



Protecting Vulnerable Subjects

Addressing vulnerability in the Declaration of Helsinki

Expert Conference on the Revision of the Declaration of Helsinki

5 – 7 December 2012, Cape Town

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Outline

1. Fields of discussion and major questions
 2. Vulnerability in the DoH
 3. Suggestions for the current revision process of the DoH
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Fields of discussion and major questions

- Defining “vulnerability”
 - Listing of vulnerable groups
 - Protection of vulnerable subjects
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Vulnerability in the Declaration of Helsinki

Defining vulnerability

“9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research **populations** are particularly vulnerable and need special protection. These include **those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.**” (DoH 2008)



Vulnerability in the Declaration of Helsinki

Listing of specific vulnerable groups:

“9. [...] those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.”
(DoH 2008)



Vulnerability in the Declaration of Helsinki

Special protection:

“17. 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.” (DoH 2008)



Suggestions for the current revision process of the DoH

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research **subjects** are vulnerable and have **an increased likelihood of incurring additional and greater wrong**. They need special protection.



Suggestions for the current revision process of the DoH

17. Medical research involving a **vulnerable** population or community is only justified if the research is **responsive to the health needs and priorities** of this population or community, if there is a reasonable likelihood that this population or community stands **to benefit from the results of the research** and if the research cannot be equally carried out with other research subjects.



Thank you.

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