

International Round Table AIFA-UNICRI

Biomedical research in Developing Countries: the Promotion of Ethics, Human Rights and Justice

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Kristiina Kangaspunta
UNICRI Executive Officer

Recommendations

1) Implementation of the normative framework at the national level (International and Regional Guidance and Regulations):

To reach:

National Legislation;

Judicial system to enforce legislation;

Efficient Evaluation (National Research Ethics Committees);

Sufficient Regulation (Inspectorates and Regulatory Agencies).

2) Securing Protection

Based on:

Legislation;

Independence of application;

Respect of the Rule of Law;

Promotion of rights of participants;

United Nations
Interregional Crime and Justice Research Institute
Liaison Office in Rome

P.za di San Marco, 50 - 00186 Rome, Italy Tel.: (+39) 06 6789 907 - Telefax: (+39) 06 6780 668 E-Mail: unicri.rome@unicri.it - Web site: www.unicri.it Ensuring the benefit to participants;

Avoidance of ethical imperialism;

Safeguarding the wellbeing of individuals, the communities and societies at the macro level;

Reducing the gap between health and development

3) Increasing knowledge, transparency and awareness

- Research
 - o leading to action addressing the needs of countries where it is conducted
 - o leading to sustainable plans to secure benefits in developing countries
- Transparency in reporting
 - o increases the knowledge base
 - o increases the trust among the general public and policy makers
- Awareness
 - o rights, risks and benefits
 - o among all stakeholders
- 4) Increasing Capacity Building
 - o Training
 - o Adequate and sustainable resources
 - o Adequate infrastructure to carry out functions
 - Dedicated personnel
 - Leading to a well functioning system of research ethics bodies supported by Law
- 5) Increasing coordination of responses
 - National coordination
 - o International coordination
 - > Contributing to the knowledge and expertise at both levels
- 6) The way forward:
 - o Publication of results of the round table
 - o Creation of a discussion panel
 - o Coordinating activities among partners towards increasing joint efforts

- o Identification of resources for:
 - Training of research ethics committees
 - Training of judiciary and policy makers
- o Identification of priority actions towards the establishment of an international instrument or a global forum to:
 - Address the inequities in research priorities
- Assist in the development of policies that meet the needs of developing countries
- Monitor on-going research to safeguard participants and communities from exploitation