



# Research on Enhancement – an Issue for the Declaration of Helsinki?

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# Enhancement – an issue?

- The practice of enhancement is growing.
  - Neuroenhancement, aesthetic surgery, fitness...
  - The debate on enhancement is growing.
  - The efforts in enhancement will increase!
  - **Enhancement is an issue of the future!**
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# Research on enhancement – an issue?

- Mainly **off-label use**
- Currently **no evidence** for all of the alleged enhancement technologies about efficacy, effectiveness, safety, unwanted effects. (Except drugs with unacceptable side-effects).

“The claimed and assumed benefits are often exaggerated.” (Saskia Nagel)

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# Research on enhancement – an issue?

- Research on enhancement is necessary.
  - Current use is not based on valid information.
  - Scientific evidence is also needed for a social and political debate!
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# Norms in research on enhancement?

- All norms for research involving human beings are valid in research on enhancement.
  - In addition: There is no health benefit in case of successful research on enhancement.
    - Risk/benefit assessment is different
  - The patient must be informed about the nature of the research: no health benefit!
    - Informed consent is different
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# Research on enhancement is not explicitly mentioned in the DoH

**Art. 7** : “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 (methods, procedures and treatments).”

Research on enhancement: research with **medical technologies** for **non-medical** purposes

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# Are the norms for research on enhancement covered by the DoH?

Yes, implicitly:

Part B: **PRINCIPLES FOR ALL MEDICAL RESEARCH**

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# Are the norms for research on enhancement covered by the DoH?

**risk/benefit assessment:**

**Art. 18:** “Every medical research study involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.”

**Art. 21:** “Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.”

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# Are the norms for research on enhancement covered by the DoH?

## Informed consent:

**Art 24:** “In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, **and any other relevant aspects** of the study.”

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## **A proposal for a new paragraph:**

The norms of the Declaration are also valid for medical research on enhancement. The risk/benefit assessment must be extremely careful, if no medical benefit can be gained by the research. The participants must be informed about the non-medical purposes of the research.

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## Final remarks

- The final decision whether to implement a paragraph on research on enhancement is a **political decision**.
  - There are other issues that could be regulated explicitly in the DoH as well.
  - Other considerations have to be taken into account (length of the DoH, importance of the issue, are explicitly mentioned norms necessary?...)
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