

World Medical Association

Revision of Helsinki Declaration

Post Study Access or What Happens
once Research is Over?

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Context

In 2000 the WMA added a new provision to the Declaration of Helsinki stating that at the end 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 in the study or to other appropriate care or benefits.

International controversy ensued over the implications of this new provision and the WMA issued a clarification note in 2004. The most recent version (2008) amended the paragraphs relating to post-trial access: 'the protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits'.



Relevant Paragraphs

The Declaration emphasizes that it should be read as a whole and each of its constituent paragraphs should not be applied without consideration of all relevant Paragraphs

1. The Declaration of Geneva of the WMA binds the physician with the words, “the health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient’s best interest when providing medical care”
2. In medical research involving human subjects, the well being of the individual research subject must take precedence over all other interests
3. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, , right to self determination, privacy and confidentiality of personal information of research subjects
4. The protocol should describe arrangements for post-study access by study subjects to interventions identified as beneficial in the study or access to other appropriate care or benefits
5. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research
6. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions. Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and equality



Context – (1) Council for International Organizations of Medical Sciences (CIOMS)

In collaboration with WHO in 2002-

For research conducted in communities with limited resources-

‘the sponsor and the investigator must make every effort to ensure that any intervention or product developed , or knowledge generated , will be made reasonably available for the benefits of that community or population’ and
‘if an investigational drug has been shown to be beneficial, the sponsor should continue to provide it to the subject after the conclusion of the study and pending its approval by the drug regulatory authority’



(2) CIOMS – International Guidelines for Ethical Review of Epidemiological Studies

‘Where findings could be applied in public health measures to improve community health, they should be communicated to the health authorities....research protocols should include provision for communicating such information to communities and individuals’ Principle 13

‘While studies are in progress, particularly in developing countries, the opportunity should be taken to train local health workers in skills and techniques that can be used to improve health services. For instance, by training them in the operation of measuring devices and calculating machines, when a study team departs it leaves something of value, such as the ability to monitor disease or mortality rates.’ Principle 17



(3) CIOMS – International Guidelines for Ethical Review of Epidemiological Studies

- As a general rule, the sponsoring agency should ensure that, at the completion of successful testing, any product developed will be made reasonably available to inhabitants of the undeveloped community in which the research was carried out; exceptions to this general requirement should be justified.’ Commentary on guideline 8
- ‘Consideration should be given to whether the sponsoring agency should agree to maintain the host country, after the research has been completed, health services and facilities established for purposes of this study’. Commentary on guideline 15
- ‘The research protocol should specify what, if any resources, facilities and other goods or services will be made available... After the research to the community from which the subjects are drawn and to the host country’. Commentary on guideline 15



(4) UNAIDS ' Ethical considerations in HIV Preventive Vaccine Research' (2000)

Any HIV preventive vaccine demonstrated to be safe and effective, as well as other knowledge and benefits resulting from HIV vaccine research, should be made available as soon as possible to all participants in the trials which it was tested, as well as other populations at high risk of HIV infection. Plans should be developed at the initial stages of HIV vaccine development to ensure such availability.' Guidance point 2

Strategies should be implemented to build capacity in host countries so that they can practice meaningful self determination in vaccine development, can ensure the scientific and ethical conduct of vaccine development, and can function as equal partners with sponsors and others in a collaborative process.' Guidance point 3



(5) USA and some major Sponsors

The US Code of Federal Regulations does not mention post trial access.

Some major sponsors of research are prohibited from funding post trial access (NIH) or state that their remit excludes this (Wellcome Trust, 2004)



(6) MRC Guidelines on Ethics for Medical Research

There should be benefit to a host country community in which research is undertaken, such as access to the best proven prophylactic, diagnostic and therapeutic methods identified in the study



Thank You



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