

Extreme Ethics:

*Unusually Difficult
Challenges in
Epidemiology and
Human Subjects
Research*

October 12-14, 2000
Hyatt Regency Miami
Knight Conference Center
Miami, Florida



ETHICS PROGRAMS

Supported by a grant from the National Institutes of Health

Speakers and Program

THURSDAY, OCTOBER 12

5:30 p.m. Registration, Dinner Reception

6:30 – 7:30 p.m. Dinner Presentation
Genetics, Computing and Ethics:
Some Problems for the Next Few Hundred Years

Kenneth W. Goodman, Ph.D.

The intersection of three broad areas of inquiry – genetics, computer science and bioethics – promises to invigorate scientific and public debate for the foreseeable future. Scientists, clinicians, policy makers and others need to have a better understanding of the utility of bioethics to address new and unfamiliar problems, conflicts and challenges.

FRIDAY, OCTOBER 13

7:45 – 8:40 a.m. Registration, Continental Breakfast

8:40 – 8:45 a.m. Introduction and Welcome

8:45 – 10:00 a.m. Good Intentions, Bad Outcomes:
History and Key Concepts of Human-Subject Research Ethics

Arturo Brito, M.D.

Most problematic research and inappropriate scientific behavior are conducted by well-meaning people who are either ignorant of rules and regulations, or who are trying to follow regulations that are vague, inapplicable or otherwise inadequate to the task. While ignorance might be blameworthy, a greater challenge occurs in trying to hew to old rules in the face of new science.

Tough Calls: The Role of IRBs in Evaluating Ethically Challenging Protocols

Jay M. Sosenko, M.D., M.S.

Responsibility for protecting subjects and participants in research falls to institutional committees that are often overworked, undertrained and overwhelmed by challenges shaped by scientific and moral conflict. When especially difficult research requires IRB evaluation, how should these committees rise to the occasion?

10:00 – 10:45 a.m. Case Studies, Breakout Sessions

10:45 – 11 a.m. Break

11 a.m. – 12:15 p.m. Social Goals of Public Health Research

Jeffrey P. Brosco, M.D., Ph.D.

The very act of choosing to study one problem and not another is shaped by often unarticulated assumptions which are sometimes, perhaps often, related to class, political goals and other “nonscientific” criteria.

Scientists as Advocates for Social Policies

Lee Crandall, Ph.D.

When an investigator believes, by virtue of her research, that a particular approach will best redress a social or health problem, should she become an advocate for that approach? To fail to use one’s scientific findings to help humanity engenders doubt about the very point of the research enterprise. Yet, to enter public discourse with a position on a contentious issue is to risk allegations of conceptual or political conflicts of interest.

12:15 – 1:00 p.m. Case Studies, Breakout Sessions

1:00 – 2:30 p.m. Lunch

2:30 – 3:45 p.m. Ethics and Biostatistics

Robert C. Duncan, Ph.D.

The intersection of ethics and biostatistics is fertile ground for exploration and education. This is fortunate in that investigators need to be clearer about ethical issues raised by statistical analysis, and IRBs and other entities must evaluate a number of study features – perhaps especially risk to subjects – based on probabilistic data.

Data Sharing and Proprietary Interests in Bioinformatics

Kenneth E. Rudd, Ph.D.

The growth of computational genomics, including structural genomics, has seen extraordinary conflict over data sharing and dissemination. Trying to balance the social need for open communication and the claims of those who seek to recoup investment in crucial research is proving to be one of the most difficult tasks in contemporary science.

3:45 – 4:30 p.m. Case Studies, Breakout Sessions

SATURDAY, OCTOBER 14

8:30 – 9:00 a.m. Continental Breakfast

9:00 – 10:15 a.m. Research in Genetically Isolated Communities

Lisa L. Baumbach, Ph.D.

While the challenges of genetic research are increasingly well known, much less is understood about the duties of investigators who seek out groups that are distinct by virtue of geography, race or ethnicity.

Ethical Issues in Occupational and Environmental Health

Lora Fleming, M.D., Ph.D.

Ethical issues raised by workplace health services and research provide an exciting and too-little explored opportunity for education and analysis.

10:15 – 11:00 a.m. Case Studies, Breakout Sessions

11:00 – 11:15 a.m. Break

11:15 a.m. – 12:15 p.m. Synthesis and Summary

Arturo Brito and Kenneth W. Goodman

12:15 p.m. Adjournment and Evaluations

PROGRAM NOTE

The “case study, breakout sessions” are roundtable sessions at which small groups of participants will join faculty members in discussing and debating cases related to the presentations.

Accreditation

The University of Miami School of Medicine is accredited to sponsor continuing medical education for physicians.

Faculty Disclosure

The University of Miami School of Medicine, in accordance with accreditation requirements, will disclose any significant financial interest or other relationship with manufacturer(s) of any commercial products(s) and/or provider(s) of commercial services discussed in an educational presentation and with any commercial supporters of the activity.

Credit Hours

The University of Miami School of Medicine designates this educational activity for a maximum of 10 hours in category 1 credit towards the AMA Physician's Recognition Award. Each physician should only claim those hours of credit that he/she actually spent in the educational activity.

Psychologists

The University of Miami School of Medicine is an APA approved internship program. This program is acceptable for a maximum of 10 credit hours for Florida psychologists.

Course Description

This course will feature review and discussion of issues for which standard models of valid consent and scientific practice may be inadequate and for which too little attention has been devoted in research and the literature.

Objectives

By the end of this short course, participants will be better able to:

- Identify core ethical issues in epidemiology and human subjects research
- Articulate ethically optimized strategies for addressing these issues
- Identify exceptionally difficult or unusual problems
- Articulate ethically optimized strategies for addressing them

Audience

This course is appropriate for those who conduct or oversee epidemiologic or human subjects research, including physicians, nurses, scientists, administrators, lawyers and others.

Course Directors

Kenneth W. Goodman, Ph.D.

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Registration Form

Please complete this form and mail it with check, money order or credit card information to UM Division of CME, P.O. Box 016960 (D23-3), Miami, FL 33101 (fax 305-243-5613). Or see our Web sites, <http://cme.med.miami.edu> and www.miami.edu/ethics. For more information, contact the Division of CME, 305-243-6716, or the Ethics Program at 305-243-5723, ethics@miami.edu

Name _____

Degree(s) _____

Title/Organization _____

Specialty _____

Address _____

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Phone _____ Fax _____

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Credit Card _____ Card Number _____

Expiration Date _____ Signature _____

Course Tuition

\$95.

Tuition includes admission to program sessions, meals and breaks and course syllabus. Refunds will be made only if written notice of cancellation is received before October 1, 2000.

Accommodations

Hyatt Regency Miami, 400 SE Second Avenue, Miami, FL 33131

Telephone: 305-358-1234, Fax: 305-679-3294, Reservations Direct: 1-800-233-1234

The Hyatt Regency Miami adjoins the Knight Conference Center in the heart of downtown Miami and overlooks the Miami River. This hotel is ten minutes from Miami International Airport and one block from the Miami business district and downtown shopping such as Bayside marketplace on Biscayne Bay. Additional Hyatt amenities include outdoor heated swimming pool, health facility and the River Walk Restaurant open for breakfast, lunch and dinner.

A block of rooms has been reserved for program attendees at the Hyatt Regency Miami. Reservations must be received by September 13, 2000. After September 13, 2000, reservations will be confirmed on a space and rate availability basis.

Special daily rate for this meeting is: \$150 Single or Double Occupancy, plus tax (one night's deposit is required).

Services for the Disabled

Please contact the Division of CME at 305-243-6716 prior to September 13, 2000, if you have any special needs that may require additional assistance.



Ethics Programs
P.O. Box 016960 (M-825)
Miami, FL 33101

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