adverse events” from the FDA regulations and the definition of “unanticipated problems involving risks to subjects and others” from the DHHS regulations. Negative events that occur during a research study usually fall under one—but may qualify for both—of these definitions and the associated regulations.

Adverse events are generally limited to clinical trials with experimental drugs, devices, or biologics. Events are classified as “expected” when the nature and severity of the reaction has been previously observed and documented for the study product. “Unexpected” events include reactions that have not been previously observed, even if these might have been anticipated because of the pharmacologic properties of the investigational product. Adverse events are also classified as “serious” based upon specific criteria that demonstrate a certain level of jeopardy to the subject. Serious adverse events generally must be reported more quickly to regulatory agencies, sponsors, and IRBs than nonserious events. Finally, when reporting adverse events, investigators are asked to provide their assessment regarding the relatedness of the event to study participation.

Some institutions classify adverse social consequences that occur as a result of study participation, such as abandonment, physical violence, or economic harm as “social risk events.” Investigators must also report these occurrences to the IRB. The importance of establishing study-specific rules for defining events that need to be reported was emphasized, as well as the need for IRBs to formulate protocols for reviewing different levels of adverse events. Researchers should encourage their host-country collaborators to monitor and report adverse events. This monitoring can reveal not only the risks for subjects but deficiencies in the study protocol and any remedial training needs. The session concluded with a discussion of international case studies and how to classify and report the adverse events described for these studies.

Breakout Session C1 (Repeat of Session B3)
Informed Consent Issues
See speakers and summary for this session under Session B3.

Breakout Session C2
Subject Recruitment Abroad: Cultural Issues
Glen Drew, DHHS Office for Human Research Protections (OHRP)
Vasantha Muthuswamy, Indian Council of Medical Research (ICMR), India
Wendee M. Wechsberg, RTI International
Moderator: Norman Goco, RTI International

This panel addressed issues to consider when designing recruiting strategies for international studies, including using the flexibility afforded by the U.S. federal regulations to recruit and enroll vulnerable populations. For example, the regulations allow IRBs to waive the requirement for signed informed consent or to approve consent procedures that have been customized to fit a particular study population.

Recognizing the diversity among study participants is key to successful recruiting. Rather than assuming a blending of cultural identities in a defined geographic location, researchers should take into account the differing social structures and beliefs of cultural subgroups. Other factors that impact recruiting success include getting community buy-in, selecting study staff who can serve as cultural liaisons between the researchers and the community, and setting up recruiting sites that are accessible and welcoming to potential study participants.
The speakers in this session discussed ethical issues related to collecting biospecimens and personal data for research. Examples of how these types of private information are perceived by different cultures were given for research being done in Guatemala, China, India, Peru, Russia, and Zimbabwe.

Getting proper informed consent for the collection of biospecimens is complicated. The study participants must be told what tests will be done with their specimens, whether they will receive their test results, and whether the specimens will be shared with other researchers. If the specimens will be stored, the participants need to know this and also whether the specimens will remain linked to their names. Genetic testing of specimens introduces some uncertainty in informed consent. A person may or may not want to know the results of a yet-to-be-discovered genetic test, but there are no clear guidelines about how to obtain consent for these future, unknown tests. It was noted that although tissue and DNA repositories are very useful to researchers, these may be hard for some international study participants to understand because repositories are outside of their experience.

Study subjects in some locations have little or no experience with biospecimen collection in other parts of their lives, so they may be unsure or suspicious about it. Therefore, the researchers should take care to explain the process to the subjects very carefully, show them the collection equipment, talk to them about possible pain or risks, make sure the collection area is private, assure the confidentiality of the results (e.g., provide them in sealed envelopes), and provide the proper level of counseling and referrals. Some specific cultural beliefs surrounding biospecimen collection were discussed, including:

- Blood samples are being taken for some hidden purpose such as cloning or satanic rituals.
- It may not be appropriate or socially acceptable to take some types of samples (e.g., vaginal swabs from unmarried women or stool samples).
- People may not want to provide a sample or get results if the test is for a disease for which there is no cure.

Concerns about providing specimens may be more pronounced when the samples are transported out of the host country.

Speakers underscored the value of involving the community in studies that collect biospecimens and private information. Not only does this increase trust of the researchers and buy-in for the study, but it allows the community members to provide input about what the results of the study may mean to them. For example, finding a high rate of HIV among residents of a community could be stigmatizing for the entire community. Community perceptions about what is private also vary, and people may be reluctant to disclose this information to researchers. Strong promises of confidentiality and assurances about data destruction can increase reporting of sensitive information by study subjects.

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**Breakout Session C4**

**Biomedical Research: International and Domestic Standards of Care and Providing Resources for Research Subjects**

Joseph Mfutso-Bengo, Malawi Bioethics Research Unit, College of Medicine, Malawi
Maureen E. Power, National Institute of Allergy and Infectious Diseases (NIAID)
Francis P. Crawley, European Forum for Good Clinical Practice, Belgium

Moderator: Diana Sparrow, RTI International

The speakers in this session discussed the controversy surrounding the “standard of care” issue and whether it is ethical to offer a standard of care to research participants in developing countries that does not meet the highest level of care that is available internationally. In some circumstances, a case can be made that care that is less than the “best” standard of care is appropriate. However, there is more agreement
internationally that the highest level of care should be provided to research participants.

Beyond the level of medical care provided to participants during a study, there is also considerable debate about the level of care that should be provided to subjects who are harmed as a result of study participation. Even when it is agreed that there is an obligation to provide care to study participants, there may be questions about who is responsible for financing and delivering the care.

Opportunities for increased access or better health care can be powerful incentives for people who live in developing countries and may unduly influence their decisions about study participation. Another potential problem can occur if research activities result in health care resources becoming less available to nonstudy participants. For example, if all the nurses in a particular clinic are recruited to work on a study, they may not be available to provide routine patient care. Also, if the research screens for and identifies a disease, what is the researchers’ responsibility to provide care for that disease? These issues have been brought forward in the Declaration of Helsinki and its recent revisions, and in the Nuffield Council on Bioethics guidelines.

It was agreed that standard of care issues need to be addressed in a study protocol. It is also important to educate potential subjects on the difference between research participation and health care. Discussion must continue on the issue of appropriate level of care and fair methods of ensuring access to care for international research participants.

Breakout Session D1
Working with Vulnerable Populations in Other Cultures
Judith Brooks, DHHS Office for Human Research Protections (OHRP)
Aníbal Martínez, School of Medicine, University of the Republic, Montevideo, Uruguay
Steve Morin, University of California, San Francisco
Moderator: Margaret Park, RTI International

The speakers in this session discussed ways to involve and protect vulnerable subjects in international research studies. The Belmont Report, specifically its principle of “Respect for Persons” and the U.S. regulations (including the additional safeguards given in the three 45 CFR 46 Subparts for pregnant women, prisoners, and children) provide guidance for working with people with limited autonomy or increased vulnerability or susceptibility to risk. It was noted that the condition of vulnerability may be temporary (e.g., pregnancy) or permanent (e.g., mentally disabled). Also, in some cases, a person may have multiple levels of vulnerability (e.g., a woman who is pregnant as well as economically or educationally disadvantaged). Researchers should consider how to satisfy the three elements of fully informed consent—information, comprehension, and voluntariness—as they relate to involving vulnerable subjects in their studies.

Examples of how to protect vulnerable subjects in studies conducted in Uruguay and Zimbabwe were described. Using both oral and written explanations is a good way to increase understanding during the consent process. Some examples of difficult decisions that researchers need to make when they involve vulnerable populations in their studies include:

♦ Making a referral to food programs rather than directly providing food to malnourished subjects to avoid potential coercion
♦ Deciding to test for a disease as part of a study protocol when no treatment for the disease is available through the study
♦ Determining whether to provide smoking cessation advice to pregnant women who are participating in a survey about tobacco exposure and attitudes.

CAbs can be very helpful in suggesting ways to protect vulnerable community members and reviewing the proposed consent information from a cultural perspective. Obtaining consent from vulnerable subjects has multiple dimensions and may involve multiple groups—the community, the family, and the subject. Consent information should be presented in multiple ways (oral, written, pictorial) and the subjects’ comprehension of the information should be tested. Finally, the consent information should be provided to the subjects multiple times during the course of the study.

It is important for researchers from wealthy countries to recognize the limited resources available in a host country and to guard against exploitation of the host community. It was
pointed out that both the National Bioethics Advisory Commission (NBAC) and the Declaration of Helsinki state that the research must either benefit the host country or be responsive to the health needs of the host country.

Breakout Session D2

Lessons Learned from Unexpected Findings
David Borasky, Family Health International (FHI)
Suellen Miller, University of California, San Francisco
Francis P. Crawley, European Forum for Good Clinical Practice, Belgium
Moderator: Juesta Caddell, RTI International

The speakers in this session addressed unexpected negative consequences and challenges that were encountered while conducting research in international settings and the lessons that can be learned from these experiences. Such experiences can be classified into three basic categories: the unexpected serious adverse event, the unexpected social event, and the accusation and complaint.

Unexpected difficulties with consent procedures were revealed in a clinical trial in Tibet. The researchers conducting this study took particular care to conduct formative research with community members to guide development of a culturally relevant informed consent process for the largely illiterate study population. Results of this effort indicated that obtaining a thumbprint as a sign of consent (a common substitute for a signature with illiterate subjects) was not well advised for this study population since providing a thumbprint was associated with oppressive historical and political events in Tibet. An alternative method that would be culturally acceptable was to have a literate family member sign for the study participant with a witness present. However, GCP guidelines specify that consent must be provided by the individual either by signature or thumbprint with a witness present. The Tibetan IRB ultimately decided that the thumbprint method must be used, thus placing adherence to international regulations before efforts to respond to cultural concerns.

Other examples were presented from a large clinical trial in Africa. Although the trial included external oversight and monitoring through both a Steering Committee and a Data Safety and Monitoring Board (DSMB), several problematic issues arose:

♦ Many trial participants did not understand the concepts of randomization or placebo despite conscientious and repeated efforts to explain them.
♦ Some investigators published articles about areas related to the study (but not directly part of the trial) before the trial was finished.
♦ During the course of the trial, it became apparent that the role of the DSMB was not clearly defined and there was no specification of who had the authority to stop or unblind the trial.
♦ There were no plans for providing care for trial participants when it was decided to end the trial six months early.
♦ The sponsoring agency wanted to hold a press conference to release findings from the trial prior to informing trial participants of the findings.

Although it is impossible to anticipate all potential negative consequences of research, one important lesson learned is that the IRB should set up procedures in advance to address unexpected events (e.g., a standard operating procedure or SOP). In addition, it is incumbent upon both the researchers and the IRB to have a monitoring plan in place prior to conducting a study so that these events can be detected and addressed in a systematic and timely manner.

Breakout Session D3

Behavioral and Social Science Research: What Are the Risks?
Kathleen M. MacQueen, Family Health International (FHI)
Sarah B. Putney, Harvard School of Public Health
Wendee M. Wechsberg, RTI International
Moderator: Deborah McFadden, RTI International

This session focused on delineating the risks inherent in behavioral and social science research, as well as measures that can be taken to minimize such risks. The risk of a breach of confidentiality is a primary and widely recognized concern when conducting behavioral and social science research. While any breach of confidentiality is serious, a breach of confidentiality in highly stigmatized populations (e.g., HIV-positive study participants) can lead to
significantly increased vulnerability. Thus, confidentiality protection should be of particular concern to researchers working with those groups. The potential consequences of a breach can be grave including perceived coercion, shame or embarrassment, loss of status, and stigma and discrimination. It was noted that the stigma associated with HIV-positive status, in particular, cuts across physical, behavioral, and social domains and therefore can impact virtually every aspect of a person’s life were there to be a breach of confidentiality in a study.

Researchers must recognize that a breach of confidentiality can occur in many different ways, all of which must be anticipated and ameliorated (e.g., inadequate data security, subjects being seen with researchers, inappropriate signage at research sites, walls without soundproofing in interview rooms, and lack of discretion by other research participants).

Behavioral and social science research can also lead to emotional and psychological distress among subjects who learn negative information about their health status as a function of their study participation (e.g., first learning about HIV-positive status or a sexually transmitted disease). In addition, women in strongly patriarchal societies can be put at serious risk if their male partners take offense at their study participation or learn of negative health issues about or affecting their partner as a function of her study participation. For example, in this type of society, a male partner may punish a woman upon learning of her HIV-positive status even though he may have transmitted the infection to her.

The risks of social and behavioral research can extend beyond the research participants to the field staff. The field staff may be vulnerable while they are conducting community outreach if the research site is not secure or if they fail to follow appropriate study protocols when working with research subjects who have infectious diseases. Hiring the right field staff person for the right position is key to minimizing field staff and community risks.

Behavioral and social science researchers must anticipate and provide resources to address all these potential risks and negative consequences (e.g., provide ongoing training regarding protecting subjects’ privacy, provide crisis intervention or referral services, provide a secure and safe research site). Furthermore, these risks cannot be fully discerned from a distance. Therefore, it may be helpful for IRB representatives to make site visits, obtain input from field staff and CAB members, and to consult with host IRBs to gain a richer understanding of the risks in a local research setting as well as how those risks might feasibly be managed. Audience discussion focused in part on the difficulty of defining which types of social and behavioral harms should be reported to the IRB, as well as how to define adverse events in a social and behavioral context, rather than a biomedical context.

Breakout Session D4

Protecting Research Subjects’ Confidentiality and Privacy

Shirley J. Hicks, DHHS Office for Human Research Protections (OHRP)
Helen McGough, University of Washington
Robert Ssengonzi, RTI International
Moderator: Debra Paxton, North Carolina State University

This session provided information about privacy and confidentiality and how to protect both in diverse settings. The federal regulations (45 CFR 46) and some ethical guidelines (Belmont Report, Declaration of Helsinki, and those of CIOMS) were reviewed for references to how private information is defined, the requirements for the investigator and the IRB to maintain privacy and confidentiality, and how best to convey these safeguards to the research subject during the informed consent process.

What is considered private varies widely across cultures. These differences must be respected by the researcher and incorporated into study methods. Operational issues related to privacy during recruiting include who approaches a potential study subject, and how (in person or by telephone) or where (public place, clinic, home) the person is approached.

Examples of how privacy and confidentiality were addressed in studies in sub-Saharan Africa were discussed. In these studies, subjects answered personal questions about their sexual history, gave blood samples, and were given a health exam. It was noted that although persons other than the study subject might be involved in the consent process, these persons should not be present during the interviews with the subjects. The concept of “shared confidentiality”
was described in which the study subjects, not the researchers, inform their partners of study results that may also affect them (e.g., HIV status). Standard data security procedures were used in these studies, including the use of identification numbers, separate data files for data and identifiers, password protection for all computers used for the study, and releasing results only in aggregate form. Protecting access to photographs of the study subjects was discussed because photographs are commonly used as a way to make sure the correct person is being involved in the study (especially for studies that involve medical intervention). Another important confidentiality issue to address in the study protocol is how long to retain hard-copy questionnaires.

7. **Conclusions and Recommendations**

Several themes arose repeatedly throughout the conference sessions. These included the following general guidelines for international researchers:

- Design studies that are responsive to the health priorities of the host country.
- Involve the host community, both community members and local researchers, in all phases of the research—planning, conduct, and dissemination of results.
- Promote leadership of local researchers in the study to ensure appropriate attention to the local context and to foster the future of science in developing countries.
- Use every opportunity to incorporate methods into the research that help build infrastructure and capacity in the host country.
- Explore innovative ways to present informed consent as a process that extends from recruitment through dissemination of study results.
- Provide feedback to community members about the research findings.
- Encourage more dialogue on issues such as culturally appropriate approaches for obtaining informed consent, how to protect privacy and confidentiality, what is the appropriate standard of care for research participants, and how to explain issues related to biospecimen collection.
- Make sure the voices of international researchers are included in international debates about ethics and research to fully understand the difficult ethical issues inherent in conducting research in diverse cultures.
- Partner with international IRBs because this will most certainly be a valuable two-way learning opportunity.
- Become familiar with not only the regulations, but also the ethical guidelines for the protection of human subjects in specific countries and internationally.

Each research situation is unique, so it is impossible to be prescriptive in how to design and conduct ethically sound international research. However, the presentations and discussions at the conference revealed guidelines that we hope will prove useful to researchers who do this important work.
Appendix A: Conference Planning Committee

Wendy Visscher, PhD
Conference Chair
Director, Office of Research Protection & Ethics
RTI International

David Borasky, CIP
Associate Director, Office of International Research Ethics
Family Health International

Juesta Caddell, PhD
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Roberto Rivera, MD
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Darlene Marie Ross, BS
Education Coordinator
DHHS Office for Human Research Protections

Evelyn Studer, CIP
IRB Administrator
RTI International
Appendix B: Speaker Biographies
SPEAKER BIOGRAPHIES

Edward E. Bartlett, PhD

Ed Bartlett has 30 years experience in the healthcare field. Dr. Bartlett received his undergraduate degree in the behavioral sciences from Ohio University, his Master’s of Public Health from the University of Illinois at Chicago, and his doctorate in public health from Johns Hopkins University. He has worked as an Army medical corpsman, teacher, researcher, consultant, and IRB administrator. He was the Editor-in-Chief of Patient Education and Counseling journal for eight years. Dr. Bartlett has published over 100 scholarly articles on doctor-patient communications, informed consent, confidentiality, and other topics. In 1998, he received the Innovations in Risk Management Award from the American Hospital Association. He has traveled extensively internationally, and is fluent in Spanish. Dr. Bartlett currently serves as the International Human Research Liaison at the Office for Human Research Protections. He is responsible for supporting the development of human research protections in the international setting.

David Borasky, CIP

David Borasky Jr., CIP, is the Associate Director of the Office of International Research Ethics at Family Health International (FHI). Mr. Borasky is a Certified IRB Professional and a contributing author of Research Ethics Training Curriculum and Institutional Review Board: Management and Function (Amdur and Bankert, eds.). His responsibilities include management of the day-to-day operations of FHI’s IRB, training of FHI research staff in basic research ethics principles, and serving as liaison between the IRB and FHI staff. Mr. Borasky is also interested in capacity building for international IRBs. He has provided training and consultation to institutions and IRBs in Asia, Africa, and the Caribbean. Mr. Borasky is President of the Applied Research Ethics National Association (ARENA). He is also a member of the University of North Carolina at Chapel Hill School of Dentistry IRB and the Copernicus Group IRB in Cary, NC.

Judith Brooks, BSN, MS

Judith Brooks is a Public Health Analyst in the Division of Education and Development at the Office for Human Research Protections (OHRP), US Department of Human Services. Before joining OHRP in 2001, she served as program official for NIH-sponsored, AIDS multi-center clinical trials. Other research positions held by Ms. Brooks include Clinical Research Associate in the Department of Clinical Investigations at Walter Reed Army Medical Center, as well as membership on the Investigational Review Board at Walter Reed. She holds a bachelors degree in nursing from Fitchburg State College and a master’s degree in health services administration from Central Michigan University. Recently, Ms. Brooks was appointed Chair of the OHRP’s Public Education Initiative Committee, which is tasked with developing materials designed to increase public awareness of issues involving human subject research.

Ward Cates, MD, MPH

Ward Cates is President and CEO of the Family Health Institute of Family Health International (FHI). Before joining FHI ten years ago, Dr. Cates was at CDC for two decades, where he directed the STD/HIV Prevention efforts for half that time and headed CDC’s abortion surveillance activities for the other half. He received a combined M.D.-M.P.H. degree from Yale School of Medicine, and trained clinically in Internal Medicine at the University of Virginia Hospital, and is board certified in Preventive Medicine. He is an Adjunct Professor of Epidemiology at the University of North Carolina-Chapel Hill School of Public Health and the University of Michigan School of Public Health, and a Clinical Professor in UNC’s Departments of Medicine and Obstetrics/Gynecology. Dr. Cates is a Member of the Institute of Medicine, National Academy of Sciences, the American College of Preventive Medicine, and past President of the Society for Epidemiologic Research. He has
authored or co-authored over 400 scientific publications. He is co-editor of a major textbook on contraception and a past co-editor of *Sexually Transmitted Diseases, 2nd edition*. Dr. Cates is currently Principal Investigator for FHI’s Contraceptive Technology Research (USAID) and the HIV Prevention Trials Network (NIH) Cooperative Agreements. His keynote talk on international research ethics is derived from experience with these projects.

**Dan-My T. Chu, PhD**

Dan-My T. Chu serves as a Public Health Analyst at the Office for Human Research Protections (OHRP), US Department of Health and Human Services in Rockville, MD. She is a Lieutenant Commander in the United States Public Health Service. Before joining OHRP in 2003, Dr. Chu served as a Research Scientist Officer at the Center for Food Safety and Applied Nutrition at the U.S. Food and Drug Administration. She holds a Ph.D. in Microbiology and Immunology from the Medical College of Virginia at the Virginia Commonwealth University. Dr. Chu is a member of the OHRP Public Education Research Initiative and the OHRP Internal Education Committees.

**Francis P. Crawley**

Francis P. Crawley is the Secretary General and Ethics Officer of the European Forum for Good Clinical Practice (EFGCP) and a member of the Steering Committee for the Strategic Initiative for Developing Capacity in Ethical Review (SIDCER). He is a philosopher specialised in ethical, legal, and regulatory issues concerning biomedical research, and he teaches at several European universities. Mr. Crawley has acted as an author or expert for the leading international and European ethics guidelines, as well as for several in-country guidelines in Asia, Africa, the Americas, and Europe. He is currently Chairman of the Ethical Review Committee of the International Network for Cancer Treatment and Research (INCTR), a member of the INCTR Tissues Committee, a member of the Ethics Committee of the European Organization for Research & Treatment of Cancer (EORTC), a member of the joint EMVI-AMVTN Ethical Review Committee, a Permanent Liaison Officer to the International Bioethics Committee of UNESCO, and a Contact Officer for the Council of International Organisations of Medical Sciences. He also served for four years on the UNAIDS Ethical Review Committee. In addition, he is a member of the Working Group on Ethical Principles in Paediatrics, Confédération Européenne des Spécialistes en Pédiatrie, l’Union Européenne des Médecines Spécialistes, a member of the Steering Committee for the Global Forum for Bioethics in Research, a member of the Committee of Interested Parties of the Centre for the Management of Intellectual Property in Health Research & Development, a member of the European Science Foundation’s Education Working Group, a member of the WHO GCP Guideline Revising Group, and a member of the Steering Committee for the European Commission support project ‘The Development of European Standards on Confidentiality and Privacy in Healthcare among Vulnerable Patient Populations’, as well as the two recently completed projects: ‘Ethical Function in Hospital Ethics Committees’ & ‘Ethical Considerations in Clinical Trial Collaboration with Developing Countries’. He is also a member of several regional organizations for ethics in research in Central and Eastern Europe, Asia, Africa, and Latin America. Mr. Crawley also serves on several editorial boards for international journals. He is an Honorary Member of the Faculty of Pharmaceutical Medicine, Royal College of Physicians, United Kingdom.

**Glen Drew, MS, JD**

Glen Drew joined the Office for Human Research Protections (OHRP) in 2001, after a 30-year career in the U.S. Public Health Service Commissioned Corps. During that time, he served in assignments with the National Institute for Occupational Safety and Health of the Centers for Disease Control and Prevention, the Department of Health and Human Services Office of General Counsel, the Food and Drug Administration, the National Bioethics Advisory Commission, and OHRP. Mr. Drew has been involved directly in human subjects protection operations and policy issues since 1992, and has participated as an investigator or subject in research studies and clinical
investigations. He holds engineering degrees from Tufts University, and a law degree from Georgetown University.

**Dafna Feinholz-Klip, PhD**

Dafna Feinholz-Klip is the Chairperson of the Latin American Forum for Ethics Committees in Health Research (FLACEIS, its acronym by its name in Spanish). She serves as Academic Coordinator of the National Commission of Human Genome for the Ministry of Health in Mexico. She has previously served as the Research and Planning Director of the Women and Health Program for the Ministry of Health and as Head of Reproductive Epidemiology at the National Institute of Perinatology. In addition to academic and teaching experience at the university level, she has extensive experience in the areas of bioethics and research ethics. Dr. Feinholz-Klip has taken formal coursework on research ethics and bioethics at Harvard, and at the Joseph P. and Rose F. Kennedy Institute of Ethics, and she is currently studying to obtain a Master’s Degree in bioethics. Dr. Feinholz-Klip has served on the Ethics Committee at the National Institute of Perinatology, as well as an external member of the National Institute for Public Health Research Committee. She also serves as an external member and advisor for the constitution of the National Commission on Ethics in Research for the National System of Social Security in Mexico. In the area of international research ethics, Dr. Feinholz-Klip was an invited member for the international team gathered by the World Health Organization (WHO) to write the operational guidelines for Ethics Committees that review biomedical research that were published in 2000. Dr. Feinholz-Klip holds a Ph.D. in Research Psychology.

**Shirley J. Hicks, RN, CIP**

Shirley Hicks is the Director of the Division of Education and development in the office for Human Research Protections (OHRP). In this position, Ms. Hicks is responsible for the development and conduct of education and quality improvement activities to enhance the protections for human research subjects. Ms. Hicks came to this position after working in the Division of Education and Development for two years. Prior to joining OHRP, she worked in the field of regulatory compliance for more than eight years; the last four years were at the Division of AIDS, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH). Ms. Hicks had a more than a thirty-year nursing career that included specialization in clinical research and staff education. She received her nursing education at Union Memorial Hospital School of Nursing in Baltimore and Towson State University. Ms. Hicks is certified by the Council for Certification of IRB Professionals.

**Nancy M.P. King, JD**

Nancy M.P. King is Professor of Social Medicine at the University of North Carolina School of Medicine. She has worked extensively on issues related to informed consent in health care and research, medical decisions at the beginning and end of life, the development and use of experimental technologies, and cross-cultural questions in human subjects research. A revised edition of her book, *Making Sense of Advance Directives*, was published by Georgetown University Press in 1996. She is a co-editor, with Department of Social Medicine colleagues, of *The Social Medicine Reader* (Duke University Press 1997), and co-editor, with two UNC colleagues, of *Beyond Regulations: Ethics in Human Subjects Research* (UNC Press 1999). Her current work, including projects sponsored by the ELSI Division of the Human Genome Project, focuses on the discussion of benefit in human subjects research. Ms. King serves on UNC Hospitals’ Ethics Committee and on the UNC School of Medicine’s Committee on the Protection of the Rights of Human Subjects. She was an IRB member at RTI International from 1990-1996, and was a member of the Recombinant DNA Advisory Committee of NIH from 1998-2002. In 2002, she was elected a Fellow of the Hastings Center.
Kathleen M. MacQueen, PhD, MPH

Kate MacQueen is a Senior Scientist with the Behavioral and Social Sciences division at Family Health International (FHI). An anthropologist by training, Dr. MacQueen has been working in the area of applied research ethics and HIV prevention trials for over a decade. As a member of the HIV Prevention Trials Network Ethics Working Group, she led the development of the Network's "Ethics Guidance for Research." Both domestically and internationally, she has collaborated in preparations for HIV vaccine trials, microbicide trials and, most recently, the prophylactic use of an antiretroviral to prevent acquisition of HIV. Before coming to FHI in 2001, Dr. MacQueen spent 10 years at the CDC where she worked first as a researcher, then as a science director at the National Center for HIV, STD, and TB Prevention. She provided leadership for the Center on human subjects protections and also served as an IRB co-Chair.

Anibal Martinez, MD

Anibal Martinez is the Ethics Coordinator for the Latin American Center of Perinatology (CLAP), PAHO/WHO. Dr. Martinez has international experience in clinical research and is a graduate of the University of the Republic, Uruguay. He is an assistant researcher at the School of Medicine in Uruguay and has experience in biomedical research. While he was a post-doctoral research fellow in CLAP, he coordinated the ethical issues for different trials going on in the region and was responsible for assuring that all research conducted by CLAP is compliant with the highest ethical standards, as well as U.S., international and national regulations. He also worked together with the local IRBs during this period. He is currently a Fogarty Post Doc fellow at Wake Forest University School of Medicine, in Winston Salem, North Carolina. At Wake Forest University, he is working in the Maternal-Fetal Medicine Department doing research in ethics.

Manolo Mazariegos, MD

Manolo Mazariegos is the Director of the Madres de Maiz Project in Guatemala, one of the research studies in the NICHD-sponsored Global Network for Women’s and Children’s Health Research. In addition, he is the Head of the Metabolism and Gerontology Task Force Group at CeSSIAM in Guatemala City. Dr. Mazariegos conducts research on nutrition, metabolism and gerontology at CeSSIAM. Previously, he was Associate Professor of Biomedical Research, Institute of Visions Sciences at the University of “Francisco Marroquin”, in Guatemala City, Guatemala. Dr. Mazariegos was the recipient of a NIH Fogarty International Fellowship to study nutrition, metabolism and body composition from 1989-1992 at Columbia University St.Luke’s/Roosevelt Hospital and Brookhaven National Laboratory. He obtained his Medical Degree from University of San Carlos in Guatemala in 1983, and completed his residency in internal medicine at University Hospital General San Juan de Dios.

Deborah McFadden, MBA

Deborah McFadden is a senior research analyst at RTI International with an educational background in mathematics and business administration. She has served as project manager or project coordinator for more than 10 multisite projects during her 30 years at RTI. Her most recent projects have been international studies: the Collaborative HIV/STD Prevention Trial, sponsored by the National Institute of Mental Health, and the Global Network for Women’s and Children’s Health Research, sponsored by the National Institute of Child Health and Human Development. Together, these studies have sites in China, India, Pakistan, Russia, Tibet, Zambia, Zimbabwe, and throughout Central and South America. Ms. McFadden works with project staff to help coordinate and design the study protocols, manuals of operations, and data collection instruments, ensuring sure that IRB issues are adequately covered and that adverse events and protocol violations are documented appropriately. She also compiles project reports and participates in meetings of the Steering Committee, Data Monitoring Committee, and other project subcommittees. She has conducted site visits to monitor protocol
compliance. Additionally, Ms. McFadden has co-authored several publications on various aspects of multisite clinical, behavioral, and epidemiological studies.

Helen McGough, MA, CIP

Helen McGough has supported the human subjects review function at the University of Washington for over nineteen years. In her life before human subjects, she directed a non-profit family services agency, served as a lobbyist for children’s issues, did behavioral research in the areas of medical education and obstetrical practice, and taught social science at the university level in the U.S. and overseas. Ms. McGough has developed materials and presented them at international, national, regional, and local conferences and workshops on a variety of topics related to the involvement of humans in research. She has worked with groups of all sizes and from a wide variety of educational and cultural backgrounds. She has developed and delivered training materials for researchers, their staff, Institutional Review Board (IRB) members, and community groups on the ethical conduct of research with human subjects. She is the newsletter editor for the Applied Research Ethics National Association (ARENA), and has published in the area of human subjects protections. Ms. McGough is a member of the board of directors for Public Responsibility in Medicine and Research (PRIM&R), a non-profit organization devoted to the ethical conduct of research, and serves as a faculty member for PRIM&R’s 101 “On-The-Road” program. She is on the editorial board of the journal IRB, and is a member of the Board of Directors of the Association for the Accreditation of Human Research Protection Programs.

Joseph Mfutso-Bengo, PhD, MA

Joseph Mfutso-Bengo has been the Professor of Bioethics and Head of Department of Community Health at the College of Medicine, University of Malawi since 2003. He is also the director and founder of the Malawi Bioethics Research Unit, which is currently being funded by Wellcome Trust UK. In 2001, Dr. Mfutso-Bengo was appointed as executive secretary of the College of Medicine Research and Ethics Committee. In the same year, he became a member of the National Health Science Research Committee. Internationally, Dr. Mfutso-Bengo is a visiting scholar of Johns Hopkins Fogarty Bioethics Center and is a member of UNESCO International Scientific Committee. In January 2002, he was appointed as visiting bio-ethicist in the NIAID International Center for Tropical Disease and Research Network-Data Safety Monitoring Board, based in Washington, DC. He has also served as an external reviewer for the U.S. Institute of Medicine. His present interests are bioethical teaching, research and bio-ethics consultancy. His main area of specialisation is in Applied Ethics: with special interests in international research ethics, data safety and ethical monitoring, and IRB administration. He has published widely on research ethics and bioethics in the local and international journals. Dr. Mfutso-Bengo completed his studies in Austria and Germany, where he spent more than 11 years. He holds an MA from the University of Innsbruck Austria and a PhD specialising in practical ethics from University of Regensburg in Germany. Apart from English and his mother language Chichewa, he is fluent in German and Italian. His studies, research and international working experience has been in Malawi, Uganda, Ghana, Italy, Austria, Scotland, Germany, US, and Israel.

Suellen Miller, CNM, PhD

Suellen Miller has been active in international reproductive health projects for over 20 years. Currently she is the Director of Safe Motherhood Programs at the Women’s Global Health Imperative, University of California, San Francisco, Department of Obstetrics, Gynecology and Reproductive Sciences, with a joint appointment at the University of California, Berkeley, School of Public Health, Maternal and Child Health Program, where she teaches International Maternal and Child Health. Dr. Miller’s research includes a randomized control trial of an 800-year-old Tibetan Traditional Medicine, Zhi Byed 11, vs. misoprostol for the prophylaxis of postpartum hemorrhage in Tibet and a study of the efficacy of the Non-pneumatic Anti-Shock Garment (NASG) for the management of severe hypovolemic shock secondary to obstetric hemorrhage in Nigeria, Mexico and Egypt. She
is also a consultant to the USAID-funded *Proyecto CONECTA*, in a project designed to decrease maternal mortality among hospitalized patients in the Dominican Republic. Dr. Miller is a member of a World Health Organization consultative team working with the Population Council or a series of policy briefings and papers on the relationship of early marriage and childbearing to poor maternal and neonatal health outcomes. She has authored multiple books and papers across the reproductive health field, including the revised edition of the Hesperian Foundation, *A Book for Midwives*, “Where is the E in MCH?” an article examining the lack of evidence-based foundation for safe motherhood interventions, and recently published articles on vesico-vaginal fistula prevention and treatment and technologies for the prevention and management of postpartum hemorrhage in low resource settings.

**Steve Morin, PhD**

Steve Morin is an Associate Professor of Medicine and Director of the AIDS Policy Research Center within the University of California, San Francisco (UCSF) AIDS Research Institute. For more than ten years, Steve served a principal legislative assistant to Representative Nancy Pelosi and for five years served as associate staff to the House Appropriations Committee. From 1992 to 1997, he worked for Labor-HHS-Education Appropriations Subcommittee. During this time, he has played a part in shaping federal AIDS policy. Prior to 1987, he was an Assistant Professor of Medicine at UCSF and was one of the original scientists to initiate behavioral research on HIV prevention, which ultimately led to the Centers for AIDS Prevention Studies (CAPS). In his current position, he develops ways for UCSF to help inform national and international AIDS policies. He is currently working on mechanisms to improve HIV counseling and testing programs, expand access to HIV pharmaceuticals, and set priorities for international HIV prevention research. Dr. Morin is also working with the NIMH as an international research ethics consultant and on a multi-site study on training popular opinion leaders in other countries about reducing HIV incidence. He is also co-chair of the HIV Prevention Trials Network (HPTN) protocol development committee for a community-based VCT trial. He is also principal investigator of an HPTN-funded research project on assessing and making recommendations for enhancing community participation in national and international HIV prevention research.

**Vasantha Muthuswamy, MD**

Vasantha Muthuswamy is Senior Deputy Director General and Chief of Basic Medical Sciences at the Indian Council of Medical Research, New Delhi, and is a trained Obstetrician and Gynaecologist. As a Talent Search Scholar of the Council, she started her career in research in the area of Maternal and Child health and contraception and has been with the Council for over 25 years. She is currently Chief of the Basic Medical Sciences and is involved in funding projects in all areas of Basic research with main emphasis of Pharmacology and Drug Development, Genetics and Genomics, Molecular Biology, Biochemistry, Haematology, Immunology, Traditional Medicine, etc. She was a visiting fellow at the Kennedy Institute of Ethics, George Town University, Washington DC. She is responsible for bringing out the revised ICMR Ethical Guidelines for Biomedical Research on Human Subjects. Dr. Muthuswamy is Member Secretary of the Central Ethics Committee at the ICMR, and she is a member of ethics committees of various national and international organizations including UNAIDS, European Commission, HPTN of FHI etc. She is the Founder Secretary General of the Forum for Ethics Review Committees in Asia Pacific Region (FERCAP) since January 2000 and has conducted Ethics Workshop in more than 15 countries in the Asia Pacific region. She is closely associated with development of various ethical guidelines, both national and international. She has lectured extensively within and outside the country and has contributed chapters on Biomedical ethics in a number of publications. She is also intimately involved in the area of Ethics of Animal Experimentation.
Maureen E. Power, RN, MPH

Maureen Power has been at the National Institute of Allergy and Infectious Diseases, NIH, since 1990. She has worked with funded investigators performing clinical research in HIV/AIDS, TB, malaria and other HIV-associated and tropical infections. She has worked with a number of NIAID-sponsored Networks and Program including the Adult AIDS Clinical Trials Group, the Community Program for Clinical Research on AIDS, International Centers for Tropical Disease Research and the International Collaborations in Infectious Disease Research. Ms. Power’s particular interests include developing clinical research capacity within institutions both in the U.S. and abroad, including planning for and training new personnel, and developing systems for the orderly conduct of clinical research. She has developed and participated in number of workshops for clinicians, investigators, clinical research staff, and IRB members in South America and Africa. Prior to joining NIAID, she was a clinical research nurse and Head Nurse at the NIH Clinical Center. Ms. Power has an MPH from the Johns Hopkins University School of Hygiene and Public Heath and a BA from Simmons College.

Sarah B. Putney, JD

Sarah Putney, JD, is the Director of the Human Subjects Administration for the Harvard School of Public Health (HSPH), which runs the institutional review board (IRB). She has led the IRB staff and membership in various outreach initiatives for capacity-building in international collaborative research, including site visits, training, consent monitoring, and rapport-building with public health researchers, in-country IRB members and community advisory groups. Since 2001, the HSPH IRB has been involved in site visits and training in Bangladesh, Botswana, China, Kuwait, Nigeria, and Tanzania.

Roberto Rivera, MD

Roberto Rivera has over 35 years of international experience in health research and education. He is a graduate from the National University of Mexico, and was a post-doctoral research fellow in leading University-based centers in the US. He was founder and Director of the Scientific Research Institute of Juarez University in Durango, Mexico. Under his leadership the institute became one of leading centers in reproductive health research and education in the developing countries. He has lectured and published extensively in the area of reproductive health. Dr. Rivera joined Family Health International (FHI), Research Triangle Park, NC, in 1987 as Director of the Division of Clinical Trials. In 1992, he was designated FHI Corporate Director for International Medical Affairs, where he forged new relationships with population and reproductive health organizations worldwide. In 1999, Dr. Rivera became the Director of the Office of International Research Ethics, where he is responsible for assuring that all research conducted by FHI is compliant with the highest ethical standards and US, international and national regulations. He has been a member since its establishment of the Regional Advisory Panel for the Americas of the Special Program of Research in Human Reproduction of the WHO. Dr. Rivera is currently a member of the Board of Directors of the Latin American Forum for Ethics Committees in Health Research.

Janet E. Robinson, FIBS

Janet E. Robinson, FIBS, is director of Regulatory Affairs and Quality Assurance at Family Health International (FHI). She has over 15 years experience implementing, directing, monitoring, auditing, interpreting, and reporting data from large, multi-center clinical trials in the United States and Europe. She has a thorough knowledge of regulatory, ethical, and legal requirements, including GCP, GMP, GLP, 21 CFR Part 11, and HIPAA. At FHI, she conducts all liaison activities with the U.S. FDA and international regulatory agencies in support of applications for the conduct of clinical trials; leads pre-IND/IDE activities; directs quality assurance audits within FHI and of outside vendors; manages the acquisition, storage, and distribution of drugs and devices for clinical trials in compliance with applicable regulations; and assures the integrity and completeness of all documents submitted to regulatory agencies. From 1989 to 2002, Ms. Robinson held several positions with
Unipath Diagnostics Inc., including director of clinical and medical affairs. She was responsible for all clinical trials of Unipath’s products in the United States, covering Phase II, Phase III, and Phase IV trials.

**Jim Shelton, MD, MPH**

Jim Shelton received his M.P.H. with a major in Population Dynamics from Johns Hopkins University in 1972 and an M.D. in 1973 also from Johns Hopkins. In 1974, he joined the Epidemic Intelligence Service (EIS) at the Centers for Disease Control (CDC) where he gained additional training in family planning and reproductive epidemiology. He also completed a residency in Preventive Medicine at CDC and is Board Certified in Preventive Medicine. Dr. Shelton came to the Office of Population at USAID in 1977 and has served as Chief of its Research Division and Acting Deputy Director of the Office off and on for several years. Since 1994, he has been the Senior Medical Scientist in the Office and engages in a wide variety of technical, programmatic, and management issues. He has served as USAID’s point person for Human Subjects Research for more than 25 years. One of his main passions is the Maximizing Access and Quality (MAQ) initiative – a collaborative initiative between USAID and its Cooperating Agencies (C As) designed to improve family planning/reproductive health service delivery throughout the developing world. He also authors “Contraceptive Pearls”, a periodic e-mail to colleagues around the world on topic contraceptive issues.

**Robert Ssengonzi, PhD**

Robert Ssengonzi is a demographer, sociologist, and research health specialist who is knowledgeable about a broad array of demographic, family planning, HIV/AIDS, and other health issues. Dr. Ssengonzi is skilled in health policy analysis and design, advocacy, NGO capacity building, training, monitoring and evaluation, the use of both quantitative and qualitative research and analytical techniques, and population, reproductive health and HIV/AIDS projections. He has provided technical assistance and training to professionals in developing countries on various aspects of HIV/AIDS, population, family planning and reproductive health. He is experienced in working with people from various professional and social backgrounds ranging from public sector officials to health services professionals, religious and traditional leaders, community-based organizations, private sector organizations, and the general populace. Dr. Ssengonzi has also studied the factors associated with transmission patterns of HIV/AIDS, the impact of the HIV/AIDS epidemic on various population groups including the elderly, and the determinants of infant and child mortality in developing countries. He has extensive field experience working on the implementation of research on sensitive aspects of HIV/AIDS and contraceptive use, including field trials, HIV testing, counseling, care and treatment, partner notification, mapping of sexual networks and partnership attributes, community mobilizations and financial and program management for intervention studies. He holds a Ph.D. in demography and sociology from Pennsylvania State University and is a certified public accountant with strong financial and management skills.

**Lisa C. Strader, MPH**

Lisa C. Strader is a Research Epidemiologist at RTI International with over twelve years’ combined experience in public health research and biotechnology. In addition, she has extensive project management expertise and experience in managing large data networks. At RTI, Ms. Strader is a co-investigator and manages project activities for a large, international, multi-site HIV/STD prevention research study: the NIMH Collaborative HIV/STD Prevention Trial. This trial seeks to reduce risk behaviors using an innovative behavioral approach based on the theory of diffusion of innovations. In this capacity, Ms. Strader participates in the design and development of study protocols, manuals of operation, and data collection instruments for the five international sites – China, India, Peru, Russia, and Zimbabwe. She provides technical assistance to the study sites, monitors study progress, and oversees several sub-tasks within the study. In addition, she assists with development of training materials, leads “train the trainer” sessions, and conducts site visits to assess needs and monitor protocol compliance. Ms. Strader also provides RTI-internal leadership and collaboration to strengthen
and expand individual and institutional capacity in global health and to promote best health practices worldwide. In her previous position with a major biotechnology firm, she spent several years on a gene discovery project that targeted novel human sequences in search of protein therapeutics. In this capacity, Ms. Strader managed an Internet database of human sequences accessed by corporate clients around the world as they developed and tested new pharmaceutical products.

Paulina Onvomaha Tindana, BA

Paulina Onvomaha Tindana is a research administrator of the Navrongo Health Research Centre, a field site of the Ghana Health Service. She received her Bachelors of Arts (honours) degree from the University of Ghana in 2000 and worked at the Navrongo Health research Centre as a research assistant. She is currently an International MHSc student at the Joint Centre for Bioethics at the University of Toronto. She was instrumental in the establishment of an Institutional Review Board for her institution and subsequently became the IRB Administrator. In 2002, she was awarded a one-year fellowship in International Research Ethics at the Johns Hopkins University Bioethics Institute and conducted an explorative research on informed consent in Ghana as part of her fellowship. Ms. Tindana has been actively involved in offering training programs on research ethics to researchers and IRB members in Africa. She is an active member of the Pan African Bioethics Initiative and the Vice Chair of the Ghana Bioethics Initiative. Her areas of interest are international health, research ethics and informed consent issues.

Wendee M. Wechsberg, PhD

Wendee M. Wechsberg is Program Director of the Substance Abuse Treatment Evaluations and Interventions Research Program in the Center for Interdisciplinary Substance Abuse Research at RTI International. She has more than 20 years of clinical experience and has directed outpatient drug-free, methadone, and residential substance abuse treatment programs. She was a National Institute on Drug Abuse (NIDA) clinical trainer in the early 1980s. Since receiving a doctorate in community psychology, Dr. Wechsberg has devoted her career to applied research to develop and test the efficacy of interventions among different populations of substance abusers, using both quantitative and qualitative methods. She has served as principal investigator/project director on previous studies with the Centers for Disease Control and Prevention (CDC), and the Robert Wood Johnson Foundation, and NIDA. Dr. Wechsberg is currently principal investigator/project director on the Woman-Focused HIV Prevention Intervention, the Pretoria Women’s HIV Prevention Study, and the Pretreatment intervention, all large randomized field experiments funded by NIDA and National Institute on Alcohol Abuse and Alcoholism (NIAAA). She also has received a minority training supplement for teaching graduate students how to conduct community-based studies and has trained several minority investigators. She has been a regular member of NIDA’s Initial Review Committee for AIDS and Behavioral Sciences and has reviewed for other NIDA, NIAAA and National Institutes of Health (NIH) Committees. Dr. Wechsberg also is a consultant for various national studies and is on the Scientific Advisory Board for the Comprehensive International Research on AIDS (CIPRA) in Johannesburg and Cape Town, South Africa. She has published in the areas of gender and ethnicity, outreach, HIV risk, and women substance abusers. Dr. Wechsberg has an extensive network of health and community providers and key personnel at the governmental level. She utilizes a community advisory board in the US and in South Africa to establish networks and linkages, in addition to obtaining feedback and to keep community stakeholders involved and informed.

Wayne L. Wilson, MPH

Wayne L. Wilson is presently the Senior Advisor for Site Identification and Development at Family Health International (FHI). Prior to this position, he was Community Program Manager for FHI's HIV Prevention Trial Network where he worked to develop, oversee and coordinate the HPTN community involvement program to support partnerships with the communities where HIV prevention research was being conducted. This included
assisting in the development and maintenance of international Community Advisory Boards (CABs) and other advisory mechanisms to ensure participant populations were included in research decision-making. Prior employment included being Project Manager for Phase III and IV clinical trials at PPD International, Community Planning Program Manager at the North Carolina HIV Prevention and Care Branch, and Supervisor at the US CDC National STD Hotline. Mr. Wilson holds a master's degree in public health from the University of North Carolina at Chapel Hill with a focus on Health Behavior and Health Education. He has co-authored a soon-to-be published ethics curriculum specifically for community representatives entitled, Research Ethics Curriculum Training for Community Representatives" (in press) that is based on FHI's research ethics curriculum. He has done additional community work through volunteering with a local gay, lesbian, bisexual and transgender (LGBT) community-based organization conducting training of health care providers on cultural competence for LGBT clients.

Cynthia Woodsong, PhD

Cynthia Woodsong is a medical anthropologist with over 20 years of field experience in the areas of health, population policy, health care delivery systems, and international development. Currently, her work is focused on the development of topical microbicides for prevention of HIV. This work includes social and behavioral science research conducted in conjunction with microbicides clinical trials, preparedness studies for upcoming trials, and development of the informed consent process for microbicides research. Dr. Woodsong has designed and executed projects used in the development and evaluation of HIV/AIDS, reproductive health and family planning programs for populations in sub-Saharan Africa, Latin America and the Caribbean, Asia, Eastern Europe and the United States. Her project experience and interests have included HIV/AIDS prevention, research ethics, post-abortion care, dual protection for pregnancy and HIV/AIDS prevention, and the integration of traditional and modern approaches to health care. She has worked among community groups in East and Southern Africa to facilitate the conduct of and access to research to inform HIV/AIDS and reproductive health policy advocacy efforts. Additionally, Dr. Woodsong has served on several multisite behavioral studies investigating ways to best serve those with HIV/AIDS and prevent future infections. In addition to her research endeavors, she conducts training in qualitative research methods, research ethics, advocacy for HIV/AIDS and reproductive health policy, and evaluation methodologies, as well as integration of qualitative and quantitative research design.
### Appendix C: List of Additional Resources

#### List of Links for Resources about Protection of Human Subjects/International Research

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<th>Title</th>
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<tr>
<td>International Ethical Guidelines for Biomedical Research</td>
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<td>Involving Human Subjects</td>
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<tr>
<td>Declaration of Helsinki, World Medical Association</td>
<td><a href="http://www.wma.net/e/ethicsunit/helsinki.htm">http://www.wma.net/e/ethicsunit/helsinki.htm</a></td>
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<td>That Review Biomedical Research (available in seven languages)</td>
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<td>Practices</td>
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<td>the Harvard School of Public Health</td>
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