

# AORTIC PRE-CONFERENCE WORKSHOP FUNDAMENTALS OF CLINICAL RESEARCH

Tuesday, 10 November 2009

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*Sponsored by The University of Chicago Office of Clinical Research  
and the Global Health Initiative*

## WORKSHOP CHAIRS

Keymanthri Moodley, MBChB | University of Stellenbosch, South Africa

Adeyinka Falusi, PhD | University of Ibadan, Nigeria

Olufunmilayo Olopade, MD | University of Chicago, USA

Christopher 'Sola Olopade, MD, MPH | University of Chicago, USA

## TARGET AUDIENCE

- Physicians
- Research Nurses
- Research Coordinators
- Data Managers
- Research Nurse Associates
- Research Assistants
- Medical Students
- All other research staff members

## COURSE OBJECTIVES

1. Define clinical research.
2. Summarize the evolution of good clinical practice and its impact on the conduct of research.
3. Compare and contrast the degree of oversight among regulatory bodies for the conduct of clinical research.
4. Identify techniques for improving subject recruitment and retention.
5. Highlight the essential components for documenting the informed consent process.
6. Describe tools for assisting research staff in meeting the documentation requirements for the conduct of clinical research.
7. Review the regulatory mandates for reporting on subject safety.
8. Outline the steps for ensuring and documenting investigational product accountability.
9. Discuss the importance of scientific integrity and conflict management in recommendations for meeting and documenting all ethical expectations.

## TOTAL CREDITS

This program is approved for 4.5 hours of Continuing Medication Education Credit and 4.5 hours of Illinois Nurses Association Credit.

## SCHEDULE

Time	Session	Speaker
9:00-9:30	Pre-Test	
9:30-9:55	What is Clinical Research?	O. Olopade (USA) S. Olopade (USA)
10:00-10:25	Evolution of Good Clinical Practice	K. Moodley (South Africa)
10:25-11:00	<i>Refreshment Break</i>	
11:00-11:25	Regulatory Oversight	S. Olopade (USA)
11:30-11:55	Subject Recruitment and Retention	K. Moodley (South Africa)
12:00-12:25	Informed Consent	A. Falusi (Nigeria)
12:30-12:55	Document Management	P. Gonzalez (USA)
12:55-2:00	<i>Lunch Break</i>	
2:00-2:25	Safety Reporting	P. Gonzalez (USA)
2:30-2:55	Investigational Product Accountability	C. Babalola (Nigeria)
3:00-3:25	Scientific Integrity/Conflict of Interest	S. Olopade (USA) A. Afolabi (Nigeria)
3:30-4:00	Post-Test	

## SPEAKER BIOGRAPHIES

**Adefemi Oladiran Afolabi, MB, BS** is a Senior Lecturer in Surgery at the College of Medicine, University of Ibadan and University College Hospital (UCH), Ibadan, Nigeria. In collaboration with the London School of Hygiene and Tropical Medicine, Dr. Afolabi is currently researching the clinical randomization of an antifibrinolytic in significant hemorrhage. The study is a double blind placebo controlled trial of tranexamic acid in all adult trauma patients who present within eighth hours of injury with ongoing significant hemorrhage. Dr. Afolabi also has a special interest in medical informatics, and in 2003, he completed the Fogarty International Center Training Program in Medical Informatics at the Medical University of South Carolina. He also completed the Training in Clinical Research Course of the University of California at San Francisco between January and March 2007. In addition, he served as General Secretary and is currently the Vice-Chairman of the Medical and Dental Consultants Association of Nigeria of UCH, Ibadan and is a member of the Nigerian Medical Association, Nigerian Surgical Research Society, and West African College of Surgeons.

**Chinedum Peace Babalola, PhD** is a pharmacist and a Professor in the Department of Pharmaceutical Chemistry at the University of Ibadan, Nigeria. Professor Babalola is also the Director of General Studies Programme at the University of Ibadan. She has an interest in generating pharmacokinetic profiles of antimalarials and anti-infectives in volunteers and patients in Africa, so as to guide dosage regimes. She also researches in pharmacogenetic polymorphisms in African populations and has just completed a study on pharmacogenetic disposition of proguanil in sickle cell patients and normal population. Her other areas of research interest include antimalarial/antibiotic drug-drug interactions in humans, developing novel methods for drug determination in pharmaceutical dosage forms and biological fluids, formulation of clinically useful quinine suppositories, drug use studies and ethics of human research.

**Adeyinka G. Falusi, PhD** is Professor of Hematology, Head of the Genetic and Bioethics Research Unit and current Director of the Institute for Advanced Medical Research and Training, College of Medicine, University of Ibadan. Her specialty is in genetics of sickle cell disease, breast cancers and ethics of research. She is the coordinator of the immunohistochemistry screening laboratory for breast cancer classification at Ibadan. She is a recipient of many prestigious awards including the Fellowship of the Nigerian Academy of Science, the L'OREAL/UNESCO Award for Outstanding Woman of Science (Africa 2001), and the 2003 Rare Gems Award in Science & Technology. In addition, Dr. Falusi currently serves as the President of the Sickle Cell Association of Nigeria (SCAN) and the President of the Nigerian Bioethics Initiative (NIBIN).

**Pamela Gonzalez, RN** is Associate Director of Education and Auditing in the Office of Clinical Research (OCR) at the University of Chicago Medical Center. She has worked in HIV research in varying capacities since 1992 until joining OCR. In addition, Ms. Gonzalez has worked as a data collector, research coordinator, and sub-investigator on phase III and IV studies and on federally funded grants. She also coordinates educational programs for the OCR and conduct audits for human subject studies at the University of Chicago. Ms. Gonzalez is a 2008-2009 bioethics fellow at the MacLean Center for Clinical Medical Ethics.

**Keymanthri Moodley, MBChB** is Associate Professor and Head of the Bioethics Unit at the University of Stellenbosch. She is recognized as a leading authority in the field of bioethics. She is a member of the Editorial Board of the South African Family Practice Journal and a member of the College of Family Physicians of South Africa. She received the Claud Leon Harris Medal for outstanding services. Dr. Moodley is also recognized as a world leader in HIV research and ethics.

**Christopher 'Sola Olopade, MD, MPH** is Professor of Medicine at the University of Chicago (UC) and Clinical Director of the UC Global Health Initiative. Dr. Olopade is a pulmonary specialist with clinical expertise in managing obstructive lung diseases especially asthma. His research focuses on better understanding of the interaction between environmental and genetic factors in the expression of asthma in developing country settings. He has a special interest in global health and bioethics and served as a member of the University of Illinois IRB for many years. He currently serves as the president of the Nigeria Higher Education Foundation, a MacArthur-supported foundation based in New York, charged with the responsibility of making the case for support of higher education at five Nigerian universities. He is also the founder and president of the Healthy Life for All Foundation, a non-governmental foundation based in Nigeria with the objectives of promoting healthy lifestyles, capacity building through technology transfer and collaborative research, and development of a clinical trial infrastructure and private/public partnerships in achieving the aforementioned goals.

**Olufunmilayo (Funmi) Olopade, MD** is the Walter L. Palmer Distinguished Service Professor of Medicine and Human Genetics, Associate Dean for Global Health, and the Director of the Center for Clinical Cancer Genetics at the University of Chicago. Dr. Olopade is an international leader in breast cancer research and a highly skilled oncologist with proven expertise in cancer risk assessment. Her current research interests include identifying the source of ER-negative breast cancer, an aggressive form of the disease that is resistant to hormone therapy. Dr. Olopade aims to improve screening standards and early detection for moderate- and high-risk populations. She has a special interest in women of African descent, who are at higher risk for the more aggressive forms of breast cancer and who are more likely to be diagnosed at a younger age. Dr. Olopade is also the recipient of numerous honors and awards, including the James S. McDonnell Foundation Scholar Award, the Doris Duke Distinguished Clinical Scientist Award, and a 2005 MacArthur Fellowship "Genius" Grant. In 2008, Dr. Olopade was inducted into the Institute of Medicine of the National Academies.