



United Nations Educational,
Scientific and Cultural Organization

Social and Human
Sciences

FOOD FOR THOUGHT, THOUGHT FOR ACTION

Working Panel: Presidential Commission for the Study of Bioethical Issues

UNESCO'S PERSPECTIVE

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The Big Challenges

- How is it possible to universally assure the same quality and level of protection for human research participants in all countries and for all international and cross-border research?
- We also have to take into account the diversity of legal, ethical and review systems, the diversity of health systems and resources available for research, often involving different levels of empowerment of participants.
- We encounter similar challenges when addressing questions of cultural diversity and dealing with different and sometimes competing values, including a diversity of stakeholders involved in research.

The Context

- Practices vary and cut across boundaries: there exists an ambiguity regarding existing laws and regulations of individual member states, including different rights traditions and the different relevant authorities identified as pertinent.
 - Two examples:
 - The trans-border flow of tissue collection, DNA samples and genetic data.
 - Biomedical research in poor communities demands greater vigilance to avoid exploitation.
- Note:** Ethical principle in human interaction: Violation of HR concerns the entire international community



Globalization leads to spreading scientific and technological advances but also creates and spreads bioethical dilemmas.

The global character of contemporary science and technology and the increasing number of research coming from different countries make a global approach to bioethics necessary.

UNESCO was founded to enable debate by providing a unique global and pluralist forum.

Universal Declaration of Bioethics and Human Rights

(Adopted in 2005 by acclamation)

- The 2005 declaration consists of a global agreement guaranteeing basic ethical principles and safeguarding their application. 191 governments signed up to it. They have committed themselves to:
 - Pass national legislation,
 - Promote national research ethical review system
 - Promote and enhance education:
 - Encourage public debate.



Amongst the many principles we find already a number of important aspects included:

- Human dignity and human rights
- Benefit and harm
- Autonomy and individual responsibility
- Consent
- Persons without capacity to consent.
- Respect for Human Vulnerability and personal integrity
- Privacy and confidentiality





- Equality, Justice and Equity
- Non discrimination and non-stigmatization
- Respect for cultural diversity and pluralism
- Solidarity and Cooperation
- Social Responsibility and Health
- Sharing of benefits
- Protecting future generations
- Protection of the environment, the biosphere and biodiversity.

Zooming in on ARTICLE 21

TRANSNATIONAL PRACTICES

- Calls for States to ensure compliance with the principles of the Declaration
 - Regardless of diverse geographical context and ambiguity of regulations and authorities
- The need for multiple review (I): avoiding different ethical standards in research.
 - Exploitation of poor, ignorant, disempowered populations in international research documented
 - Mistake: Often levels of disease in poorer countries exempt researchers from developed countries to take ethical considerations into account (time vs ethics/ends often justify the means).

(cont.)ARTICLE 21 TRANSNATIONAL PRACTICES: Key messages.

- The need for multiple review (II):
 - Identify the local needs and urgent global health problems
 - Promote harmonizing discordant policies towards transnational practices in research , bioterrorism, illicit traffic in organs, biological tissues and samples, genetic resources and genetic related materials.
 - Defining and ensuring access to benefits



(cont.) ARTICLE 21 TRANSNATIONAL PRACTICES: Key messages.

Article provides basis for an international initiative to:

- Foster equal participation in negotiation of terms of collaboration.
- Foster more horizontal collaboration between host and funding countries.
- Foster capacity building of developing and emerging economy countries of researchers and Ethics Committees.
- Foster confidence between countries.

For consideration.

- Transnational research practices:
- Growing role of industry in conducting clinical trials on biotechnology, pharmaceuticals and medical devices.
- Expansion of market but unequal solutions to health.
- Research and health care needs of the poor severely underserved.
- Note: Benefit Sharing and Social Responsibility

