Extreme Ethics: Unusually Difficult Challenges in Epidemiology and Human Subjects Research

October 18-20, 2001
Sheraton Biscayne Bay Hotel
Miami, Florida

Supported by a grant from the National Institutes of Health
Never before in the health sciences have so many investigators been scrutinized and challenged on so many issues with such intense passion – and such high stakes. From the laboratory to the evening news, the growth of biomedical science is reshaping our sense of public duty and broadening our responsibilities to science and society. This NIH-supported program reviews the foundations of institutional review of human subjects research and explores an ensemble of exceptionally difficult and under-addressed issues in this domain, as well as in epidemiologic and public health research. The course is suitable for physicians, scientists, nurses, public health practitioners, IRB members and others interested in these issues.
Speakers and Program:
Day One

**Foundations: Elements of High Quality IRB Scrutiny**

**THURSDAY, OCTOBER 18**

<table>
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<th>Time</th>
<th>Event</th>
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<tr>
<td>8:30 – 8:50 a.m.</td>
<td>Registration</td>
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<td>8:50 – 9:00 a.m.</td>
<td>Welcome and Introductions</td>
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<td>Kenneth W. Goodman, Ph.D., UM Ethics Programs, Program Chair</td>
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<td>9:00 – 10:00 a.m.</td>
<td>Alright, Pal – Put Your Hands in the Air and Step Away from that Protocol: The IRB as Cop in a Shifting Legal Framework</td>
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<td>Mike Novo, J.D., assistant general counsel, UM School of Medicine</td>
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<td>10:00 – 11:00 a.m.</td>
<td>Genetics Research and Special Populations</td>
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<td>Stephanie Anderson, M.D., J.D.</td>
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<td>Third District Court of Appeal and University of Miami Ethics Program</td>
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<td>11:00 – 11:15 a.m.</td>
<td>Break</td>
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<td>11:15 a.m. – 12:15 p.m.</td>
<td>Financial, Political and Social Conflicts of Interest</td>
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<td>Robin N. Fiore, Ph.D., Department of Philosophy, Florida Atlantic University</td>
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<td>12:15 – 1:15 p.m.</td>
<td>Lunch</td>
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<td>1:15 – 2:15 p.m.</td>
<td>What HIPAA Will Mean for Researchers and IRBs</td>
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<td>Anita Cava, J.D., UM Department of Business Law</td>
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<td>2:15 – 3:15 p.m.</td>
<td>Valid Consent: Foundations and Frustrations</td>
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<td>Charles M. Culver, M.D., Ph.D., Barry University</td>
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<td>3:15 – 4:00 p.m.</td>
<td>Adjournment and Evaluation</td>
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**Program Note:**
The Day 1 workshop, comprising 5 contact hours, is available as a stand-alone program; see the Registration Form for tuition options. Attendance at this workshop meets University of Miami requirements for initial education in human subjects research.
THURSDAY, OCTOBER 18
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 19
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.

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.

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.

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?

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

SATURDAY, OCTOBER 20
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. and Robin N. Fiore, 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 by the Accreditation Council for Continuing Medical Education (ACCME) 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. Presenters will also disclose off-labeled or investigational use of a product.

Credit Hours
Physicians
The University of Miami School of Medicine designates the Extreme Ethics Program for a maximum of 10 hours and the workshop on Elements of High Quality IRB Scrutiny for a maximum of 5 hours in category 1 credit towards the AMA Physician’s Recognition Award. Each physician should claim only those hours of credit that he/she actually spent in the educational activity.

Nurses
This program meets the criteria for 15 contact hours for nurses. CEUs will be awarded through the University of Miami School of Nursing (FSBN) Provider #FBN3066.

Psychologists
The University of Miami School of Medicine is an APA approved internship program. This program is acceptable for a maximum of 15 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.
Arturo Brito, M.D.
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Email: ethics@miami.edu
Please complete this form and mail it with check or money order (payable to UM Ethics Programs) or credit card information (MC, Visa, Discover) to UM Division of CME, P.O. Box 016960 (D23-3), Miami, FL 33101; fax: 305-243-5613.

Name __________________________________________________________

Degree(s) _______________________________________________________

Title/Organization ______________________________________________

Specialty ________________________________________________________

Address _________________________________________________________

City, State, Zip __________________________________________________

Phone __________________________ Fax ____________________________

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Credit Card ___________________ Card Number ______________________

Expiration Date ___________ Signature ______________________________

**Course Tuition**

Day 1: $75. Days 2-3: $95. Both programs: $150. Tuition includes admission to program sessions, course syllabus and meals and breaks. Thursday dinner is reckoned as part of Days 2-3. Refunds will be made only if written notice of cancellation is received before October 7, 2001.

**Accommodations**

Sheraton Biscayne Bay, 495 Brickell Avenue, Miami, FL 33131
Telephone: 305-373-6000; 800-325-3535; Fax: 305-374-2279

The Sheraton Biscayne Bay is conveniently located just south of downtown Miami in the thriving Brickell section, just 10 minutes from Miami International Airport, adjoining the Miami Circle archaeological site and minutes from shops and fine restaurants.

A bloc of rooms has been reserved for program attendees at a special daily rate of $119, single or double occupancy. For reservations, call the Sheraton Biscayne Bay directly and identify yourself as an ethics conference attendee. Reservations received after September 17, 2001, are subject to availability.

**Services for the Disabled**

Please contact the Division of CME at 305-243-6716 prior to September 19, 2001, if you have any special needs that may require additional assistance.
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Dated Material