Revisions on the Declaration of Helsinki

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Introduction

- The World Medical Association (WMA)was established after the WW2 in reaction to the atrocities committed by physicians
- It was meant to be a global representative body for physicians
- Currently, there are 48 National Medical Associations and approximately 7 million physicians
- WMA adopted the Declaration of Helsinki (DoH) in 1964

The Roles of the WMA in Biomedical Research

- Establishment of high-level global ethical standards for biomedical research
- Bridge between physicians and researchers
- Advocate for patients serving as human subjects
- Participant in capacity-building initiatives

Brief History of DoH

- First adopted in 1964
- Significant additions in 1975
- Minor amendments in 1983, 1989 and 1996
- Major revision and reorganization 2000
- Notes of clarification in 2002 and 2004
- Another revision in 2008

Influence of DoH

- CIOMS guidelines follow the DoH quite closely
- ICH-GCP guidelines require adherence to "principles that have their origin in the DoH"
- The UNESCO *Declaration on Bioethics and Human Rights* cites the DoH
- The EC Directive on Clinical Trials and the US FDA require adherence to the principles of DoH
- DoH is the most cited research ethics document by research ethics committees

Proposed Amendments in the 2012 Consultation Draft

- Paragraph 11: It should be revised to read; "It is the duty of the **researcher** in medical research to protect the life, health, privacy, **confidentiality** and dignity of the **human subject**"
- Paragraph 12: It should be revised to read; "Appropriate caution must be exercised in the conduct of research which may affect the environment, and the **welfare of human subjects** and animals used for research must be respected."

Proposed Amendments in the 2012 Consultation Draft

- Article 14 the ethics committee should provide the researchers with a checklists of documentation and requirements for independent scientific and ethical review process
- The researcher should also submit to the committee, for review, information regarding funding, sponsors, institutional Affiliations, other potential conflicts of interest and incentives for subjects. I propose to add "**Post trial access plan if appropriate and community engagement plan.**"

Proposed Amendments in the 2012 Consultation Draft cont'd

- Paragraph 28: It should be revised to read: " When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative. **However, emancipated minors should be allowed to give their own informed consent." e.g., minors who are mothers.**

Proposed Amendments in the 2012 Consultation Draft cont'd

- Paragraph 31: It should be revised to read; "The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship. **And if a conflict of interest (CoI) exists between a physician cum researcher and a patient, the physician must disclose the CoI to the patient and recuse him/herself from recruiting the patient as a human subject."**

Proposed additional principle

- Paragraph : **“Human subjects who participate in clinical trials involving investigational products whose safety profiles are unknown should be provided with clinical trials insurance”**

Exportation and importation of clinical and research samples

- There is growing trend of exporting human tissues from developing countries to laboratories in developed countries for clinical diagnosis or clinical research. Especially for clinical samples have the potential for abuse and lack of accountability
- There is need to create safeguards to avoid the abuse of those human tissues.
- Hence we propose that there is a need to have a material transfer agreement(MTA).
- The MTA agreement form should have a clear description of namely:

1. The destination
2. Ownership
3. The intention of export/import
4. Access and control of the samples
5. Safety and security of the samples
6. Capacity building issues
7. Justification
8. Permission
9. Signatures

How to resolve conflicting decisions between ethics committees in multi-centered clinical trial

- Incase of conflict between a remote and a local ethics committee. The voice of the local ethics committee ought to be taken into consideration
- The scientific and ethical justification should not be ignored

Conditions for supporting local ethical jurisdictions

1. Members of the local population and, in this situation, the local ethical committee is the best judge of what is appropriate
2. Exception: local review is sufficient only if the host country/institution has a system of substantive protections that are equivalent to international acceptable standards.
3. The basis of this argument is the principle of justice: that equals should be treated equally. Local ethical committees should be allowed to adjudicate conflicts between remote and local committees, One approach to resolving the impasse could be to distinguish between fundamental, qualitative and non-arguable principles and more relative, quantitative and circumstantial applications.

- (6) Ethical principles cannot be universal without being contextual

Conditions for supporting local ethical jurisdictions

- (1) The local committee must be constituted and its deliberations executed according to internationally recognized ethical standards (e.g. The World Medical Association's Declaration of Helsinki; The Belmont Report: Ethical Principles*).
- A clear SOPs of decision-making process
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Conclusion

- Developing countries are vulnerable to unscrupulous researchers
- Collective responsibility in protecting the rights, safety, and welfare of human subjects is critical.
- This calls for fair and objective regulations and guidelines that aim at promoting research and development while at the same time not compromising the protection of human subjects