# AIFA-UNICRI-OPBG-NIMR

## Training Course

## "Good Clinical Practice in developing settings: the promotion of international harmonization for the respect of ethical principles, human rights and justice"

**11-14 June 2012**

**The National Institute for Medical Research (NIMR) Isamilo Road, Mwanza United Republic of Tanzania**

**Provisional programme**
**Updated 7 June 2012**

The training course has, among its main objectives:

a) To increase the professional expertise of officers and professionals from both governmental and non-governmental not-for-profit organizations, working in the field of clinical research of drugs with human participants.
b) To strengthen knowledge of the ethical, scientific and regulatory aspects of the GCP requirements, so as to increase compliance to EU standards of research studies conducted in Africa and facilitate marketing authorization. To this end, particular attention will be devoted to GCP ethical requirements in the European Union.
c) To set up an African – European Network;

Eligible participants include personnel employed/to be employed as:

- members of ethical committees;
- officials of the National Regulatory Authorities in charge of authorizing and/or evaluating Clinical trials;
- officials employed in GCP and pharmacovigilance inspectorates;
- officials employed in Quality Assurance Services;
- investigators;
- Mwanza Pediatric Postgraduate Medical School M.D.s;
- clinical trials nurses;
- other professionals working in the control, evaluation, assessment and quality guarantee of clinical trials;
- legal advisors, lawyers, lay members, policy makers, judiciary and law enforcement involved in clinical research issues.

The duration of the course will be of 4 working days. Each day is divided into a theory and a practice session. The theory sessions are dedicated to all trainees; the practice sessions are divided in two parts, each dedicated to two different groups of trainees:

– ***GROUP A: "Investigators, Assessors, Ethics Committees and Regulatory Group"***: this group of trainees includes professionals employed/to be employed in the field of clinical trial planning and conduct, evaluation and ethical and scientific approval of clinical trials, scientific monitoring of pharmacovigilance evaluation and control of clinical trials, regulatory/legislative activities related to clinical trials, investigators or similar fields.

- ***GROUP B: "GCP Compliance Group***": this group of trainees includes mainly GCP and pharmacovigilance inspectors as well as professionals employed/to be employed in the control of clinical trials compliance to GCP and in pharmacovigilance requirements and in GCP quality monitoring activities; clinical trial nurses; clinical trial auditors; quality assurance personnel.