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Upcoming Educational Workshops

March 29, 2003
Town and Country Resort & Convention Center
San Diego, California

7:30AM - 8:30AM Registration & Continental Breakfast

8:30AM - 5:00PM Workshops begin

Sponsors

Public Responsibility in Medicine and Research (PRIM&R)
 Applied Research Ethics National Association (ARENA)

Learn more about these March 2003 educational workshops.
 Click the links below for course descriptions and agendas.

[HIPAA 101](#)

[IACUC 101](#)

[RCR 101](#)

IACUC 101 CLOSED*

*Contact Bridget for information regarding a waiting list. (bgardner@primr.org or 617.423.4112)

Overview: ARENA IACUC 101 is a full day didactic and interactive training course for new as well as seasoned IACUC members, IACUC affiliates including IACUC administrators, trainers, veterinarians, animal care staff, researchers, regulatory personnel, individuals responsible for their institution's animal care program and others interested in IACUC roles and responsibilities. The program, sponsored by ARENA, OLAW, and the University of California at San Diego, is delivered by a top-notch faculty renowned for their expertise in institutional animal care and use issues and program development including representatives from both private and academic biomedical research institutions as well as the AAALAC, USDA and OLAW.

Content: The morning and early afternoon sessions will provide a basic yet comprehensive overview of the laws, regulations, and policies that govern the humane care and use of laboratory animals supplemented with examples and possible approaches for successful and effective administration. Current available resources to help IACUCs keep abreast of the latest information as well as take advantage of networking opportunities will also be covered. The materials and information provided during the course will be applied during the later afternoon session when students will be challenged to consider, deliberate and develop action plans for a variety of potential IACUC scenarios. Students receive an extensive resources manual as well as copies of relevant laws, regulations, policy and guides.

AGENDA

Saturday, March 29, 2003 7:30 AM - 5:00 PM

7:30 AM	Registration and Continental Breakfast
8:30	Introduction
8:45	Historical Perspectives
9:15	Key Components
9:45	Q & As
9:55	Break
10:10	IACUC Functions
10:40	Q & As
10:50	Program Evaluations and Inspections
11:35	Q & As
11:45	Lunch
12:45 PM	Written Q & As OLAW; USDA, AAALAC
1:00	Protocol Review
1:45	Q & As
1:55	Personnel Qualifications & Training
2:25	Q & As
2:35	Break
2:50	Scenario Shorts Mock IACUC Deliberations Faculty and Mentors
3:40	Scenario Shorts Responses - OLAW; USDA, AAALAC
4:30	Final Q & As, Evaluation Forms and Attendance Certificates

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RCR 101

RCR 101 is a one-day workshop on developing programs of instruction in responsible

conduct of research (RCR). The focus of RCR 101 is to review and discuss the goals, content, format, and tools for instruction for all of the core areas of normative behavior in science. The workshop includes experience with a variety of useful methods and tools. A demonstration lecture will be presented during the workshop to illustrate one approach to teaching about the responsible conduct of research. On completion of RCR 101, participants should be prepared to implement a practical and effective program of RCR instruction for their home institutions. The primary audience for this workshop is the scientists, bioethicists, educators, and administrators responsible for developing or teaching RCR courses.

On completion of RCR 101, participants will be able to:

- Articulate the purpose of having an effective RCR instruction program
- Describe topics to be covered in a program of effective RCR instruction
- Identify and explain advantages and disadvantages of different formats and tools for RCR instruction
- Find additional resources to develop and refine programs of RCR instruction
- Implement a practical and effective program of RCR instruction

Faculty:

Mike Kalichman, Ph.D.,
Department of Pathology and Research Ethics Program
University of California
San Diego, CA

Francis Macrina, Ph.D.,
The Philips Institute of Oral and Craniofacial Molecular Biology
Virginia Commonwealth University

AGENDA

Saturday, March 29, 2003 7:30 AM - 4:30 PM

7:30 AM **Registration and Continental Breakfast**

8:30 - Lecture

12:00

Introduction *Frank Macrina*

8:30

Goals *Mike Kalichman*

8:45

Content *Mike Kalichman*

9:15

Formats *Frank Macrina*

9:45

Break

10:15

Tools *Frank Macrina*

10:30

Case Studies *Frank Macrina*

11:30	Working Lunch
12:00 - 1:30	Research with Animal Subjects <i>Frank Macrina</i>
	Practicum
12:30 PM	Video <i>Frank Macrina</i>
1:30 - 4:00	Role Playing and Narrative Ethics <i>Frank Macrina</i>
1:30	Break
2:00	Surveys <i>Mike Kalichman</i>
2:30	Getting a Program Started <i>Mike Kalichman</i>
2:45	Open Questions, Conclusion <i>Mike Kalichman, Frank Macrina</i>
3:15	<u>Back to Top</u>
3:30	

COLLABORATIVE WORK

Mike Kalichman and Frank Macrina began collaborating in teaching responsible research conduct in 1993. Mike's publication reporting survey research on scientific misconduct (Kalichman and Friedman, 1992) opened communication between the two. Frank began using a version of Mike's survey as a teaching tool in his course and the two began working together to develop specialized surveys to probe attitudes about research behavior. The Kalichman and Friedman survey was an appendix in the first edition of Scientific Integrity text authored by Frank.

Mike and Frank served together on a 1997 National Academy of Sciences panel charged to consider how best to teach responsible conduct in science. In 1998, they created a workshop on authorship that was presented at a national conference on managing biomedical research laboratories co-sponsored by the University of Arizona and the US DHHS Office of Research Integrity. In 1999, they worked together as invited faculty to present a series of talks at a national meeting on teaching RCR sponsored by PRIM&R. The focus of these presentations was on course content and evaluation. Again in 1999, they presented a workshop on authorship to faculty and trainees at Virginia Commonwealth University. This workshop included conducting a VCU faculty-wide survey and analyzing the results, which were presented at the workshop.

Currently, Frank serves as a consultant to Mike on an ORI-sponsored project to build a Web site for RCR teaching resources. For the past three years, Frank and Mike have run their scientific integrity courses in parallel allowing discussion of cases between their trainees via e-mail. Mike has visited Richmond under the aegis of an endowed Sanger Professorship and given lectures in the VCU scientific integrity course. Finally, for the second edition of Frank's book Scientific Integrity, Mike wrote a section on the use of surveys for RCR instruction, included a collection of sample surveys.

Frank Macrina and Mike Kalichman are both receiving extramural funding for research on RCR. They began co-teaching the RCR 101 workshops in May of 2001.

HIPAA 101

Overview: The Health Insurance Portability and Accountability Act (HIPAA) and its accompanying Privacy Rule will require a number of changes in the every day business of healthcare. While the majority of these changes focus on the myriad activities that directly influence the provision of patient care, there are many that will have significant effects on the conduct of human subject research. The "covered entity," in consultation with the Institutional Review Board (IRB)/Privacy Board, will be responsible for implementing those changes relevant to research. Education on the issues related to HIPAA is necessary in order to ensure successful implementation. HIPAA 101 is geared toward those leading and administering human research protection programs and IRBs, as well as those involved in the conduct of human subjects research.

Content: This conference will provide an overview of the Privacy Rule with specific attention to the impact on research and what the covered entity/IRB must do to be in compliance with the Rule. Specific topics will include: background and history of HIPAA, key concepts for successful HIPAA compliance, identifiability, individual rights, limited data sets, authorization and how it relates to informed consent, waiver of authorization, new subject's rights provided by the Rule, and specific concerns for IRBs.

Faculty:

Mark Barnes, J.D., L.L.M.
Ropes & Gray
New York

P. Pearl O'Rourke, M.D.
Director, Human Research Affairs
Partners Healthcare System

Ada Sue Selwitz, M.A.
Director, Office of Research Integrity
University of Kentucky

AGENDA

Saturday, March 29, 2003 7:30 AM - 4:30 PM

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| 7:30 AM | Registration and Continental Breakfast |
| 8:30 | Welcome and Workshop Overview |
| 8:45 | HIPAA Nuts and Bolts I
<i>Pearl O'Rourke, M.D.</i> |
| 10:30 | Break |
| 10:45 | What Type of Covered Entity Are You?
<i>Mark Barnes, J.D.</i> |
| 11:15 | Helping IRBs Get Ready for April |
| 12:30 PM | <i>Ada Sue Selwitz, M.A.</i> |
| 1:45 | Lunch |

2:45 **Case Studies for Applying HIPAA Requirements to Clinical Trials and Epidemiological Research** *Pearl O'Rourke, M.D., Ada Sue Selwitz, M.A., Mark Barnes, J.D.*

3:00 **Break**

4:00 **Case Studies for Applying HIPAA Requirements to Clinical Trials and Epidemiological Research** *Pearl O'Rourke, M.D., Ada Sue Selwitz, M.A., Mark Barnes, J.D.*

4:30 **Question & Answer**

Adjournment

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126 Brookline Avenue, Suite 202, Boston, MA 02215, USA
(Phone) 617.423.4112 | (Fax) 617.423.1185 | (E-mail) info@primr.org

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