United Nations
Interregional Crime and Justice
Research Institute

"Promoting Social Justice through the Development of Ethical and Legal Frameworks"

AIFA – UNICRI – FDA Training Course on GCP Inspectorates and GCP Inspections

Accra, Ghana, 7-11 July 2014

Alessandra Liquori O'Neil (1), Jonathan Lucas (2)

(1) Programme Officer
(2) Director, formerly: Secretary, INCB and Commission on Narcotic Drugs

U N I C R I

United Nations Interregional Crime and Justice Research Institute

- Countering the Threat of Crime to Security and Development
- Increasing the Efficiency of Criminal Justice Systems and Protection of Vulnerable Groups
- Promoting International Criminal law and Practice
- Sharing Best Practices, Building Capacity to Promote Human Rights and Access to Services
- Security Governance and Countering the Appeal of Terrorism
- Training and Advanced Education: Building Capacity in Crime Prevention and Criminal Justice

U.N. Millennium Development Goals

1. Eradicate extreme poverty and hunger
2. Achieve universal primary education
3. Promote gender equality and empower women
4. Reduce child mortality
5. Improve maternal health
6. Combat HIV/AIDS, malaria and other diseases
7. Ensure environmental sustainability
8. Global partnership for development

Sharing best practices, building capacity to promote human rights and access to services

Assisting Governments to effectively safeguard the rights and well-being of participants in biomedical research, by strengthening health research ethics capacity and national legislative frameworks, through research and training.

A proper legislative framework, the correct application of international standards and adequate capacity for ethical review evaluation and on-site inspection and monitoring of clinical research with human beings are all key factors for ensuring the protection and promotion of human rights, safety and well being of research participants all around the world.

To this regard, UNICRI, in collaboration with AIFA and other UN and international stakeholders has developed a series of tools, including training kits and distance learning platforms, to support the effective governance of clinical research and protect participants, while facilitating access to medicines and advancing scientific knowledge.

Sharing best practices, building capacity to promote human rights and access to services

International Round Table

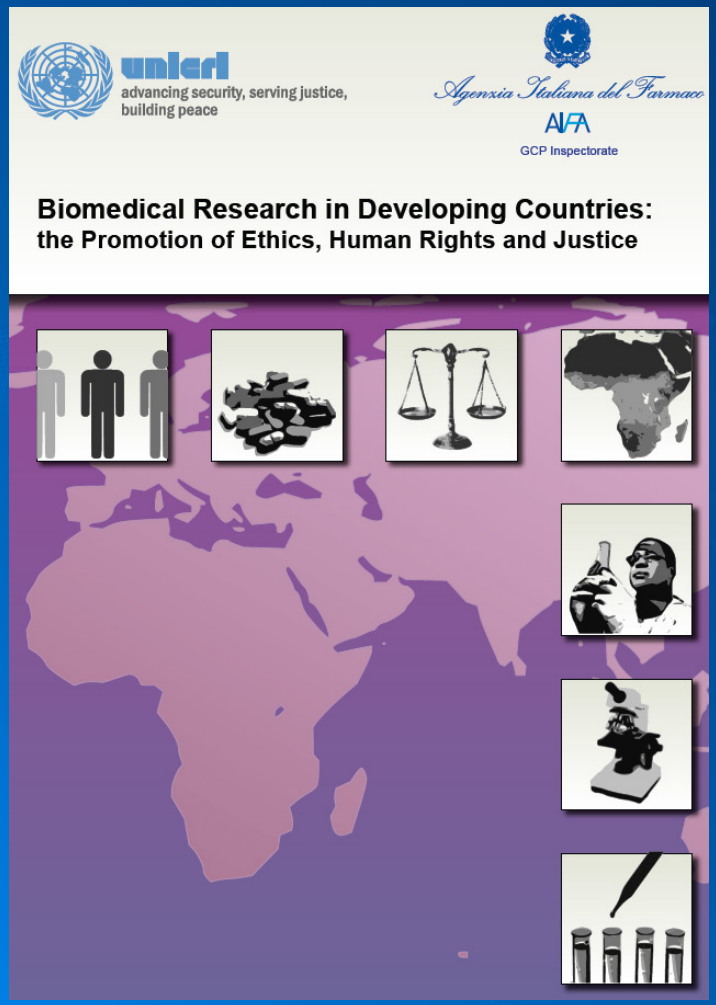
Rome, 15–16 December 2008

UNICRI's long standing expertise coupled with the support from the Italian Medicines Agency (AIFA), made possible the organization of an international Round Table on "Biomedical Research in Developing Countries: the Promotion of Ethics Human Rights and Justice" in December 2008.

The Round Table discussion provided a platform for internationally renowned experts in the field, including WHO, WMA and UNESCO to present their analyses of the various challenges posed by biomedical research with human participants. International instruments developed by the United Nations and other relevant organizations regarding ethical and legal protections for human participants in clinical research trials were also discussed. It was agreed that increasing participants' knowledge and understanding of the issues and their capacity to address the emerging challenges should be a main objective that the international community should support.

The Round Table event also provided an opportunity to compare national and international experiences on the protection of participants in clinical trials, with presentations by experts from Cameroon, Ghana, Kenya, Nigeria, Senegal, South Africa. Lectures included the founding principles of the research on ethics and its guidelines. How far is the international community from reaching a consensus on a global strategy for the protection of human participants in biomedical research, Strengthening of ethical review processes and regulatory capacities in medical research with human participants in developing settings.

Sharing best practices, building capacity to promote human rights and access to services



***Biomedical Research in Developing Countries: the Promotion of Ethics Human Rights and Justice* (UNICRI, 2009)**

This publication summarizes the results of a research study carried out by UNICRI, in collaboration with the Italian Medicines Agency (AIFA), the responsible Agency in Italy for pharmaceutical control, to investigate the ethical and legal challenges posed by conducting clinical trials with human participants, particularly in developing settings, where the need to respect international ethical and scientific standards, may be overshadowed by the need to access healthcare provisions and may lead to criminal implications, such as the risks of fraudulent behavior, non-compliance with the standards of ethical reviews and the lack of control on the quality of drugs and/or of the established protocols, which sometimes bring about serious consequences for participants. The research study included a focus on Africa and a survey of the current national legislations and guidelines protecting human participants in biomedical research as well as the status of ethical review capacity in the Region. The results of the research are published in the book *Biomedical Research in Developing Countries: the Promotion of Ethics Human Rights and Justice* (UNICRI, 2009), available on the UNICRI website.

Sharing best practices, building capacity to promote human rights and access to services

Training of Ethical Review Board Members

11-14 June 2012, Mwanza, Tanzania

Upon specific request from the Government of Tanzania, UNICRI teamed with AIFA, the Pediatric Hospital Bambino Gesù and the Tanzanian National Institute for Medical Research (NIMR) to deliver a one- week intensive training programme for Members of Ethical Review Boards and Clinical Monitors to build capacity in the ethical evaluation of protocols and in the regular monitoring of ongoing studies.

UNICRI continues to support countries in their effort to harmonize their standards to the international standards, in order to increase GCP compliance and protection of the safety, well-being and rights of human participants in clinical trials of drugs.

EDCTP Capacity Building Grant

"Support for the establishment and the strengthening of African National Ethics Committees or Institutional Review Boards" Harare, Zimbabwe, October 2012

In Zimbabwe, UNICRI is engaging in training activities to assist in the establishment of the Zimbabwean Forum of Research Institutions (ZIMFRI), which can be used as a platform for strengthening and harmonizing health research ethics in Zimbabwe and be a focal point for the Region.

The expected outcomes of the project are (i) improved ethical review processes in terms of efficiency, transparency and independence; (ii) enhanced knowledge about monitoring of health research and clinical trials (iii) formation of IRBs at institutions that currently do not have IRBs; (iv) improved knowledge about national guidelines and requirements as stipulated by the Medical Research Council of Zimbabwe (MRCZ); (v) collaborative partnerships of Zimbabwean institutions under the auspices of ZIMFRI; and (vi) South-North collaborative partnership of ZIMFRI and the United Nations Interregional Crime and Justice Research Institute (UNICRI) based in Italy.

The project is contributing towards ensuring that health research conducted in Zimbabwe meets internationally acceptable ethical and scientific standards so as to protect the welfare of the public who participate in research and eventually use products or interventions derived from the research. The high standards would also help to attract research funding to ZIMFRI institutions, leading to research findings that address health related problems affecting the country. The training on conduction of clinical trials and clinical trial monitoring would strengthen ZIMFRI institutions to levels that meet GCP standards.

Increasing the efficiency of criminal justice systems and protection of vulnerable groups

Drugs and Alcohol Women Network, in collaboration with UNODC and UNWOMEN

- Tailored interventions for women on alcohol and drug use
- A network of professionals trained to promote and diffuse the best practices on gender differences in drug addiction
- Promotion of human rights/well-being of drug addicted women/young girls through prevention, treatment and rehabilitation intervention

Endorsed by the resolution of the Commission on Narcotic Drugs, March 2012

Training of West African National Competent Authorities on the implementation of the International Drug Control Treaties in collaboration with the International Narcotic Control Board 17-21 June 2013, Addis Ababa, Ethiopia

Training seminar for representatives of 12 West African countries: Benin, Burkina Faso, Cape Verde, Ethiopia, Ghana, Guinea, Cote d'Ivoire, Liberia, Mali, Niger, Nigeria, Sierra Leone and Togo.

Protecting vulnerable population: the case of albinism

Addressing human rights protection in cultural conflicts, in collaboration with Zimbabwe.

UNICRI contributed to the report submitted to the 24th session of the Human Rights Council on the basis of Resolution HRC/A/23/L.25 adopted on 13 June 2013 "*Attacks and discrimination against persons with albinism*"

Thank you for your attention

a.oneil@unicri.it

www.unicri.it