Day 1: Wednesday, March 21, 2012

7:00 AM – 8:15 AM  Registration and Continental Breakfast

8:15 AM – 8:45 AM  Welcome and Introduction

**Linda Birnbaum, PhD, DABT, ATS**
Director, National Institute of Environmental Health Sciences and National Toxicology Program Division

**Nancy McFarlane** (Tentative)
Mayor of Raleigh, North Carolina

**Fred Miller, MD, PhD**
Acting Director, National Institute of Environmental Health Sciences Clinical Research Program and Principal Investigator, Chief of Environmental Autoimmunity Group at National Institute of Environmental Health Sciences

8:45 AM – 9:45 AM  Keynote Address: Defining the Spectrum of Community Engaged Research: What it is? Who are the stakeholders and their roles, and Discussion of Ethical Considerations?

**Keith Norris, MD**
Professor of Medicine, Departments of Internal Medicine, Charles Drew University of Medicine and Science and holds a dual appointment at the David Geffen School of Medicine at UCLA

9:45 AM – 10:00 AM  Networking and Refreshment Break

10:00 AM – 11:15 AM  Plenary Session: Does the Belmont Report Provide Considerations for Community Risks and Benefits?

**Bob Levine, MD**
Professor of Medicine, Yale School of Medicine, Executive Committee Chair, Yale Interdisciplinary Center for Bioethics, Director, Law, Policy and Ethics Core, CIRA

**Nancy Shore, PhD, MSW, MPH**
Assistant Professor, University of New England, School of Social Work

11:15 AM – 12:30 PM  Plenary Session: The Role of IRB’s in Reviewing Community – Engaged Research

**Ivor Pritchard, PhD**
Acting Director, Department of Health and Human Services – Office for Human Research Protections

**Julia Brody, PhD**
Executive Director, Silent Spring Institute
### Native American Considerations in Community Engaged Research

**Johnneye Lewis, PhD, DABT**  
Research Professor, Director, Community Environmental Health Program,  
Department of Pharmaceutical Sciences, University of New Mexico

**Ronny Bell, PhD**  
Professor, Department of Epidemiology & Prevention,  
Division of Public Health Science, Wake Forest University School of Medicine

### Afternoon A: Break-Out Sessions

#### A1 – Panel: Community Engaged Research Community Engaged Research in the Era of Genomics

**Josyf Mychaleckyi, MA, Dphil** (Associate Professor, Public Health Sciences, University of Virginia School of Medicine);  
**Greg Hawkins, PhD** (Associate Professor, Wake Forest School of Medicine);  
**Misha Angrist, PhD** (Assistant Professor of the Practice, Institute for Genome Sciences & Policy, Duke University)

#### A2 – Working With Local IRBs in International Research

**Dave Borasky, MPH, CIP** (RTI International);  
**Ruth Ellis, MD, MPH** (National Institute of Health/National Institute of Allergy and Infectious Diseases)

#### A3 – Protecting Communities from Harm: Data Security in the Digital Age

**Wendy Visscher, PhD, MPH** (Senior Advisor & Privacy Officer, Office of Research Protection, RTI International);  
**Mark Koyanagi** (RTI International);  
**Dan Nelson, MS** (Professor, Social Medicine, Adjunct Professor, Pediatrics, Director, Office of Human Research Ethics, The University of North Carolina at Chapel Hill)

#### A4 – Evaluating Psychological, Social, or Legal Risks in Community Engaged Research: How Do We Protect Communities From Exploitation?

**Donna Chen, MD, MPH** (Assistant Professor, Department of Public Health Sciences, Department of Psychiatric Medicine & Center Biomedical Ethics, University of Virginia School of Medicine);  
**Lois Shephard, JD** (Associate Professor of Public Health Sciences; Professor of Law, University of Virginia)

#### A5 – Ethical Challenges When Conducting Research in the Midst of Social Injustice

**Liza Dawson, PhD** (National Institute of Health/National Institute of Allergy and Infectious Diseases/Division of Acquired Immunodeficiency Syndrome);  
**Ross McKinney, MD** (Director, Clinical & Translational Research Ethics, Law & Policy, Professor of Pediatrics, Director, Trent Center for Bioethics, Humanities, and Medical History, Duke University)

#### A6 – Nuts and Bolts of 45 CFR Part 46

**Elyse Summers, JD** (Director, Division of Education and Development, Department of Health and Human Services – Office for Human Research Protections)

#### A7 – Community Engaged Research: Partnerships with Schools

**Aryeh Stein, PhD, MPH** (Associate Professor, Emory University);  
**Susan McCammon, PhD** (Professor and Director of Clinical Training, East Carolina University);  
**Jan Key, MD** (Professor, Director, Division of Adolescent Medicine, Medical University of South Carolina)
4:00 PM – 5:15 PM  Afternoon B: Break-Out Sessions

**B1 – Ethical Challenges to Conducting Research in Resource Poor Settings**

*Stuart Rennie, PhD, MA* (Research Assistant Professor, Social Medicine Co-Chair, UNC Behavioral Institutional Review Board, The University of North Carolina at Chapel Hill); *Michael Sweat, PhD* (Professor, Family Services Research Center, Medical University of South Carolina)

**B2 – How to Use/Apply the Flexibility in the Regulations at 45 CFR Part 46/What Needs IRB Review**

*Ivor Pritchard, PhD* (Acting Director, Department of Health and Human Services – Office for Human Research Protections); *Bob Levine, PhD* (Professor of Medicine, Yale School of Medicine, Executive Committee Chair, Yale Interdisciplinary Center for Bioethics, Director, Law, Policy and Ethics Core, CIRA)

**B3 – Doing Community Engagement: A Community Engagement Exercise**

*Kate MacQueen, PhD, MPH* (Senior Scientist in Behavioral and Social Sciences, FHI 360, Adjunct Professor at The University of North Carolina at Chapel Hill); *David Jolly, DPH, MSPH, MED* (Associate Professor and Chair in the Department of Public Health Education, North Carolina Central University)

**B4 – Panel: Working with Community Advisory Boards in Community Engaged Research**

*Sharon Elliott-Bynum, PhD, MA, RN, BSN* (Executive Director, Healing with CAARE Inc.); *Stella Kirkandale, MPH* (Senior community program manager with the Behavioral and Biomedical Research (BBR) Division at FHI 360); *Susan Newman, PhD, RN, CRRN* (Assistant Professor and Junior Research Scientist in the College of Nursing, Medical University of South Carolina); *Janet Archer, MS* and *Mwenda Kudumu* (Researchers, Social and Scientific Systems, Inc.)

**B5 – FDA: Community Consultation and Public Disclosure in Emergency Research**

*Ruth Gaare Bernheim, JD, MPH* (Director, Division of Public Health Policy and Practice, Department of Health Evaluation Sciences, School of Medicine; Associate Professor of Public Health Sciences, School of Medicine; Associate Director, Institute for Practical Ethics and Public Life, University of Virginia); *Nancy King, JD* (Department of Social Sciences & Health Policy Division of Public Health Sciences, Wake Forest School of Medicine)

**B6 – Definitions, Policies and Potential Solutions Regarding IRB Review of Community Engaged Research**

*Heather Pierce, JD, MPH* (Association of American Medical Colleges (AAMC)’s Senior Director for Science Policy and Regulatory Counsel in Scientific Affairs); *Ross McKinney, MD* (Director, Clinical & Translational Research Ethics, Law & Policy, Professor of Pediatrics, Director, Trent Center for Bioethics, Humanities, and Medical History, Duke University)

**B7 – Ethical and Regulatory Considerations in Human Environmental Exposure Research**

*David Resnik, JD, PhD* (Bioethicist and National Institute of Environmental Health Sciences IRB Chair, National Institute of Environmental Health Sciences); *Warren Lux, MD* (Human Subjects Research Review Official, Director, Program in Human Research Ethics, US Environmental Protection Agency)
### Day 2: Thursday, March 22, 2012

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<tr>
<td>7:00 AM – 8:00 AM</td>
<td>Continental Breakfast</td>
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<td>8:00 AM – 8:15 AM</td>
<td>Morning Greetings, Announcements, and Introduction of Keynote Speaker</td>
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| 8:15AM – 9:15 AM | **Keynote Address:** Ethical Considerations in Community–Engaged Research in International Studies  
 *Ruth Ellis, MD, MPH* (National Institute of Health/National Institute of Allergy and Infectious Diseases) |
| 9:15AM – 10:30 AM | **Panel Discussion:** Communicating Research with the Community  
 *Linda Birnbaum, PhD, DABT, ATS* (Director, National Institute of Environmental Health Sciences and the National Toxicology Program Division);  
 *Christine Bruske Flowers, MPA* (National Institute of Environmental Health Sciences);  
 *Robin Tutor, MPH, OTR/L* (East Carolina University);  
 *Ted Emmett, MD, MS* (Hospital of the University of Pennsylvania) |
| 10:30 AM – 10:45 AM | Networking and Refreshment Break                                      |
| 10:45 AM – 12:15 PM | Morning C: Break-Out Sessions                                         |

**C1 – Informed Consent in Biobanking and Biorepositories**  
*Laura Beskow, PhD, MPH* (Associate Director, Clinical and Translational Research Ethics, Law & Policy, Assistant Research Professor, Duke Institute for Genome Sciences and Policy, Duke University)

**C2 – Assessment of Consent Comprehension in Study Participants and Informed Refusal**  
*Amy Corneli, PhD, MPH, CHES* (Scientist I, Behavioral and Social Sciences, Research Group, FHI 360);  
*Kerry Kilbridge, MD* (Mongan Institute for Health Policy, Massachusetts General Hospital Hematology Oncology, Beth Israel Deaconess Medical Center Harvard Medical School and Visiting Assistant Professor, Department of Public Health Sciences University of Virginia)

**C3 – Best Practices and Pit Falls**

**C4 – Environmental Justice in Community Engaged Research**  
*Steve Wing, PhD, MA* (Associate Professor, UNC Gillings School of Global Public Health, The University of North Carolina at Chapel Hill School);  
*Ted Emmett, MD, MS* (Emeritus Professor CD of Emergency Medicine, Hospital of the University of Pennsylvania)

**C5 – Panel: What is Appropriate Training for Community Partners in National and International Studies?**  
*Michael Sweat, PhD* (Professor, Family Services Research Center, Medical University of South Carolina);  
*Dave Borasky, MPH, CIP* (RTI International);  
*Janet Archer, MS* and  
*Mwenda Kudumu* (Researchers, Social and Scientific Systems, Inc.)
10:45 AM – 12:15 PM Break-Out Sessions (continued)

**C6 – Community Based Participatory Research in Action: LinCS to Durham**

**David Jolly, DPH, MSPH, MED** (Associate Professor and Chair in the Department of Public Health Education, North Carolina Central University); **Kate MacQueen, PhD** (Senior Scientist in Behavioral and Social Sciences, FHI 360, Adjunct Professor at The University of North Carolina at Chapel Hill)

12:15 PM – 2:15 PM Lunch

**Keynote Address and Panel – Ethical Considerations of Community Engaged Research in Minority and Disadvantaged Communities**

**Stephen Thomas, PhD** (Professor of Health Services Administration in the School of Public Health and Director of the University of Maryland Center for Health Equity at the University of Maryland in College Park)

2:30 PM – 4:00 PM Morning D: Break-Out Sessions

**D1 – Research Participants Reimbursements and Reporting Requirements to the IRS**

**Summer Young, JD, MPH** (Medical University of South Carolina); **Kathryn Magruder, PhD** (Associate Professor, Public Psychiatry Division, Medical University of South Carolina)

**D2 – Certificates of Confidentiality: Do They Really Protect**

**Lauren Dame, JD, MPH** (Associate Director, Genome Ethics, Law and Policy, Duke University School of Law); **Laura Beskow, PhD, MPH** (Associate Director, Clinical and Translational Research Ethics, Law & Policy, Assistant Research Professor, Duke Institute for Genome Sciences and Policy, Duke University); **Ann Hardy, DrPH** (National Institute of Health Extramural Human Subjects Protections Officer, National Institute of Health/Office of Extramural Research/OD)

**D3 – Panel: Return of Results to Participants and Return of Aggregate Results to Communities**

**Julia Brody, PhD** (Executive Director, Silent Spring Institute); **Rodolfo M. Pascal, MD** (Wake Forest School of Medicine); **Sara Quandt, PhD** (Professor, Department of Epidemiology & Prevention Division of Public Health Sciences Wake Forest University Health Sciences, Wake Forest School of Medicine); **Thomas Arcuray, PhD** (Professor and Research Director in the Department of Family and Community Medicine, Wake Forest University School of Medicine, with cross-appointments in the Department of Epidemiology and Prevention, and the Maya Angelou Research Center on Minority Health. He is also Adjunct Professor of Anthropology, Wake Forest University, and Adjunct Professor of Health Education and Behavior, University of North Carolina at Chapel Hill); **Kathy Walker**, Protocol Analyst (Wake Forest School of Medicine)

**D4 – Public Health and Community Benefits**

**Claire Sterk, PhD** (Community Member on IRB, Emory University); **Carlos Pavao, MPA** (Community Member on IRB, Emory University); **Mark Wolfson, PhD**. (Professor, Department of Social Sciences & Health Policy, Division of Public Health Sciences, Wake Forest University Health Sciences, Wake Forest School of Medicine)
2:30 PM – 4:00 PM  Break-Out Sessions (continued)

**D5 – NCI Community Cancer Clinical Trials**

*Glenn Lesser, MD* (Professor, Hematology and Oncology Comprehensive Cancer Center Brain Tumor Center of Excellence Neurosurgery, Wake Forest School of Medicine)

**D6 – Social Media Tools and Research: The Use of New Electronic Data Collection Methods and the Benefits and Problems They Pose for Researchers and IRBs**

*Scott Rushing* (Director, Research Information Systems, Wake Forest School of Medicine)

4:00 PM – 5:00 PM  Closing Reception