UNESCO AND DoH

EXPERT CONFERENCE ON THE REVISION OF THE DECLARATION OF HELSINKI

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Declaration of Helsinki

Recognized by UNESCO as one of the leading international guidelines.

Important for UNESCO to participate in the debates to collaborate in the efforts to ensure DoH remains relevant and with a prominent role.

For Whom?

- From and for Physicians, yes but….
- Aspiration: should be good to anybody!
- The principles are relevant for other researchers and other actors (funders, publishers)
- DoH in fact, invites others.
- De facto, it is a reference for non physicians and for many engage in research with human research.
- Its a responsibility also to assume the relevance it has gained. Integrated in some countries legislation.

Some of the challenges

- Maintaining the specificity, and readable in 15 minutes, should not exclude to keep relevant in a the wider (including dissemination of knowledge), changing and increasingly complex context in which research takes place.

- I will refer basically to post trial arrangements/benefit sharing and ethics committees.

Relevant principles of Universal Declaration of Bioethics and Human Rights

15. Sharing of benefits

Related to Articles 4: Benefit and harm: In applying and advancing scientific knowledge, medical practice and associated technologies, direct and indirect benefits to patients, research participants and other affected individuals should be maximized…."

Art 13 Solidarity and Cooperation

Art 21: " Transnational health research Research should be responsive to the needs of host countries…."

Relevant principles of Universal Declaration of Bioethics and Human Rights

Art. 10: Equality, justice and Equity

Human rights framework of UN and the Declaration:

International Covenant on Economic, Social and Cultural Rights:

"Enjoy the benefits of science and technology and its applications."

Relevant principles of Universal Declaration of Bioethics and Human Rights

15. Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries.

In given effect to this principle, benefits may take any of the following forms:

a) Provision of new diagnostic and therapeutic modalities or products steaming from research
b) Access to quality health care
c) Access to scientific and technological knowledge
d) Support for health services
e) Capacity-building facilities for research purposes.

Relevant principles of Universal Declaration of Bioethics and Human Rights

Art 14. ….."Description of arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care of benefit."

Positive:

Call for a description in the protocol, which should imply prior negotiation

Caution:

Post study (access to successfully tested ..) and other benefits (health care during the research, etc) together. Does not mean choosing, but differently as appropriate.

Relevant principles of Universal Declaration of Bioethics and Human Rights

Negative:

No specification of whose obligation it is to discharge post study obligations. How will ethics committees will evaluate and promote compliance with these obligations?

Article: 33. "At the ***conclusion*** of the study, patients entered into the study ***are entitled*** to be informed about the outcome of the study and to share any benefits that result from it, for example access to interventions identified as beneficial or to other appropriate care or benefit.

But…..

- What about other benefits during the research? Access to health care, etc.

- Of course it could elicit the problem of undue inducement, but that would also need to be sorted out.

Relevant principles of Universal Declaration of Bioethics and Human Rights

- Compared to : ….."every patient entered into the study should be assured of access"
- "are entitled" vs. should be *assured*…. and not clearly by whom…….
- Different stakeholders, different type of research, participants (not only patients), but there is a need to:
- define who will be responsible particularly in ensuring access to successful outcome or other benefits,
  - When this will be decided (before the trial starts)
  - What are the benefits
  - Who are the beneficiaries

Relevant principles of Universal Declaration of Bioethics and Human Rights

- As different stakeholders are involved and had different obligations, there is a need to identify potential responsible and indicate the need for a mechanism to agree.

- Some countries like Brazil have local legislation in order to assure “access to medicine being tested”…

Relevant principles of Universal Declaration of Bioethics and Human Rights

21. Transnational Practices

2. When a research is undertaken or otherwise pursued in one or more States (the hosts State(s) and funded by a source in another State, such research should be the object of an appropriate level of ethical review in the host State(s) and the State in which the funder is located. (Dual review)

4.When negotiating a research agreement, *terms for collaboration and agreements on the benefits* of research should be established with equal participation by those party to the negotiation (taking into account power and minimum basis)

Relevant principles of Universal Declaration of Bioethics and Human Rights

- Indicate the role of ethics committee in reviewing and ensuring appropriate post study access and benefit sharing arrangements and who will be responsible.
- Indicate the need for host country committee to fully participate in the review of the protocol in international research.
- Previous version included reporting sources of funding, sponsors and other sources of conflict of interest to Ethics Committees, and is lacking here, ...they are mentioned in the information to the research participant.