



**The AIDS International Research and Training Programs (AITRP) at
Dartmouth/Boston University, Duke University and the Harvard School of Public Health
in collaboration with Kilimanjaro Christian Medical Centre and Muhimbili University
College of Health Sciences
present**

Critical Research Ethics Issues in the Era of HIV in Tanzania

**Thursday & Friday, 14-15 April 2005
The Courtyard Hotel, Dar es Salaam**

and

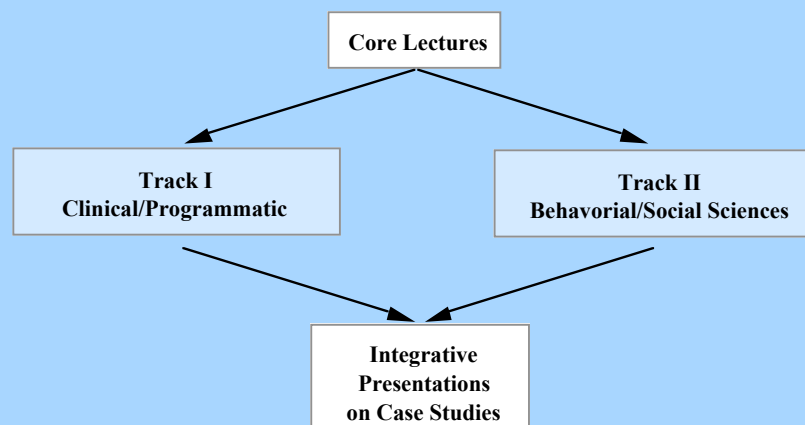
**Monday & Tuesday, 18-19 April 2005
Kilimanjaro Crane Hotel, Moshi**

Course Description

This 2 day course is designed for Tanzanian health care professionals, researchers, administrators and others who (1) conduct research that includes human participants and (2) who want to incorporate fundamental ethical considerations in the design and implementation of their research or institutional programs. The training offers:

- An overview to the development and philosophy of research ethics
- Case studies so that the participant can consider and evaluate real-world examples of ethical issues and practical dilemmas
- Materials to help design studies and programs that respect local regulations, cultures and expectations while conforming to international guidelines
- Reference documents and links to resources on modern perspectives that shape the field of research ethics.

The course will be divided into three major sessions as shown in the figure below.



Session One will consist of core lectures on major topics of interest to all participants including principles and foundations of research ethics, responsible conduct and supervision of research involving humans, and critical issues on informed consent. Following that, Session Two will break attendees into two tracks for targeted training of interest using a case study approach involving dynamic participation. Track 1 will focus on clinical aspects of research and Track 2 will focus on behavioral and social research/administrative aspects of research. Session Three will integrate the material learned in Session Two, rounding out the case study in all its perspectives for all attendees. Each of the groups and their respective faculties will present their perspectives and findings in the form of interactive discussions, selected group presentations, poster sessions and interchange

The international faculty will include lecturers from the United States and Tanzania. The course is sponsored by the Fogarty International Center of the National Institutes of Health (US) in conjunction with Dartmouth Medical School, Boston University School of Public Health, Duke University, Harvard School of Public Health, Muhimbili University College of Health Sciences, and Kilimanjaro Christian Medical Centre (KCMC).

Who should attend this training program?

Physicians/researchers, clinical officers and research nurses, members of ethics review committees, institutional administrators and research managers, social and behavioral health professionals, people involved in monitoring health research as well as those teaching research ethics and research methods, and others who have an interest in research ethics in Tanzania.

Faculty

Course Directors

John Hamilton, MD

Professor of Medicine and Chief, Division of Infectious Diseases and International Health, Duke University Medical Center, USA

Sarah Putney, JD

Director, Human Subjects Committee, Harvard School of Public Health, USA

Richard Waddell, DSc

Assistant Professor of Medicine, Dartmouth Medical School, USA

United States

Elizabeth Bankert, MA

Director, Committee for the Protection of Human Subjects, Dartmouth College

Mark Barnes, LLB, JD

Ropes and Gray, New York

Edward Bartlett, PhD

International Human Research Liaison, Office for Human Research Protection (OHRP)

John Bartlett, MD

Professor of Medicine, Division of Infectious Diseases and International Health, Duke University Medical Center

Lia Haley, JD
Human Subjects Committee, Harvard School of Public Health

Saidi Kapiga, MD, MPH, ScD
Assistant Professor of Reproductive Health, Harvard School of Public Health

Jeremy Sugarman, MD, MPH, MA
Professor of Bioethics and Medicine, Johns Hopkins University School of Medicine

Nathan Thielman, MD
Assistant Professor of Medicine, Division of Infectious Diseases and International Health, Duke University Medical Center

Tanzania & Uganda

Banson Barugahare, MD
Joint Clinical Research Centre, Kampala, Uganda

Sylvia Kaaya, MD, MSc
Senior Lecturer of Psychiatry, Muhimbili University College of Health Sciences (MUCHS), Dar es Salaam

Karim Manji, MD, PhD (invited)
Associate Professor of Pediatrics, MUCHS, Dar es Salaam

Amos Y. Masele, MD, PhD (invited)
Chair and Director, Research and Publications and the Research Ethics Committee, MUCHS, Dar es Salaam

Frank Mosha, PhD
Secretary, KCMC Ethics Committee, Kilimanjaro Christian Medical Centre, Moshi

Gernard Msamanga, MD, DPH, ScD
Associate Professor of Community Health, MUCHS, Dar es Salaam

Lillian Mtei, MD
Clinical Director, DARDAR Health Study, Dar es Salaam

Sabina Mtweve, MD
Lecturer of Community Health, Kilimanjaro Christian Medical Centre, Moshi

Noel Sam, MD, MMed
Associate Professor of Microbiology, Kilimanjaro Christian Medical Centre, Moshi

John F. Shao, MD, MSc, PhD
Executive Director and Professor of Microbiology, Kilimanjaro Christian Medical Centre, Moshi

Course Schedule (for both venues in Tanzania)

Day One, Keynote Address and Plenary Presentations—ALL Participants

Time	Topic	Faculty
7:00-8:00	<i>Check-in and Continental Breakfast</i>	
8:00-8:15	Introductions and Welcoming Remarks	Waddell & Shao
8:15-9:00	Fundamental Principles of Human Subject Research	Barnes (Dar) & Sugarman (Moshi)
9:00-9:30	Overview of US & European Guidelines for Research involving Humans	Bankert & Putney
9:30-10:00	The African Perspective on Global Research Ethics	Maselle (Dar) & Mosha (Moshi)
10:00-10:20	<i>Break</i>	
10:20-10:50	The Ethics Committee and the Role of the Institution	Kapiga
10:50-12:20	<i>Panel Presentation & Discussion:</i> Major Elements of Informed Consent	Sam, Sugarman, Mtei & E. Bartlett
12:30-13:30	<i>Lunch and INVITED PLENARY SPEAKER</i> The role and relevance of research in Africa with special reference to Tanzania	Shao

Day One Track 1: Clinical and Programmatic Issues in Research Ethics

Time	Topic	Faculty
13:45-14:30	Cross-cultural Ethical Perspectives in HIV Clinical Trials	Barugahare
14:30-15:15	Reporting Adverse Events, Unanticipated Problems and Handling Complaints	Manji
15:15-15:30	<i>Break</i>	
15:30-16:15	Challenges of IRB Management in Tanzania	Maselle (Dar) & Mosha (Moshi)
16:15-17:00	Partnerships with International IRBs and Capacity Building	Haley & Putney

Day One, Track 2: Behavioral and Social Science Issues in Research Ethics

Time	Topic	Faculty
13:45-14:30	Building Knowledge about the Research Subjects and their Communities	Gernard Msamanga, MD Harvard group/MUCHS
14:30-15:15	Ethical issues faced by home-based care organizations	Mtweve
15:15-15:30	<i>Break</i>	
15:30-16:15	Getting Towards Meaningful Informed Consent	Sugarman
16:15-17:00	Subject Recruitment: Cultural Issues, Gender, Confidentiality and HIV	Mtei

Day One, 19:00-21:00 Gala Buffet Dinner and Group Photo

KEYNOTE ADDRESS: Ed Bartlett, PhD

“The Common Rule Regulations and Their Application in the African Setting”

Day Two Track 1: Clinical and Programmatic Issues in Research Ethics

Time	Topic	Faculty/Group Leader
7:30-8:00	<i>Continental Breakfast</i>	
8:00-9:45	<u>Roundtable A Case Studies: Ethics Committees—Criteria and Considerations for Multiple IRB Review & Approval</u>	E. Bartlett & Thielman
9:45-10:00	<i>Break</i>	
10:00-11:45	<u>Roundtable B Case Studies: Harmonization of US and Tanzania Guidelines</u>	Putney & Haley
11:45-12:30	Preparation for Track 1 Group Presentation	Faculty

Day Two, Track 2: Behavioral and Social Science Issues in Research Ethics

Time	Topic	Faculty/Group Leader
7:30-8:00	<i>Continental Breakfast</i>	
8:00-9:45	<u>Roundtable A Case Studies: Informed Consent From Theory to Practice</u>	Waddell & Mtei
9:45-10:00	<i>Break</i>	
10:00-11:45	<u>Roundtable B Case Studies: Establishing an Effective Community Advisory Board</u>	Kaaya & J. Bartlett
11:45-12:30	Preparation for Track 2 Group Presentation	Faculty

Day Two, ALL Participants

Time	Topic	Faculty
12:30-13:30	<i>Lunch</i>	
13:45-14:30	Track 1 Group Presentations & Discussion	Moderator: John Hamilton
14:30-15:15	Track 2 Group Presentations & Discussion	Moderator: Sarah Putney
15:15-15:30	<i>Break</i>	
15:30-16:15	Pulling It All Together and Closing Remarks	Shao & other faculty
16:15-17:00	Presentation of Certificates, Evaluations, Adjourn	Faculty

How to Register

There is no fee for you to attend this course, but advanced registration is required by **31 MARCH 2005**. Attendance is limited to 70 participants at each location so early registration is encouraged.

To register, go to the following website:

<http://www.dartmouth.edu/dms/aitrp/shortterm/application/>