

# *Extreme Ethics:*

*Unusually Difficult Challenges in  
Epidemiology and Human Subjects Research*

October 24-26, 2002  
Sheraton  
Biscayne Bay Hotel  
Miami, Florida

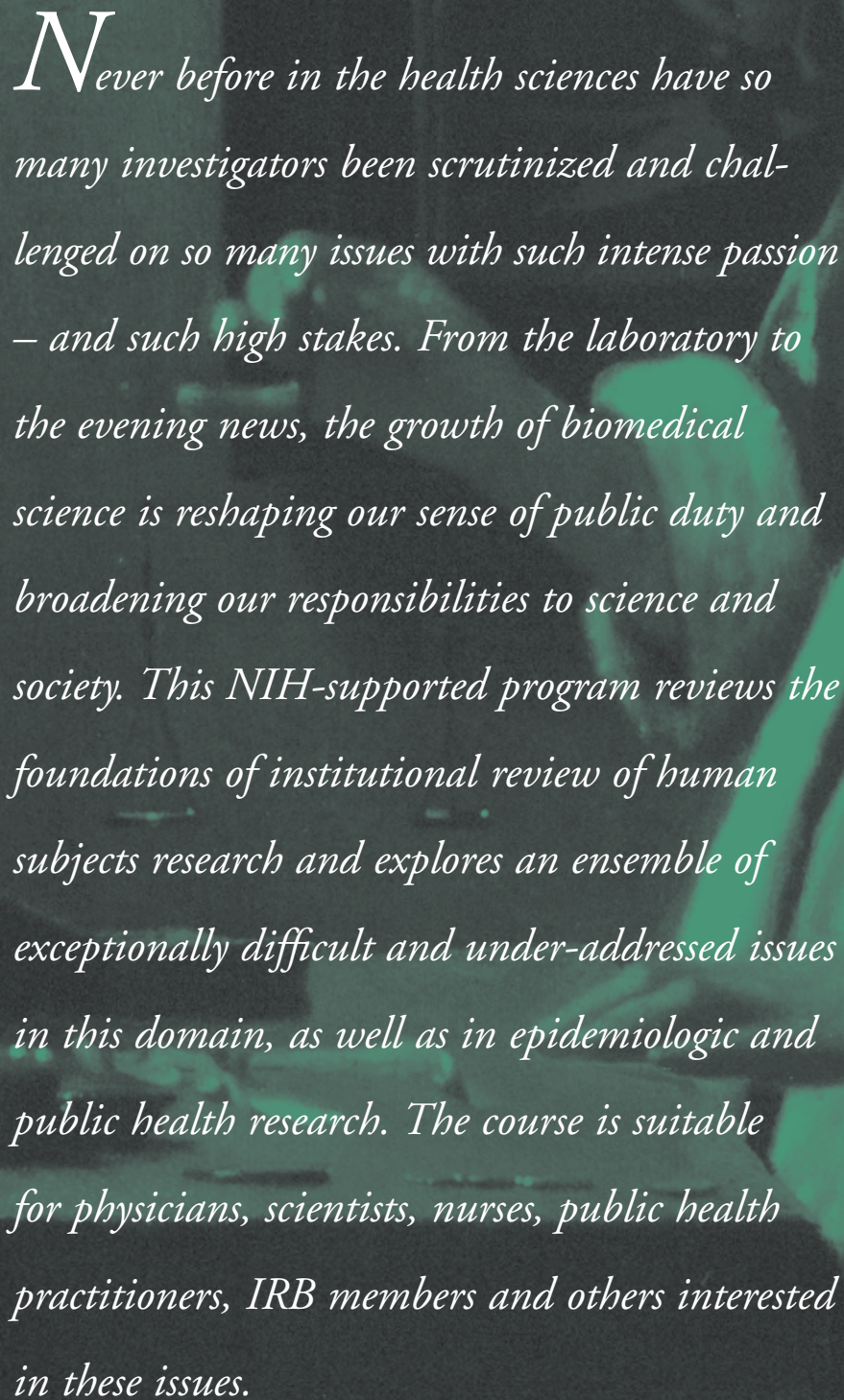
*Including  
The Popular  
“IRB Foundations”  
Workshop*



UNIVERSITY OF  
**Miami**

ETHICS PROGRAMS

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 24

**8:00 – 8:50 a.m.**  
**Registration**

---

**8:50 – 9:00 a.m.**  
**Welcome and Introductions**  
Kenneth W. Goodman, Ph.D., UM Ethics Programs, Program Chair

---

**9:00 – 10:00 a.m.**  
**Alright, Pal – Put Your Hands in the Air and Step Away from that Protocol:  
The IRB as Cop in a Shifting Legal Framework**  
Mike Novo, J.D., Assistant General Counsel, UM School of Medicine

---

**10:00 – 11:00 a.m.**  
**Genetics Research and Special Populations**  
Stephanie Anderson, M.D., J.D.  
Third District Court of Appeal and University of Miami Ethics Programs

---

**11:00 – 11:15 a.m.**  
**Break**

---

**11:15 a.m. – 12:15 p.m.**  
**Financial, Political and Social Conflicts of Interest**  
Robin N. Fiore, Ph.D., Department of Philosophy, Florida Atlantic University

---

**12:15 – 1:15 p.m.**  
**Lunch**

---

**1:15 – 2:15 p.m.**  
**What HIPAA Will Mean for Researchers and IRBs**  
Anita Cava, J.D., UM Department of Business Law

---

**2:15 – 3:15 p.m.**  
**Valid Consent: Foundations and Frustrations**  
Charles M. Culver, M.D., Ph.D., Barry University

---

**3:15 – 4:00 p.m.**  
**Adjournment and Evaluation**

**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.*

## **Speakers and Program: Opening Reception, Day Two and Day Three**

### **THURSDAY, OCTOBER 24**

**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 25**

**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.

---

**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.

---

**10:00 – 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 26**

**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.

---

**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.

---

**10:15 – 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.

### Psychologists

The University of Miami School of Medicine is an APA approved internship program. This program is acceptable for a maximum of 15 CEUs 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.

University of Miami

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

Telephone: 305-243-5723, Fax: 305-243-6416, Pager: 305-839-1170

Email: [ethics@miami.edu](mailto:ethics@miami.edu)

# Registration Form

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.

See our Web Sites for a printable registration form:

<http://cme.med.miami.edu> or <http://www.miami.edu/ethics>

Name \_\_\_\_\_

Degree(s) \_\_\_\_\_

Title/Organization \_\_\_\_\_

Specialty \_\_\_\_\_

Address \_\_\_\_\_

City, State, Zip \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

E-mail \_\_\_\_\_

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 15, 2002.

## Accommodations

Sheraton Biscayne Bay, 495 Brickell Avenue, Miami, FL 33131

Telephone: 305-373-6000; Toll Free: 866-MIAMI-4U (866-642-6448); 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 block of rooms has been reserved for program attendees at a special daily rate of \$99, single or double occupancy. For reservations, call the Sheraton Biscayne Bay directly and identify yourself as an ethics conference attendee.

Reservations received after September 23, 2002, are subject to availability.

## Services for the Disabled

Please contact the Division of CME at 305-243-6716 prior to September 23, 2002, if you have any special needs that may require additional assistance.

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

Presort First Class  
US Postage  
PAID  
Miami, FL  
Permit No. 438

**Extreme Ethics**

October 24-26, 2002  
Sheraton  
Biscayne Bay Hotel  
Miami, Florida

**Dated Material**