Appendixes

Appendix A: Participant List
Appendix B: Consultation Agenda
Appendix C: Selected Readings on Ethical Issues in Microbicide Development
Appendix A

PARTICIPANT LIST

International Consultation on Ethical Issues in the Clinical Testing of Microbicides

Council on Foundations
October 23–24, 2003

Amy Allina
National Women’s Health Network
514 Tenth Street, NW 4th floor
Washington, DC 20004
(tel) 202 347 1140
(email) aallina@womenshealthnetwork.org

Emily Bass
IAVI
110 Williams Street, 27th Fl
New York, NY 10038
(tel) 212 847 1051
(email) ebass@iavi.org

Eduard J. Beck
McGill University, Purvis Hall
1020 Pine Avenue West
H3A 1A2, Montreal, Canada.
(tel) + 1 514 398 6271
(email) eduard.beck@mcgill.ca

Rafia Bhore
Center for Drug Evaluation & Research
FDA
9201 Corporate Boulevard, HFD-725
Rockville, MD 20850
(tel) 301 827 2373
(e-mail) bhorer@cdcer.fda.gov

Debra Birnkrant
Center for Drug Evaluation & Research
FDA
9201 Corporate Blvd
Gaithersburg, MD 20850
(tel) 301 827 2330
(email) birnkrant@cdrer.fda.gov

Marianne Callahan
CONRAD
1611 N. Kent Street, #806
Arlington, VA 22209
(tel) 703 276 3915
(email) mcallahan@conrad.org

Marge Chigwanda
15 Phillips Avenue, Belgravia
Harare, Zimbabwe
(tel) 263 4 704920
(email) marge@uz-ucsf.co.zw

Kata Chillag
HIV Epidemiology Branch
CDC, MS E45
8 Corporate Blvd
Atlanta, GA 30329
(tel) 404 639 0948
(email) kchillag@cdc.gov

Brendon Christian
Gender AIDS Forum
Suite 817 Sangro House
417 Smith Street, Durban
South Africa 4000
(tel) +27 31 3077723/5
(email) Brendon_Christian@hotmail.com

Lee Claypool
USAID
1300 Pennsylvania Ave., NW
Washington, DC 20523-3601
(tel) 202 712 0334
(email) lclaypool@usaid.gov
Anne Coletti  
Family Health International  
52 Washington Street  
Reading, MA 01867  
(tel) 781 779 1511  
(email) acoletti@fhi.org

Barbara Friedland  
Population Council  
1 Dag Hammarskjold Plaza  
New York, NY 10017  
(tel) 212 339 0629  
(email) bfriedland@popcouncil.org

Lorna Colquhoun  
MRC/DFID Microbicides Development Programme (MDP)  
Clinical Trials Centre, St. Mary's Campus,  
Imperial College London  
Norfolk Place, London W2 1PG, UK  
(tel) 44 0 20 7886 6787  
(email) l.colquhoun@imperial.ac.uk

Megan Gottemoeller  
Global Campaign for Microbicides  
1800 K Street, NW Suite 800  
Washington, DC 20006  
(tel) 202 822 0033  
(email) mgottemoeller@path.org

Liza Dawson  
Fogarty International Center  
National Institutes of Health  
16 Center Drive MSC 6705  
Bethesda, MD 20892-6705  
(tel) 301 496 1739  
(email) dawsonl@mail.nih.gov

Forrest C. Greenslade  
149 Tinderwood  
Fearrington Post, NC 27312  
(tel) 919 545 9743  
(email) fcg@forrestgreenslade.com

Kim Dickson  
University of Witwatersrand  
Chris Hani Baragwanath Hospital  
PO Bertsham 2013  
Soweto, South Africa  
Current address:  
DFID Nigeria  
Plot 607  
Bobo St (Off Gana)  
Maitama, Abuja  
Nigeria  
(tel) +234 0 9 413 7710  
(email) K-Dickson@dfid.gov.uk

Vera Grigorieva  
Clinical Research Department  
Family Health International  
(tel) 919 544 7040, ext. 390  
(email) vgrigorieva@fhi.org

Michael Gross  
1601 18th St., NW Ste. 716  
Washington, D.C. 20009  
(tel) 202 232 2766  
(email) m144@earthlink.net

Polly Harrison  
Alliance for Microbicide Development  
8484 Georgia Avenue, Suite 940  
Silver Spring, MD 20910  
(tel) 301 588 8091  
(email) pharrison@microbicide.org

Tim Farley  
World Health Organization  
Avenia Appia  
1211 Geneva 27, Switzerland  
(tel) +41 22 791 3310  
(email) farleyt@who.int

Lori Heise  
Global Campaign for Microbicides  
1800 K Street, NW Suite 800  
Washington, DC 20006  
(tel) 202 822 0033  
(email) lheise@Path-Dc.org
Carel IJsselmuiden  
School of Health Systems and Public Health,  
Faculty of Health Sciences, University of  
Pretoria  
New contact information:  
Council on Health Research for Development  
(COHRED)  
11, rue de Cornavin  
1201 Geneva, Switzerland  
(tel) +41 22 591 8900  
(email) Carel@cohred.ch

Jerry Jennings  
RRB; USAID; GH/OHA  
1300 Pennsylvania Ave, NW  
Washington, DC 20523  
(tel) 202-712-1084  
(email) gjennings@usaid.gov

Neelam Sanjay Joglekar  
National AIDS Research Institute  
73 ‘G’ block MIDC  
Bhosari Pune 411026  
Maharashtra, India  
(tel) 011 91 20 7121342/43  
(email) joglekarneelam@yahoo.com

Elof Johansson  
Population Council  
1230 York Avenue  
New York, NY 10021  
(tel) 212 327 8717  
(email) e-johansson@popcouncil.org

Heidi Jones  
Population Council  
One Dag Hammarskjold Plaza  
New York, NY 10017  
(tel) 212 339 0658  
(email) hjones@popcouncil.org

Anatoli Kamali  
MRC Programme on AIDS in Uganda  
Plot 51-59, Nakiwogo Road  
PO Box 49  
Entebbe, Uganda  
(tel) 256 (0) 41 320 272  
(email) anatoli.kamali@mrcuganda.org

Miriam Katende  
TASO Headquarters  
PO Box 10443  
Kampala, Uganda  
(tel) 256 77 767 637  
(email) katendepm@yahoo.com

Marc-Andre LeBlanc  
Canadian AIDS Society  
309 Cooper St., 4th floor  
Ottawa ON K2P 0G5  
Canada  
(tel) 613 230 3580  
(email) marcl@cdnaids.ca

Reidar Lie  
Department of Clinical Bioethics  
National Institutes of Health  
10 Center Drive Building 10  
Room 1C118  
Bethesda, MD 20892-1156  
(tel) 301 496 2429  
(email) RLie@mail.cc.nih.gov

Naomi Lince  
Ibis Reproductive Health  
2 Brattle Square  
Cambridge, MA 02125  
(tel) 617 349 0042  
(email) nlince@ibisreproductivehealth.org
Alex John London
Department of Philosophy
135 Baker Hall
Carnegie Mellon University
Pittsburgh, PA 15213-3890
(tel) 412 268 4938
(email) ajlondon@andrew.cmu.edu

Kathleen MacQueen
Family Health International
PO Box 13950
Research Triangle Park, NC  27709
(tel) 919 544 7040 ext. 587
(email) kmacqueen@fhi.org

Esther Maleka
c/o Medunsa
PO Box 211
Medunsa, South Africa
(tel) +27 12 521 4251
(email) bitso@medunsa.ac.za

Petronella Mabitso Marumo
c/o Medunsa
PO Box 211
Medunsa, South Africa
(tel) +27 12 521 4251
(email) bitso@medunsa.ac.za

L. Camille Massey
International AIDS Vaccine Initiative
110 William Street, 27 Floor
New York, NY 10038
(tel) 212 847 1047
(email) cmassey@iavi.org

Elizabeth McGrory
Consultant
24 Second Ave
Nyack, NY 10960
(tel) 845 353 0902
(email) emcgroty@ipm-microbicides.org

Sophia Mukasa Monico
Global Health Council
1701 K Street Suite 600
Washington, DC 20006
(tel) 202 833 5900 ext. #3235
(email) smukasamonico@globalhealth.org

Barbara Moscicki
University of California, San Francisco
3333 California Ave. Suite 245
San Francisco, CA. 94118-0503
(tel) 415 476 5139
(email) annam@itsa.ucsf.edu

Promise A.C. Mthembu
ICW, c/o Gender AIDS Forum
108 SANGRO House
517 Smith Street
Durban 4001, South Africa
(tel) +27 31 3071253
(email) pmthembu@icw.org

Margaret Kamya Muganwa
Makerere University Institute of Public Health
PO Box 40382
Kampala, Uganda
(tel) 256 77 469880
(email) mmuganwa@hotmail.com

Paula Munderi
MRC Programme on AIDS
Uganda Virus Research Institute
P O Box 49
Entebbe, Uganda
(tel) + 256 41 281/4
(email) paula.munderi@mrcuganda.org

Shyamala Nataraj
c/o South India AIDS Action Programme
NO. 4, First Street, Kamaraj Avenue
Adyar, Chennai, Tammil Nadu, India
(tel) 044 24416141
(email) shyamnats@hotmail.com
Busisiwe Nkala  
Department of Obstetrics & Gynaecology  
Chris Hani Baragwanath Hospital  
P.O. Bertsham, 2013  
Soweto, Johannesburg.  
(tel) +27 11 933 1228 ext. 206  
(email) b.nkala@rhrujhb.co.za

Malcolm Potts  
School of Public Health  
University California, Berkeley  
Warren Hall, # 314  
Berkeley, CA 94707  
(tel) 510 642 6915  
(email) potts@socrates.berkeley.edu

Renee Ridzon  
Bill & Melinda Gates Foundation  
PO Box 23350  
Seattle, WA 98102  
(tel) 206 709 3383  
(email) reneer@gatesfoundation.org

Audrey Smith Rogers  
NICHD  
6100 Executive Blvd. 4B11K  
Rockville, MD 20852  
(tel) 301 435 6873  
(email) rogersa@mail.nih.gov

Zeda Rosenberg  
International Partnership for Microbicides  
1010 Wayne Avenue, Suite 510  
Silver Spring, MD 20910  
(tel) 301 608 2221  
(email) zrosenberg@ipm-microbicides.org

Shira Saperstein  
Moriah Fund  
1634 1 Street, NW Suite 1000  
Washington, DC 20006  
(tel) 202 783 8488  
(email) ssaperstein@moriahfund.org

Brooke L. Shearer  
International Partnership for Microbicides  
1010 Wayne Avenue, Suite 510  
Silver Spring, MD 20910  
(tel) 301 608 2221  
(email) blshearer07@aol.com

Stephanie Skoler  
Population Council  
1230 York Avenue  
New York, NY 10021  
(tel) 212 327 7003  
(email) sskoler@popcouncil.org

Catherine Slack  
HIV/AIDS Vaccines Ethics Group  
School of Psychology  
University of Natal, Pietermarizburg 3209  
KwaZuluNatal, South Africa  
(tel) 27 33 260 6166  
(email) Slackca@nu.ac.za

Dawn Smith  
BOTUSA Project  
Plot 5348  
Ditlhakore Way  
PO Box90  
Extension 12  
Gaborone, Botswana  
(tel) 267 390 1696  
(email) dks0@botusa.org

Harris Solomon  
Office of Population and Reproductive Health, Bureau for Global Health, USAID  
1300 Pennsylvania Ave NW  
Washington, DC 20523-3601  
(tel) 202 712 1841  
(email) hsolomon@usaid.gov
Global Campaign for Microbicides, www.global-campaign.org

Alan Stone
38 Hollycroft Avenue
London NW3 7QN
United Kingdom
(tel) 44 207 431 8532
(email) alan.stonex@virgin.net

Laurie Sylla
19 Morris Causeway
New Haven, CT 06512
(tel) 203 737 2361
(email) laurie.sylla@yale.edu

Amanda Troxler
Family Health International
2224 E. NC Hwy S4
Durham, NC 27713
(tel) 919 544 7040 ext. 301
(email) atroxler@fhi.org

Lut Van Damme
CONRAD
1611 N. Kent Street, #806
Arlington, VA 22209
(tel) 703 276 4020
(email) lvandamme@conrad.org

Rebekah Webb
Flat 2, 56 Norton Road
Hove
East Sussez BN3 3BH
United Kingdom
(tel) +44 0 1273 240489
(email) rwebb@global-campaign.org

Susan Wood
Ford Foundation
Suites 1502 - 1503 - 1504, 15th Floor
Vietcombank Tower
198 Tran Quang Khai Street
Hoan Kiem District
Hanoi, Vietnam
(tel) 84 4 934 9766/7/8/9
(email) swood@fordfound.org

Cynthia Woodsong
Family Health International
PO 13905
Research Triangle Park, NC 27709
(tel) 919 544 7040 ext. 448
(email) cwoodsong@fhi.org

Teresa C. Wu
Center for Drug Evaluation & Research
FDA
9201 Corporate Blvd
Gaithersburg, MD 20850
(tel) 301 827 2359
(email) wut@cder.fda.gov
Appendix B

CONSULTATION AGENDA

Pre-Meeting on Clinical Trials and Ethical Reasoning

October 22, 2003
PATH
1800 K Street, NW, Suite 800
Washington, DC

Prior to the consultation the Global Campaign for Microbicides sponsored a one-day pre-meeting on clinical trials and ethical reasoning. This course, now available upon request, is designed to familiarize participants with the basics of clinical trial design; provide background data on ethical guidance and principles; and provide an opportunity, through case studies, to apply these principles in practice.

1:00 to 1:30 Welcome and Introductions
1:30 to 2:15 Overview of Clinical Trials
2:15 to 2:50 Introduction to Ethical Reasoning (Part 1)
3:00 to 3:30 Informed Consent Case Study
3:30 to 3:45 Ethical Reasoning (Part 2)
4:00 to 5:00 Vaccine Trial Case Study

International Consultation on Ethical Issues in the Clinical Testing of Microbicides

October 23, 2003
Council on Foundations
1828 L Street, NW, Suite 505
Washington, DC

Day One:
8:30 Welcome and Introductions
Kim Dickson, Reproductive Health Research Unit, South Africa
Steering Committee, Global Campaign for Microbicides
9:00  **Contextualizing the Field Since the 1997 Ethics Consultation**
Lori Heise, Director, Global Campaign for Microbicides

Meeting goals and agenda; history of the earlier consultation; shifts that emerged in thinking and strategy because of the 1997 consultation; significant events that have occurred since that time; and the evolution of HPTN ethics guidance.

9:15  **Design Issues in Clinical Trials of Microbicides**
Alan Stone, International Working Group on Microbicides, UK

Basic introduction to the design of microbicide trials; clinical trial pathway for microbicides; and discussion of key challenges: finding a placebo; selection of trial populations. Why are most microbicide trials in the developing world? Measuring effectiveness versus efficacy; and challenges of measuring sexual behavior, gel and condom use. Current controversies: one control arm or two? Length of participant follow-up.

9:45  **International Research Ethics and Debates**
Carel IJsselmuiden, University of Pretoria, South Africa

Historical origins of modern bioethics. Introduction to ethical reasoning and key principles. What makes research ethical? Basic concepts and principles; debates over universal versus pluralistic standards of care; and recent controversy around placebo-controlled trials. Dealing with culture and community. What makes HIV prevention trials different—stigma, healthy individuals, etc.?

10:30  **Session 1: Informed Consent: From Theory to Practice**
Marge Chigwanda, UZ-UCSF Collaborative Research Program, Zimbabwe
Cynthia Woodsong, Family Health International, USA

Discussion of the microbicide field's efforts to address informed consent. Issues that remain; examples of creative approaches to achieving and sustaining informed consent, including videos, assessment of comprehension, etc.

11:30  **Session 2: Benefits and Burdens to Participants and Communities—Conceptualizing Fair Benefits**
Reidar Lie, National Institutes of Health, USA/Norway

Evolution of ethical thinking on this issue; insights from guidance; balancing risks and benefits; NIH consultation on fair benefits; balancing benefits and “undue inducement”; What is the difference between inducement and “undue” inducement? Ensuring reasonable availability of interventions post trial.

1:15  **Session 2: (Continued): Benefits and Burdens**
Evaluating Carraguard—A look at burdens and benefits from multiple vantage points
Heidi Jones, Population Council—General reflections
Barbara Friedland—Population Council—Phase II coordinator
Mabitso Marumo—counseling coordinator, MEDUNSA
Esther Maleka, Former Phase II trial participant, South Africa
Discussant: Alex London, Carnegie Mellon University
3:00  Session 3: Defining the Standard of Care
Considering Standard of Care from a Research Ethics Perspective
Liza Dawson, Fogarty International Center

Multiple uses of this concept; insights from Guidance; context of global health inequities; moral basis of standard of care debates; health care versus research ethics; international debates and tensions (local standard; best proven; highest attainable and sustainable; ratcheting up).

Ethics Meets the Rough Grounds
Kathleen MacQueen, HPTN Ethics Working Group

Defining the range of care issues at stake (beyond ARVs). Insights from FHI’s SOC survey at HPTN sites—variations between care available in different settings. Findings of how HPTN 035 participants conceptualize “fair.”
Discussants: Anatoli Kamali (MRC-Uganda), Miriam Katende (TASO), Promise Mthembu, ICW.

Day Two:

8:30  Session 4: Men, Ethics and Microbicide Trials
What are the issues? How is the field responding?
Panel discussion:
Busisiwe Nkala, Soweto, South Africa
Neelam Joglekar, Pune, India
Michael Gross, consultant, USA
Experience from audience members

Concerns about penile safety; expectations around men’s right to control female behavior; issues around trials “excluding” men, partner consent, etc.
Discussants: Ethical- and rights-based reflections on men, culture, and trials
Carel IJsselmuiden–University of Pretoria
Brendon Christian–Gender AIDS Forum, South Africa

10:15  Session 5: HIV Treatment in the Context of Prevention Trials
Introduction to On-Going Deliberations and Debates
Lori Heise, Global Campaign for Microbicides

Providing ART: Examining the ethical arguments
Catherine Slack, University of Natal, South Africa

Scientific and Practical Challenges of Treating HIV Infections
Paula Munderi, MRC Uganda

WHO/UNAIDS Consultation on ART in Prevention Trials
Eduard Beck, McGill University, Canada

Opportunities to Partner and Leverage Outside Resources
Camille Massey, International AIDS Vaccine Initiative
Discussion
1:30  Session 6: Establishing Safety and Effectiveness in Younger Adolescents

Younger Adolescents: Do We Need Separate Data?
Barbara Moscicki, Division of Adolescent Medicine, UCSF

Ethical Reflections on Enrolling Adolescents in Trials
Audrey Rogers, NICHD Adolescent Clinical Trial Unit

A View from Botswana
Dawn Smith, BOTUSA Project, Gaborone, Botswana
Discussion

3:00  Session 7: Ethics of Second-Generation Microbicide Trials

If a RCT demonstrates some effectiveness for a first-generation product what implications would this have on the design of future trials. What role can post-approval trials play? Under what circumstances could we ethically do a confirmatory trial in a different setting?

Equipoise and the Issue of Second-Generation Trials
Alex London, Carnegie Mellon University

Scientific Challenges in Testing Next-Generation Products
Anne Coletti, Family Health International

The Potential Role for Post-Approval Studies
Forrest Greenslade, Consultant
Discussant: Tim Farley, World Health Organization

5:00  Summary Reflections and Rapporteur Report
Kim Dickson, South Africa
Appendix C

SELECTED READINGS ON ETHICAL ISSUES IN MICROBICIDE DEVELOPMENT

Contextualizing the Field Since 1997


Background Materials on Microbicides and Clinical Trials


Background Materials on Biomedical Ethics


Informed Consent


Molyneux CS, Wassenaar DR, Peshu N, Marsh K. Even if they ask you to stand by a tree all day, you will have to do it (laughter)…!: Community voices on the notion and practice of informed consent for biomedical research in developing countries. *Social Science and Medicine.* 2005, 61: 443-454.

Standard of Care


HIV Treatment in the Context of Prevention Trials


