



HEALTH RESEARCH ETHICS IN THE AMERICAS

**WYNDHAM MIAMI BEACH RESORT
4833 COLLINS AVENUE
MIAMI BEACH, FLORIDA 33141**

MAY 4-5, 2006

HEALTH RESEARCH ETHICS IN THE AMERICAS II
MAY 4, 2006, MIAMI BEACH, FLORIDA



- 8:30-9:15 A.M. REGISTRATION AND BREAKFAST** *Regency Ballroom Foyer*
- 9:15 A.M. WELCOME AND INTRODUCTIONS** *Regency Ballroom*
Gail Shor-Posner, PhD
Director, University of Miami Fogarty International Training Program
Kenneth W. Goodman, PhD
Director, University of Miami Bioethics Program
Richard J. Bookman, PhD
Associate Dean for Research and Graduate Studies, University of Miami Leonard M. Miller School of Medicine
- 9:30 A.M. FIC EFFORTS TO INCREASE BIOETHICS CAPACITY IN LOW AND MIDDLE INCOME COUNTRIES** *Regency Ballroom*
Barbara J. Sina, PhD
Program Director, Division of International Training and Research, Fogarty International Center, NIH
- 10:10 A.M. BUILDING CAPACITY: WHAT IS NEEDED, WHAT IS NOT - AND THE DIFFERENCE: PAHO'S ETHICS PROGRAM** *Regency Ballroom*
Fernando Lolas Stepke, MD
Director, Pan American Health Organization Regional Bioethics Program
- 10:50 A.M. COFFEE BREAK** *Regency Ballroom Foyer*
- 11:00 A.M. THE BIOETHICS SOCIETY OF THE ENGLISH-SPEAKING CARIBBEAN : PRACTICAL ETHICS SERVING HUMAN SUBJECTS RESEARCH** *Regency Ballroom*
Derrick Aarons, MD, MSc, PhD
Convenor, The Bioethics Society of the English-speaking Caribbean (BSEC) Faculty of Medical Sciences University of the West Indies, Mona, Jamaica
- 11:40 A.M. BUILDING A RESEARCH ETHICS TRACK RECORD: THE UNIVERSITY OF THE WEST INDIES, MONA EXPERIENCE** *Regency Ballroom*
Anthony Mullings, DM, MPH
University of the West Indies, Mona, Jamaica
- 12:20 A.M. LUNCHEON ROUND TABLE RESEARCH ETHICS IN THE AMERICAS: CHALLENGES AND SOLUTIONS** *Ocean Room*
- 1:30 P.M. THE CITI PROGRAM: WHY INTEGRITY MATTERS IN HUMAN SUBJECTS RESEARCH** *Regency Ballroom*
Paul Braunschweiger, PhD
University of Miami Miller School of Medicine
- WORKING GROUPS** *Regency Ballroom*
- 2:30 P.M. RESPONSIBLE CONDUCT OF RESEARCH WORKSHOP: STIGMA IN THE WORKPLACE**
John E. Lewis, PhD (Moderator)
Director of Education, University of Miami Fogarty International Training Program
Marija Miric, Dominican Republic, University of Miami Fogarty Trainee
Blanca Acosta, MD Colombia, University of Miami Fogarty Trainee
- DISCLOSURE: WHEN? WHERE? HOW?**
Lourdes Ila, MD (Moderator)
Director of Behavioral Training, University of Miami Fogarty International Training Program
Rosangela Mendoza, Dominican Republic, University of Miami Fogarty Trainee
Pansy Hamilton, Jamaica, University of Miami Fogarty Trainee
- POSTER SESSION**
- 4:00 P.M. HEALTH RESEARCH ETHICS IN THE AMERICAS II** *Ocean Room*

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- 8:30-9:00 A.M. BREAKFAST** *Regency Ballroom Foyer*
- 9:00 A.M. WORKING GROUP REPORT:** *Regency Ballroom*
STIGMA IN THE WORKPLACE (20 minutes)
Marija Miric, *Dominican Republic, University of Miami Fogarty Trainee*
Blanca Luisa Acosta de Velásquez, MD, *Colombia, University of Miami Fogarty Trainee*
- DISCLOSURE: WHEN? WHERE? HOW? (20 minutes)**
Rosangela Mendoza, *Dominican Republic, University of Miami Fogarty Trainee*
Pansy Hamilton, *Jamaica, University of Miami Fogarty Trainee*
- 9:40 A.M. RULES AND REGULATIONS FOR INTERNATIONAL RESEARCH** *Regency Ballroom*
Sergio Litewka, MD, MPH
University of Miami Ethics Programs
- 10:20 A.M. ETHICS – PERINATAL TRANSMISSION** *Regency Ballroom*
Gwendolyn Scott, MD
Director of Pediatric Infectious Disease and Immunology, University of Miami Leonard M. Miller School of Medicine
- 11:00 A.M. COFFEE BREAK** *Regency Ballroom Foyer*
- 11:20 P.M. FOCUS ON VULNERABLE POPULATIONS:** *Regency Ballroom*
CHALLENGES IN PEDIATRIC RESEARCH
Charles Mitchell, MD
Co-Principal Investigator, University of Miami Fogarty International Training Program
- REACHING THE HARD OF HEARING AND DEAF POPULATION**
Claudia Bisol, MS
Brazil, University of Miami Fogarty Trainee
- 12:30 P.M. NOW WHAT? FUTURE DIRECTIONS AND COLLABORATIONS IN HEMISPHERIC RESEARCH** *Regency Ballroom*
Open forum with the goal of drafting a white paper, "The Miami Declaration," on the question of transnational Internal Review Boards and harmonization of policies and procedures and educational standards.
- Gail Shor-Posner, PhD
Director, University of Miami Fogarty International Training Program
- Kenneth W. Goodman, PhD
Director, University of Miami Bioethics Program
- John Beier, PhD
Director Global Health, Miami Fogarty International Training Program
- 1:00 P.M. ADJOURNMENT AND EVALUATIONS** *Regency Ballroom*

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- 1:00 P.M. ADJOURNMENT AND EVALUATIONS** *Regency Ballroom*

**THE UNIVERSITY OF MIAMI MILLER SCHOOL OF MEDICINE FOGARTY
INTERNATIONAL TRAINING PROGRAM IN AIDS EPIDEMIOLOGY AND TB**

G. Shor-Posner, Ph.D., C.N.S.

Director

In 1988, the University of Miami School of Medicine received funding from the NIH John E. Fogarty International Center to establish an International Training Program in AIDS Epidemiology. The primary objectives of the Fogarty Program at the University of Miami School of Medicine have been to provide highly structured and individualized training to promising scientists and health care professionals from developing countries in AIDS/TB-related research, clinical trials and AIDS/TB prevention programs. The purpose of this program is to produce scholars that return home to develop and initiate research protocols in their home countries, assume leadership roles in HIV-related policy development, disseminate the new information learned at Miami to local physicians and health care workers, and introduce new HIV treatment modalities adapted to the resources and capabilities of their countries.

Under the auspices of the Fogarty Center, 290 government-endorsed scholars from developing countries have participated in epidemiological, behavioral, clinical and laboratory research training experiences related to AIDS and TB prevention and treatment at the University of Miami School of Medicine. The Miami Fogarty research training programs are closely integrated with related research studies and clinical resources affiliated with the University and the community. Collaborative activities with other training programs involve joint seminars and cooperative research projects that provide additional resources and rotation opportunities, which stimulate interactions among the faculty members and trainees from different departments.

Regional workshops have been conducted at various international sites to provide in-depth training in HIV/TB related prevention strategies and promote the exchange of epidemiological and clinical information between U.S. and foreign health care professionals. In the past decade, over 135 in-country training courses and south-to-south workshops have been conducted, in which more than 12,000 indigenous health care workers, have been provided with up-to-date-biomedical, clinical, epidemiological, and bioethics -related information.

Interactive collaborative workshops and telemedicine conferences have been developed to present in-depth training, promote scientific exchange, and foster ethical collaborative research. These experiences enable the Fogarty trainees to develop and conduct ethically sound and scientifically valid research in their home countries. The continued and on-going research collaboration between University of Miami investigators and Fogarty scholars has facilitated scientific productivity, and contributed to the expansion of in-country resources for essential prevention research, treatment and education throughout Latin America and the Caribbean.

JOHN E. FOGARTY



John E. Fogarty was born on March 23, 1913 in Providence, Rhode Island to a second-generation Irish immigrant family. The family moved to a small farm in rural Gloucester, R.I. when he was seven and where his mother died when he was twelve. Fogarty's formal education was limited and during the Depression he made his living as a master bricklayer, following in the footsteps of his father and his older brother, who were both master bricklayers.

A taste for politics was also in the family tradition. Fogarty's father had been active in ward politics in Providence and in 1936; Fogarty was elected President of Local Bricklayers Union No. 1. Three years later, he defeated five prominent Democrats for the congressional nomination and went on to victory in the general election. The year was 1939 and Fogarty was 6 years old.

John Fogarty's years in Congress as the representative from Rhode Island's 2nd district were remarkable for his repeated urgings of the nation to support international health research. At the time, America was emerging from World War II and the NIH itself was a modest organization with a 1949 budget of \$37 million. Today, the world can all too readily acknowledge the truth of Fogarty's oft-quoted argument for global research, "Because disease knows no national boundaries." But that was only one of several arguments that distinguish Fogarty as a man ahead of his times.

"I submit that investment in medical research, aside from the unending humanitarian benefits, is an economical investment in life. ...Research is the only means we have for reducing the growing federal burden of medical care costs."

"Time and again it has been demonstrated that the goal of better health has the capacity to demolish geographic and political boundaries and to enter the hearts and minds of men, women and children in the four corners of the earth....For pestilence and prolonged disability and premature death, wherever they may occur, are tragedies which strike a responsive chord in man and his governments."

KEYNOTE SPEAKERS — THURSDAY MAY 4, 2006

Richard J. Bookman, PhD

Associate Dean for Research and Graduate Studies, University of Miami Leonard M. Miller School of Medicine

Dr. Bookman is the Associate Dean for Research and Graduate Studies. He is the Director of the MD-PhD Program, Director of the University of Miami DNA Microarray Facility and Associate Professor of Molecular and Cellular Pharmacology. His primary research interests involve determination of the molecular mechanisms responsible for release of neurotransmitters and hormones.

Barbara J. Sina, PhD

Program Director, Division of International Training and Research, Fogarty International Center, NIH

Dr. Sina, is the Program Officer for the National Institutes of Health (NIH) Bioethics Fogarty program to train and provide masters-level curriculum in culturally relevant bioethics related to research to academic/health professionals/researchers from developing countries . She is also the Program Officer for the Global Infectious Diseases Research Training Program to promote sustainable research capacity in relevant infectious diseases at developing country institutions.

Fernando Lolas Stepke, MD

Director, Pan American Health Organization Regional Bioethics Program

Dr. Lolas obtained his M.D. from the University of Chile and was a Fellow at the University of Heidelberg, Germany, where he studied psychosomatic medicine and history. He is a Fellow of the Royal Spanish Academy in Madrid and Dr. Honoris Causa at several universities. Dr. Lolas is the Director of the Regional Program on Bioethics of the Pan American Health Organization in Santiago, Chile and a Professor at the University of Chile in the Department of Psychiatry.

Derrick Aarons, MD, MSc, PhD

Convenor, the Bioethics Society of the English-speaking Caribbean (BSEC) Faculty of Medical Sciences University of the West Indies, Mona, Jamaica

Dr. Aarons, who is the Caribbean's first bioethicist, received his Doctorate in Bioethics and Experimental Medicine from McGill University. He is also a family and palliative care physician specializing in the care of individuals with advanced terminal disease. Dr. Aarons has served as an associate lecturer in the office of the Dean, Faculty of Medical Sciences, and on the Ethics Committee at the University of the West Indies. , Dr. Aarons has published extensively in the areas of ethics and professional responsibilities, medical ethics, research ethics, and health care priorities.

KEYNOTE SPEAKERS — THURSDAY MAY 4, 2006

Anthony Mullings, DM, MPH

University of the West Indies, Mona, Jamaica

Dr. Mullings is the Deputy Dean of Clinical and Graduate Studies and Senior Lecturer, Department of Obstetrics Gynecology and Child Health, University of the West Indies. His current research activities include studies to identify the incidence of mycotic vulvovaginitis, and incidence of resistant strains in a Jamaican population, as well as the development of a program for prevention of mother to child transmission of HIV/AIDS.

Paul Braunschweiger, PhD

University of Miami Leonard M. Miller School of Medicine

Dr. Braunschweiger is a Professor of Radiation Oncology and co-founder of the Collaborative Institutional Training Initiative (CITI) Program hosted at the University of Miami. The CITI Program began as collaboration between the University of Miami and Fred Hutchinson Cancer Research Center in June 2000 and now provides a customizable web based instructional program in human subjects protections to nearly 600 participating organizations around the world. The CITI Program is administered through the Office of Research Education, directed by Dr. Braunschweiger who also participates as a member of the CITI Developer Group and CITI Editorial Board. Dr. Braunschweiger is the Chair of the University of Miami Institutional Animal Care and Use Committee and directs the Office of the IACUC.

RESPONSIBLE CONDUCT OF RESEARCH WORKSHOP

STIGMA IN THE WORKPLACE

John E. Lewis, PhD (Moderator)

Director of Education, University of Miami Fogarty International Training Program

Dr. Lewis, is an Assistant Professor of Psychiatry and Behavioral Sciences with special interests in biostatistics, exercise physiology and nutrition and psychopathology in children and adolescents. As the Director of Education for the Miami Fogarty Program, Dr. Lewis works closely with the trainees to develop research skills in data collection, analyses, and data management, and provides guidance in scientific writing for preparation of grant proposals and research manuscripts.

Marija Miric,

Dominican Republic, University of Miami Fogarty In-Country Trainee

Ms. Miric is a licensed clinical psychologist and research associate at *COPRESIDA* (Presidential Council on AIDS) in Santo Domingo. After completing her Miami Fogarty training program, Ms. Miric was funded by the World Bank, to examine psychological factors related to felt stigma and quality of life of HIV positive persons in the Dominican Republic. Insights obtained from this pioneering work, have been used to develop interactive workshop programs to help promote well-being and decrease discrimination related to HIV-AIDS stigma in health and work sectors in the Dominican Republic.

Blanca Acosta, MD,

Colombia, University of Miami Fogarty In-Country Trainee

Dr. Acosta is an advanced in-country Fogarty trainee, distinguished Professor at the Colombian School of Dentistry, Coordinator of the Department, and advisor to the Dean. At the *Corporación de Lucha Contra El Sida* in Cali, she is developing a patient database and is organizing research investigations to determine HIV/AIDS knowledge and behavior among dental students to reduce the burden of stigma for health care utilization. Dr. Acosta's in-country project has been designed to evaluate "Possible Association Between Oral Health Status and Cognitive Status in HIV-Infected Patients".

DISCLOSURE: WHEN? WHERE? HOW?

Lourdes Illa, MD (Moderator)

Director of Behavioral Training, University of Miami Fogarty International Training Program

Dr. Illa, Assistant Professor of Clinical Psychiatry and Behavioral Sciences, is a recognized expert in the area of child and adolescent psychiatry, especially in the context of HIV/AIDS disease. She is the Director of Behavioral Training for the Miami Fogarty Program, and the Co-Director of the Healing Place, an outpatient mental health clinic for children and families living with HIV.

Rosangela Mendoza,

Dominican Republic, University of Miami Fogarty In-country Trainee

Ms. Mendoza, an advanced in-country Fogarty scholar, is a licensed psychologist at the Robert Reid Cabral Junior Childrens Hospital in Santo Domingo, with a primary interest in HIV/AIDS disclosure issues. She recently completed coursework for her Master's in Ethics, and has worked closely with Ms. Miric to conduct interactive workshops to reduce discrimination and the burden of stigma in the Dominican Republic.

Pansy Hamilton,

Jamaica, University of Miami Fogarty In-country Trainee

Ms. Hamilton is an in-country Fogarty trainee, and the Coordinator of the research section of the Advanced Training & Research in Fertility Management Unit at the University of the West Indies. Her areas of research interest include: family attitudes to HIV positive members, the support provided, and coping measures adopted; sexual attitudes and behaviors of adolescent females living with HIV/AIDS and psychological development of children affected by HIV/AIDS.

Sexually Transmitted Disease (STD) and Human Immunodeficiency Virus Infection in STD Clinic Patients in Jamaica.

Dowe G, Smikle M, Williams E, Hylton-Kong T, Shor-Posner G

HIV Testing and Risk Factors Among Pregnant Women in Cali, Colombia.

Galindo J, Tello C, Duque J, Murillo S, Miguez MJ, Rodriguez A, Shor-Posner A.

The Impact of HIV Infection on the Development of Preschool Dominican Children.

Hernandez-Reif M, Mendoza R, Castillo R, Shor-Posner G and Zhang G.

Self-esteem, Depression and Social Support Perception Related to Felt Stigma Levels Among Dominican Persons Living With HIV/AIDS.

Miric M.

Successful Strategies for Prevention of Mother-to-Child HIV Transmission in the Dominican Republic: The Elizabeth Glaser Pediatric AIDS Foundation Project.

Pérez-Then E, Bautista C, Espinal R, Preble E, Tavarez-Rojas M, Gómez J, Canario A, Terrero P, Wilfert C, Ammann A, Shor-Posner G.

Collaborative Research in the Dominican Republic: Informed Consent Challenges and Resolution.

Quintero N and Shor-Posner G.

Perception of HIV-Infected Dominican Children's Psychosocial Behavior by HIV+ Mothers and Other Caregivers.

Quintero N, Mendoza R, Castillo R, Hernandez-Reif M, Zhang G and Shor-Posner G.

Potential Impact of Massage Therapy on Immune Function in HIV+ Children: Preliminary Findings.

Shor-Posner G, Baez J, Hernandez-Reif M, Soto S, Perez-Then E, Miguez MJ, Zhang G.

Ethical and Legal Issues Associated to the Use of Domiciliary Rapid Tests for Diagnosis of HIV/AIDS.

Vidal-Anzardo M and Gutiérrez-Rodríguez R.

KEYNOTE SPEAKERS — FRIDAY MAY 5, 2006

Sergio Litewka, MD, MPH

University of Miami Ethics Programs

Dr. Litewka is a surgeon by training, and specialist in bioethics and healthcare management. Dr. Litewka holds a Master's degree in Public Health and was a fellow in Bioethics in the Center for Medical Ethics at the University of Virginia. His international experience includes coordination of programs for improving public healthcare in Uruguay, Argentina, and Honduras. He was the Director of CEMAR, a think tank based in Buenos Aires, Argentina, for ethics and resource allocation in public and social security owned healthcare services. Dr. Litewka is currently a scholar in research ethics for Latin America and the Caribbean at the University of Miami Ethics Programs.

Gwendolyn Scott, MD

Professor and Director of Pediatric Infectious Disease and Immunology, University of Miami Leonard M. Miller School of Medicine

Dr. Scott, Professor of Pediatrics and Director of the Division of Pediatric Infectious Diseases and Immunology, has been providing leadership in the area of perinatal HIV transmission for the past two decades. Her early pioneering work described clinical and immunological manifestations of HIV infection in children, and she participated in the design and implementation of the first pediatric clinical trials of Zidovudine and Didanosine. Dr. Scott has played a significant role in the prevention of perinatal transmission of HIV, and has served as a consultant and advisor to the CDC, WHO, NIH, and the Institute of Medicine on pediatric AIDS issues. Dr. Scott's vast international experience in developing countries along with her numerous funded research activities, including NHLB, NIAID ACTG, and HRSA awards in pediatric AIDS, clinical research, and HIV support services, has provided training opportunities for numerous physician scientists from South America, the Caribbean and Africa.

Charles Mitchell, MD

Professor of Pediatrics, Co-Principal Investigator, University of Miami Fogarty International Training Program

Dr. Mitchell, Professor of Pediatrics in the Division of Infectious Disease and Immunology, has extensive experience in the care and treatment of HIV infected children and adolescents, as well as the training of physicians in HIV/AIDS research, and in the establishment of perinatal networks in developing countries. Dr. Mitchell's leadership in Pediatric AIDS includes the creation of Perinatal Research Networks in Brazil, modeled after the UM HIV Perinatal Research Network developed to conduct the PACTG Perinatal Intervention Trials, and participation as a Co-Investigator on the PACTG grant, which has been in effect in Miami since 1988 (NIAID, PI. Dr. G. Scott). Dr. Mitchell is currently a member of the Opportunistic Infections Subcommittee of the Complications of HIV RAC for the PACTG.

KEYNOTE SPEAKERS — FRIDAY MAY 5, 2006

Claudia Bisol, MS

Brazil, University of Miami Fogarty In-Country Trainee

After completing her Miami Fogarty training program, Ms. Bisol returned to Brazil to continue her studies in adolescent sexual behavior and risk factors, and HIV prevalence and its dynamics with special reference to HIV prevention efforts in adolescents who are hard of hearing or deaf. Her re-entry project entitled, "Narratives of Deaf Youths: Sexual Behavior in the Era of AIDS" will evaluate 50 deaf students ages 15-21 years, attending special schools for the deaf in the South of Brazil. A computer-based questionnaire that allows participants to self-report their sexual biographies and knowledge will be used to assess differences in sexual risk behavior and HIV/AIDS knowledge between hard of hearing students and normal hearing controls. This instrument also allows simultaneous video translation of questions to Brazilian sign language to facilitate accessibility, and offers young people a familiar, friendly, and motivating environment.

John C. Beier, Sc.D

Director, Global Public Health Research Group, University of Miami

Dr. Beier is a Professor at the University of Miami where he teaches Epidemiology. He is presently the Principal Investigator of three International Projects in the Department of Epidemiology and Public Health. Dr. Beier serves on the Board of Directors for the Hialeah Technology Center in Miami, Florida. Prior to this position, he was a Professor in the Department of Tropical Medicine School of Public Health and Tropical Medicine and Payson Center for International Development and Technology at Tulane University in New Orleans, Louisiana. He was formerly Associate Professor in the Department of Immunology and Infectious Diseases from 1991 to 1994 and in the Department of Molecular Microbiology and Immunology, School of Hygiene and Public Health, at The Johns Hopkins University, Baltimore, Maryland in 1994.

THE ETHICS OF RESEARCH RELATED TO HEALTHCARE IN DEVELOPING COUNTRIES

Members of the Working Party

PROFESSOR SIR KENNETH CAIMAN (Chairman) is Vice Chancellor and Warden,
University of Durham

DR FRED BINKA is Associate Professor of Epidemiology, School of Public Health, University
of Ghana

PROFESSOR MICHAEL ELVES is a former Director, Office of Scientific and Educational
Affairs, Olaxo Wellcome plc

PROFESSOR V I MATHAN is a senior Consultant for Health Research. Indian Council of
Medical Research. National Institute of Epidemiology. Chennai India

PROFESSOR KEITH MCADAM is Director, MRC Laboratories, Fajara. The Gambia

DR ANNE MCLAREN is at the Wellcome/CRC Institute, Cambridge

PROFESSOR BHIKHU PAREKH is Centennial Professor, The Centre for the Study of Global
Governance, London School of Economics

PROFESSOR DAVID PARKIN is Professor of Social Anthropology, All Souls College,
Oxford

PROFESSOR CATHERINE PECKHAM CBE is Professor of Epidemiology, Institute of
Child Health, University College London

PROFESSOR POVL RIIS is at the Copenhagen Ministry of Science

PROFESSOR NELSON SEWANKAMBO is Dean, Faculty of Medicine, Makerere University,
Kampala, Uganda

MRS. SHAHWAR SADEQUE is an educational & ICT Consultant

PROFESSOR PETER SMITH is Head of the Department of Infectious and Tropical Diseases,
London School of Hygiene & Tropical Medicine

DR FABIO ZICKER is Coordinator, Research Capacity Strengthening, UNDP/World
Bank/WHO Special Programme for Research and Training in Tropical Diseases [TDR]

EXECUTIVE SUMMARY

The purpose of this Report is to examine the ethical issues raised when research related to healthcare is carried out in developing countries and funded by sponsors from developed countries. Developing countries urgently need research to help to address the enormous burden of disease that they carry. The inequalities in resources between developed and developing countries pose a real risk of exploitation in the context of externally-sponsored research. Recognizing that external sponsors differ in their motives for conducting research in developing countries, the Working Party considers that all countries should set national priorities related to their provision of healthcare. When externally sponsored research is proposed which falls outside the national priorities, its relevance must be justified to the appropriate research ethics committees. To enhance the ability of developing countries to conduct research that is relevant to their needs, **the Working Party recommends that the development of local expertise in the provision of healthcare and in healthcare research should be an integral component of any proposed research.**

The Working Party recognizes that those involved in externally sponsored research are often faced with diverse and sometimes conflicting guidance as to what may be ethically acceptable. This Report aims to present an ethical framework for others to use when applying such guidance and to assist those involved in the development of national guidance for the ethical review of research. The ethical framework proposed in this Report is based on four principles: the duty to alleviate suffering; the duty to show respect for persons; the duty to be sensitive to cultural differences; and the duty not to exploit the vulnerable. It is crucial that these duties are respected when research is planned and conducted. The Working Party emphasizes the critical importance of taking into account the context, social, cultural, and economic, when applying these principles. Further, it identifies certain minimum requirements that must be met.

CONSENT

The Working Party concludes that in some cultural contexts it may be appropriate to obtain agreement from the particular community or assent from a senior family member before any prospective participant in research is approached. However, genuine consent to participate in research must also always be obtained from each participant.

STANDARDS OF CARE

The Working Party concludes that the appropriate standard of care to be provided to members of a control group in a research project can only be defined in consultation with those who work within the country in which the research is to be conducted. It must then be justified to the relevant research ethics committees. Wherever appropriate, participants in the control group should be offered a universal standard of care¹ for the disease being studied. Where it is inappropriate to offer such a standard, the minimum that should be offered is the best intervention currently available as part of the national public health system.

ONCE A RESEARCH PROJECT IS COMPLETED

The Working Party concludes that it is unacceptable for research to begin without a decision having been made about whether or not participants in the control group will be offered an intervention shown to be successful on completion of the trial. Researchers should endeavour to secure post trial access to effective interventions for all the participants in a trial who could benefit. In addition, the possibility of introducing and maintaining a successful treatment in the wider community should be considered before research is conducted. If it is thought that this will not be possible, researchers must justify to the relevant research ethics committee why the research should be carried out.

REVIEWING THE ETHICS OF A RESEARCH PROJECT

An effective system of review of the ethical propriety of research is a crucial safeguard for participants in research. It may, however, be absent or ineffective in some developing countries. **The Working Party recommends that all countries should establish an effective system for the ethical review of research, which includes the establishment and maintenance of research ethics committees that are independent of government and sponsors of research.** Research should be subject to ethical review in both the country(ies) hosting and the country(ies) sponsoring the research. The Working Party welcomes international initiatives for establishing research ethics committees, training their members and monitoring their development. Funding should be provided for these purposes by those who sponsor research in developing countries. **Furthermore, the Working Party recommends that national and international sponsors of research should ensure that adequate provision is made for training of all those professionals involved in research related to healthcare in the ethics of research.**

¹ *We use the term 'universal standard of care' to indicate the best current method of treatment available anywhere in the world for a particular disease or condition*

Disclosure of HIV Status on Informed Consent Forms Presents an Ethical Dilemma for Protection of Human Subjects

Ronald H. Gray, MD,* Nelson K. Sewankambo, MB, ChB,† Maria J. Wawer, MD,‡
David Serwadda, MB, ChB,§ Noah Kiwanuka, MB, ChB,|| and Tom Lutalo, MSc||

Summary: The privacy of copies of consent forms provided to research participants cannot be guaranteed. Therefore, consent forms that disclose a subject's HIV status may result in breach of confidentiality and cause social harms. Under the ethical principle of beneficence defined in the Belmont Report, we recommend that disclosure of HIV status be through voluntary counseling and testing; however, whenever possible, copies of consent form should not specify HIV status.

Key Words: HIV status, ethics, informed consent, disclosure, stigmatization

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For the past 15 years, we have conducted HIV prevention research and service provision in rural Rakai District of southwestern Uganda. In all our research, we endeavor to maintain strict confidentiality of information on participants' HIV status, because in these small rural communities, the maintenance of privacy is often problematic. To preserve privacy, we have used consent forms that do not divulge information on HIV status, by not mentioning the issue if it is not relevant to a specific study or by enrolling HIV-positive and HIV-negative persons into studies. These practices, which have been endorsed by our Community Advisory Board, the Uganda Institutional Review Board (IRB) of record (Scientific and Ethical Committee of the Uganda Virus Research Institute, Entebbe), and IRBs at Johns Hopkins and Columbia Universities, have proven successful and we have not experienced breaches of confidentiality in our research. We recently encountered an ethical dilemma in which US Federal regulations conflicted with our commitment to the preservation of confidentiality of HIV status information on consent forms,

however. The dilemma was as follows. We are conducting randomized trials of male circumcision for HIV prevention. The US National Institutes of Health (NIH) supported a trial of circumcision to evaluate male HIV acquisition in HIV-negative men who were willing to learn their test results and accepted voluntary counseling and testing (VCT). A parallel trial sponsored by the Gates Foundation is assessing the safety of circumcision in HIV-infected men and the efficacy of circumcision for prevention of male-to-female HIV transmission. In the latter trial, we also enroll HIV-negative men who declined to learn their HIV results. These men who refuse to learn their HIV status are not eligible for enrollment into the NIH trial, because US Department of Health and Human Services (DHHS) regulations require that HIV testing can only be conducted on persons who agree to learn their HIV results. In this population, individuals who refuse VCT have high-risk behavior profiles, and they are a subgroup in need of HIV prevention measures.

To resolve the dilemma, we proposed a single consent form that mentioned both trial sponsors and stated that the trials would enroll HIV-positive and HIV-negative men, thus masking the trial of enrollment and putative HIV status. This was not acceptable to the NIH, however, which required separate sponsor-specific consents. We thought that a sponsor-specific consent would disclose HIV status, because all NIH trial participants would be HIV-negative and, by default, Gates Foundation-sponsored trial participants would be perceived as probably HIV-positive. After lengthy negotiations and final adjudication by the NIH Office of Human Research Protection (OHRP), it was decided that the consent form for screening would include both sponsors and mention the inclusion of HIV-positive and HIV-negative men, because before screening, the trial of enrollment was unknown. The enrollment consent was silent on sponsorship and on HIV status and only indicated the sponsor by a code to satisfy US regulatory requirements. Although this dilemma was context specific, it raises general ethical and regulatory issues affecting the conduct of international research and potential conflicts between requirements of sponsoring agencies and the sociocultural setting within which the research is conducted. We discuss these general issues and our concerns about potential social harms that might arise from inadvertent disclosure of HIV status on consent forms.

Informed consent is central to the ethical conduct of research.¹ The required elements of consent include, among

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other things, that potential participants be told the purpose of the research,^{1,2} that investigators provide participants with a copy of their consent form,^{1,2} and that privacy and confidentiality be maintained.³⁻⁷ These elements are intended to ensure reasonable disclosure of essential information sufficient to ensure fully informed and voluntary consent. The Council of International Organizations of Medical Sciences (CIOMS) also requires that the consent form state “the reason for considering the individual suitable for research,” which implies disclosure of eligibility criteria (CIOMS guideline 5.1).⁶ In the case of HIV research, some US IRBs and regulatory agencies have interpreted these requirements, particularly the CIOMS guideline,⁵ to imply that if HIV status is a reason for study eligibility, this should be specified on the consent form. These guidelines do not provide guidance on disclosure of sensitive information contained in the consent form.²⁻⁷ The privacy of copies of consent forms given to research participants cannot be guaranteed, however, so if a consent form contained information on HIV status (or other sensitive matters) and a third party deliberately or inadvertently obtained the participant’s copy of the consent document, it would constitute a breach of privacy, and thus of confidentiality. The problem of privacy is compounded in developing countries, where living arrangements and social norms may limit preservation of privacy. Therefore, to minimize risk to research subjects, it would seem prudent, whenever possible, to exclude information on HIV status from copies of consent forms.

Omitting confidential information from a consent form does not imply deception or withholding of information. Rather, it suggests that sensitive information should be conveyed to participants by means other than the formal consent document so that participants can be fully informed but their privacy can be protected. The signed consent form provides evidence that consent was obtained but does not necessarily need to contain all the information conveyed via the consent process *per se*.⁸ For example, information on HIV status could be conveyed by VCT, which can be construed as part of the consent process, and the evidence that relevant information on HIV status was actually conveyed to the participant can be documented in confidential VCT records. This would allow information on HIV status to be omitted from the consent form but provide documentation of communication of HIV status using secure VCT records.

A dilemma arises with studies that require enrollment of participants who are HIV infected or uninfected, and disclosure of HIV status on the copy of a consent form by a statement of study eligibility criteria could potentially cause social harm. For example, if the research enrolled only HIV-positive individuals, disclosure of status on a written document could lead to stigmatization, psychologic distress, intimate partner violence and marital disruption, job discrimination, and other social harms.⁹⁻¹² Moreover, if it was known that a study only enrolled HIV-negative subjects, persons excluded from the investigation at time of screening could, by default, be stigmatized as HIV infected. There is thus a social risk to ineligible nonparticipants, and investigators have a responsibility to such individuals because they initially consented to the screening process. Disclosure of HIV-negative status on consent forms also entails risks to research subjects and their

sexual partners because it could lead to unsafe sexual behaviors (disinhibition) if participants use the consent copy as “proof” of HIV-negative status to negotiate unsafe sex. Moreover, in studies that enroll initially HIV-uninfected individuals, some are likely to become infected during follow-up, but they could continue to use the copy of the original consent as proof of negativity, thus placing their partners at risk for infection. Thus, any disclosure of HIV status on the copy of a consent form entails risk to the subject and to nonparticipants.

We have previously avoided this dilemma by enrolling HIV-positive and HIV-negative subjects into studies and stating this on copies of the consent forms. In many cases, this is required for the research or can be justified if the research might potentially benefit participants irrespective of their HIV status.¹¹ There are situations in which such a procedure would be problematic, however. For example, it would be inappropriate to enroll HIV-negative persons into a study of antiretroviral (ARV) therapy or prevention of mother-to-child HIV transmission (pMTCT), because treatment would be of no benefit and could entail risks to the HIV-negative mothers. To avoid this problem of unmasking HIV status by receipt of care, our pMTCT program provides all women (HIV-positive and HIV-negative) with identical packets of multivitamins, but the packets offered to HIV-positive women also contain nevirapine tablets. Thus, women receiving nevirapine cannot be identified from the medications they receive. ARV therapy cannot be masked in this manner, however, and would require disclosure, at least to household members. Similarly, it would be inappropriate to enroll HIV-positive subjects into a trial of a preventive HIV vaccine if there was no *a priori* evidence that infected individuals might benefit from the vaccine. Thus, blinding of HIV status on the copy of the consent form could not be maintained if the consent form referred specifically to enrollment or exclusion of HIV-infected or HIV-negative subjects as a condition for study eligibility. An alternative might be to allow subjects to discard their copy of the consent form or to voluntarily black out confidential information on HIV status if they considered this information to be potentially stigmatizing. Such voluntary nonacceptance or alteration of a consent form might protect the confidentiality of HIV-positive persons who wish to conceal their status, but the absence of a copy of the consent or a defaced copy could itself be stigmatizing. Conversely, it is unlikely that HIV-negative persons would be motivated to discard or alter a consent form that provided documentary evidence of their uninfected status and, as argued previously, such proof of negativity could be misused and result in social harm.

These concerns are not merely theoretic. As noted previously, we have conducted large-scale population-based HIV research in small rural communities in southwestern Uganda,¹³ where subjects know each other, frequently exchange information, and often share and compare documents such as consent forms. Under these circumstances, we have never disclosed HIV status on consent forms because of concerns over confidentiality. Moreover, when providing VCT, we convey HIV results verbally and do not provide written results to the recipient unless he or she has a specific need for such documentation (eg, for employment) and provides a written request for documentation of HIV status. Our policies on nondisclosure

of HIV status were based on privacy considerations and empiric evidence of potential social harms in Rakai. For example, in a study of marital dissolution, we found that the risk of divorce or separation was significantly increased if women were HIV infected and had received VCT. Also, in HIV-discordant couples, the risk of marital dissolution was markedly higher if the woman was the HIV-infected partner.¹⁴ This strongly suggests that disclosure of HIV results leads to marital disruption. The perception that a partner was HIV infected was a significant risk factor for domestic violence (odds ratio [OR] = 3.7), and infidelity was cited as justifying violence by 60% of male respondents.¹⁵ Similarly, perception of a partner's HIV-infected status is a risk factor for sexual coercion.¹⁶ Focus groups reveal that fear of disclosure of HIV results is a barrier to VCT acceptance, particularly among women (J. Wagman, MHS, personal communication).

We believe that disclosure of HIV status on consent forms could affect the balance of risks and benefits of participation in research. The Belmont Report, which provides the ethical principles for modern medical research, makes beneficence a central consideration (ie, "do not harm and maximize possible benefits and minimize possible harms").¹⁷ We believe that omission of HIV status from copies of the consent form is a precautionary measure consistent with this principle of beneficence because it protects subjects from potential social harms and does not conflict with other Belmont Report principles of respect for persons and justice,¹⁷ even if such an omission is in conflict with regulatory guidelines.

In summary, because the privacy of copies of consent forms given to participants cannot be guaranteed, we believe that the principle of beneficence requires that, whenever possible, sensitive and potentially compromising information on HIV status should not be included in the consent documents, even if HIV status is a criterion for study enrollment.

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