



Albert Einstein College of Medicine
OF YESHIVA UNIVERSITY

Science at the heart of medicine

Post-trial access to beneficial products of research

An ethical obligation

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Two underlying premises: Purpose of research

- The purpose of biomedical research is to investigate
 - > Safe, effective diagnostic and therapeutic methods to benefit future patients
 - > Safe, effective preventive methods to benefit at-risk populations

Two underlying premises: justice in research

- The principle of justice (as stated in the Belmont Report)
 - > ...whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.
 - Two necessary modifications
 - Not limited to support by public funds
 - Not limited to therapeutic methods

Rights-based approach

- International Covenant on Economic, Social, and Cultural Rights
 - > 1. The States Parties to the present Covenant recognize the right of everyone
 - (b) To enjoy the benefits of scientific progress and its applications
 - > “States Parties” refers to governments that have signed and ratified the Convention
 - > Human rights approach also recognizes a role for non-state actors



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The Declaration of Helsinki

- In versions before 2000, the DoH made no explicit mention of post-trial benefits
- In the DoH 2000-2002, two paragraphs addressed post-trial benefits
 - > Statement of benefits to the population in Para. 19
 - “Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research”
 - Sufficiently vague to allow a wide range of possible interpretations

DoH 2000-2002

- Explicit statement of benefits to participants in Para. 30
 - > “At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.”
 - Unrealistic?
 - Impossible to implement?
 - Would deter sponsors from initiating needed research?
 - Who should “assure” access?

2004 Note of Clarification

- The WMA hereby affirms its position that it is necessary during the study planning process to identify post-trial access by study participants to therapeutic, diagnostic, and therapeutic procedures identified as beneficial in the study or access to other appropriate care.
- Post-trial arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

2008 Para. 33: Weakening the obligation

- 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 in the study or to other appropriate care or benefits.
 - > No clear obligation to provide beneficial interventions
 - > What other care is appropriate?
 - > What other benefits are appropriate?
 - > Who is under an obligation to share the benefits?
 - > Who should decide?

Proposal for strengthening the paragraph

- Version (1) of new paragraph (preferred version)
 - > “In advance of a clinical trial, sponsors, researchers, and host-country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the study. All study participants should be informed about the outcome of the study.”
 - Names the responsible agents
 - Includes host governments as agents
 - Improvement over CIOMS guideline
 - Reverts to essence of 2002 version

Proposal (2) for strengthening

- Sponsors, researchers, and host-country governments should ensure that all participants who still need an intervention identified as beneficial in a clinical trial have access to that intervention at the conclusion of the study. All study participants should be informed about the outcome of the study.
 - > Names the responsible agents
 - > Less specific than proposal 1
 - > Does not mention when provision should be arranged

Proposal (3) for strengthening

- At the conclusion of a clinical trial, participants in the experimental and control arms who still need an intervention identified as beneficial in the study are entitled to have access to that method. All study participants should be informed about the outcome of the study.
 - > Weakest of three proposals
 - > Does not identify responsible agents
 - > Specifies the control arm as potential beneficial method
 - Does not require that access to the experimental product be provided

Conclusions

- Ensuring post-trial access is a shared responsibility
 - > Burden does not fall on sponsors alone
 - > Burden does not fall solely on governments in host countries
 - > ‘Ensuring access’ does not simply mean ‘paying for successful products of research’
 - Creative means are needed to develop cooperation between researchers and sponsors, on one hand, and other sources of funds
 - Global Fund
 - PEPFAR
 - Gates Foundation