Medicatieverstrekking ná onderzoek gezien vanuit de Declaration of Helsinki

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WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI
Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the 29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

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and amended by the:

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53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)
55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)
59th WMA General Assembly, Seoul, Republic of Korea, October 2008
64th WMA General Assembly, Fortaleza, Brazil, October 2013

Declaration of Helsinki

General Principles

10. Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. **No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.**

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Recommendations guiding physicians in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly

Helsinki, Finland, June 1964

and amended by the

29th World Medical Assembly, Tokyo, Japan, October 1975

35th World Medical Assembly, Venice, Italy, October 1983

41st World Medical Assembly, Hong Kong, September 1989

and the

48th General Assembly,Somerset West, Republic of South Africa, October 1996

Declaration of Helsinki 1996/2000

- In versie 1996 geen enkele verwijzing naar medicatieverstrekking na onderzoek.
- In versie 2000 onder III. Non-therapeutic biomedical research involving human subjects (Non-clinical biomedical research):

  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.

Declaration of Helsinki 1996/2000

Removal of an effective intervention when a study is over, especially in situations in which the intervention is otherwise unavailable to the individual, could not only be harmful, but might also contravene ethical obligations created by engaging people in research. Unfortunately, how to assure access, and whose responsibility it is, are challenges left unanswered by the 2000 declaration.

Forster et al, The Lancet 2001,358(27), 1449

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Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002

Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

Declaration of Helsinki 2004

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

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.[2]

Declaration of Helsinki 2004

[2] Note of clarification on paragraph 30 of the WMA Declaration of Helsinki

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

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Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

59th WMA General Assembly, Seoul, October 2008

Declaration of Helsinki 2008

C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

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 in the study or to other appropriate care or benefits.

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI 2013

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and amended by the:

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Declaration of Helsinki 2013

Post-Trial Provisions

34. 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 trial. This information must also be disclosed to participants during the informed consent process.

Conclusie

- De WMA spant zich in om de beschikbaarheid van de onderzochte medicatie na het onderzoek voor de proefpersonen te regelen

- De toelatingsautoriteiten lijken het hier moeilijk mee te hebben, gezien ook de verwijzing naar DoH 2008 in de nieuwe Verordening betreffende klinische proeven met geneesmiddelen voor menselijk gebruik