

HEALTH RESEARCH ETHICS IN THE AMERICAS



WELCOME

Friday, August 12, 2003

Dear Participant,

As international research grows and as the number of collaborators increases, there is a corresponding expansion of the need for investigators to attend to issues in human subjects protection and the responsible conduct of science.

These duties are often easy to state – but they can be difficult to comply with, especially when investigators must contend with a broad variety of national and international standards, policies and law. That is, sometimes the rules in one country are different than or in conflict with the rules in another country. Or sometimes one nation permits practices that are forbidden elsewhere. Whose rules rule?

A number of social and institutional resources have evolved to address these issues. The creation of institutional review boards (IRB) or research ethics committees (REC) is a positive and noteworthy attempt to guide human experimentation and surveillance. Government policies, international accords, professional standards and other tools will be essential for the success of the international research enterprise.

Education is as important as any of these tools.

The *Health Research Ethics in the Americas* workshop has been designed for investigators, support staff and scholars involved in international research. The program emphasizes current issues in international research ethics, and attempts to anticipate future challenges. You will be able to compare experiences, share concerns and receive advice from an expert faculty. The workshop is intended to be interactive, and so we emphasize roundtables and seminar-like sessions over formal lectures. Such an environment encourages candid comments, questions and open critique. It is our hope that this program will enhance your ability to identify and address ethical issues in international research. We look forward to working with you

Gail Shor-Posner, Ph.D.
Director / Professor
Miami Fogarty International Training Program

Kenneth W. Goodman, Ph.D.
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The workshop is supported in part by national institute of health (NIH) / Fogarty International Training grant in AIDS and TB (TW00017-16), the NIH under a grant for short-term courses in research ethics (T15HL69787), and NIEHS marine and freshwater biomedical sciences center grant (ES 05705)

Friday, September 12, 2003

Noon – 1:00 Registration

1:00 – 1:30 Welcome & Introduction

*G. Shor-Posner, Ph.D., Director, Miami Fogarty International Training Program in
HIV/AIDS & TB*
K. Goodman, Ph.D., Director, UM Bioethics Program

1:30 – 2:30 Principles of International Research

C. McCoy, Ph.D., Professor, Chairman Department of Epidemiology

2:30 – 3:30 Foundations and History of Human Subject Protection

*A. Brito, M.D., Department of Pediatrics; Member, National Bioethics Advisory
Commission*

3:30 – 3:45 Break

3:45 – 5:00 "*Desafíos en Investigaciones*" Challenges in Investigations

INTERACTIVE DISCUSSION PANEL

M.J. Miguez, M.D., Ph.D., Moderator, Department of Psychiatry & Behavior Sciences
A. Brito, M.D., Panelist, Department of Pediatrics
S. Litewka, M.D., M.P.H, Panelist, Visiting Professor in UM Ethics Programs
R. Mendoza, Psychologist, Panelist, Fogarty In-Country Trainee – Dominican Republic

5:00 – 7:00 Dinner and Dialogues

Batchelor Children Research Institute Building, Conference Room 206
Building directly north of the Lois Pope LIFE Center

Saturday, September 13, 2003

7:30 – 8:30 Registration and Breakfast

8:30 – 9:30 Universal Values, Local Applications

K. Goodman, Ph.D., Director, UM Bioethics Program

9:30 – 10:30 International Agreements

S. Litewka, M.D., M.P.H., UM Ethics Program

10:30 – 10:45 Break

10:45 – noon Research Challenges in Africa, South America, and the Caribbean

INTERACTIVE DISCUSSION PANEL

G. Shor-Posner, Ph.D., Moderator, Department of Psychiatry & Behavior Sciences

W. Duke, Ph.D., Panelist, Fogarty In-Country Trainee – Dominican Republic

V. Mulenga, M.D., Panelist, Fogarty Trainee – Zambia, Africa

N. Persaud, M.D., M.P.H., Panelist, Fogarty In-Country Trainee - Guyana

S. Weiss, Ph.D., Panelist, UM Vice-Chair of Research, Psychiatry & Behavioral Sciences

Noon – 1:00 Lunch

Batchelor Children Research Institute Building, Conference Room 206
Building directly north of the Lois Pope LIFE Center

1:00 – 2:00 Ethical Issues in Vaccine Research

M.J. Miguez, M.D., Ph.D., Department of Psychiatry & Behavioral Sciences

R. Campo, M.D., Department of Medicine Adult HIV Service

2:00 – 3:00 Challenges in Pediatric Research

C. Mitchell, M.D., Department of Pediatrics, Immunology / Infectious Diseases

3:00 – 3:15 Break

3:15 - 4:30 Conducting Research Across the Lifespan

INTERACTIVE DISCUSSION PANEL

G. Scott, M.D., Moderator, Department of Pediatrics, Director, Immunology / Infectious Diseases

M. Hernandez-Rief, Ph.D., Department of Pediatrics, Co-Director Touch Research

E. Perez-Then, M.D., M.P.H., Fogarty Trainee – Dominican Republic

C. Williams, DNSc, RN, BC, UM School of Nursing

UNIVERSITY OF MIAMI ETHICS PROGRAM

The Bioethics Program, the Pan American Bioethics Initiative and the Program in Business, Government and Professional Ethics are university-wide efforts dedicated to education, research and community service. Established in 1992, the Programs have jointly emerged as a leading ethics center.

EDUCATION: Program faculty conduct or help conduct courses, seminars, conferences and symposia at all three University of Miami campuses and throughout the region. On the Medical Campus, for instance, Ethics Program faculty share responsibility for education of medical and science graduate students. UM faculty conduct training sessions and provide ethics education and consulting services to health, business and government organizations throughout the region. In April 2004, the Forum will host its 12th annual "Clinical Ethics: Debates, Decisions, Solutions" conference, a gathering of health and legal professionals, clergy and others that appears to be the largest community (as opposed to professional) gathering of its kind in the United States. Ethics courses and other activities are offered through the university's Schools of Medicine, Business, Arts & Sciences, Nursing and International Studies, and numerous special programs. The Programs' privacy web site (<http://privacy.med.miami.edu>) is acknowledged as a national leader. Spring 2004 will see the Programs coordinate UM's first course in environmental ethics.

RESEARCH: The Ethics Programs are internationally recognized for research and publications in ethics and computing, business, bioethics, privacy, law, public health and epidemiology, and occupational and environmental health. Numerous research projects are available to UM students. Current interests and opportunities include, projects in computing and society, genetics, privacy, human subjects research, and immigration and health care. Recent publications have addressed issues in medical computing, evidence-based medicine, genetics, end-of-life care, and the legislative process. Additionally, the Ethics Programs coordinate Summer Ethics Internships in which, philosophy and other students, work on special projects in applied ethics.

COMMUNITY PROGRAMS AND SERVICE: The UM Ethics Programs collaborate with a variety of community, government, religious and other organizations. Faculty provide or have provided expertise to the University itself (through numerous ethics committees and special projects), the State of Florida (through the Florida Legislature, Florida Bioethics Network, Department of Corrections, Division of Children and Families and Department of Health), U.S. Government (through the Centers for Disease Control and Prevention and, via the Institute of Medicine, to the U.S. Armed Forces), and Miami-Dade County (through the Circuit Courts, the Alliance for Ethics and Government, Dade County Public Schools, etc.). The programs provide speakers for a broad array of professional, service, religious, educational and other community groups and organizations.

For more information about UM's Ethics Programs, visit <http://www.miami.edu/ethics>, email ethics@miami.edu or phone 305-243-5723.

FOGARTY INTERNATIONAL TRAINING PROGRAM

The Fogarty International Center (FIC) AIDS & TB International Training and Research Program at the University of Miami School of Medicine is a special program funded by the Fogarty International Center of the National Institutes of Health (NIH). Awarded in September of 1988, the FIC program is designed to assist investigators from developing countries who have an advanced academic degree in HIV/AIDS and/or TB related research/training and to facilitate international collaborative interaction between the HIV/AIDS and/or TB researchers at the University of Miami and foreign institutions.

The geographical focus of the University of Miami FIC program includes the developing nations, primarily in Latin America, Central America and the Caribbean (including Puerto Rico, and the U.S. Virgin Islands). The faculty in the School of Medicine, Department of Epidemiology and Public Health, the Department of Psychiatry and the Comprehensive Drug Research Center actively participate in the FIC activities. The three major areas designed to prepare individuals to conduct significant research in HIV/AIDS and/or TB is: Clinical science (biomedical research), epidemiology and prevention, and behavioral research. The Director of the Fogarty International Center Training in AIDS and TB at the University of Miami-School of Medicine, Division of Disease Prevention, Department of Psychiatry and Behavioral Sciences is Professor Gail Shor-Posner.

The University of Miami-School of Medicine is one of the world's leading research and educational institutions. The school of medicine research community has a long history of academic training in the biomedical sciences and all aspects of clinical medicine. Multidisciplinary HIV/AIDS and/or TB programs are available in immunology, virology, epidemiology and behavioral sciences. An important tradition at the school of medicine is the continuing dialogue between clinical and basic scientists, which along with the quality of research, commitment to training, availability of research funding and physical resources, has resulted in various productive international collaborations.

The Fogarty International Training and Research in AIDS and/or TB Programs provides opportunities for instruction, and long- and short-term collaboration between the school of medicine investigators and colleagues in developing countries.

This program supports only research and training related to HIV/AIDS and/or TB. Candidates are generally required to hold an advanced degree (MD, PhD, DDS, DrPH, DVM, or equivalent degree) before the beginning date of their appointment. Consideration is occasionally given to individuals with a bachelor's or master's degree in a relevant field as well as to health care workers. Applicants should have worked in an AIDS and /or TB related research programs in their home countries and must demonstrate a sincere intention to return to their home countries following their training.

For more information on the University of Miami Fogarty International Training Program log onto www.med.miami.edu/psychiatry/fogarty.html.
