

Ethics in biomedical research

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Overview

- Background
- Benefits $><$ risk for harm and burdens
- Autonomy
- Integrity
- Anonymity / self-determination
- Links



Background

- Convention of Human Rights and Biomedicine (EU)
- Declaration of Helsinki
- Danish National Committee on Biomedical Research ethics (Videnskabetisk komite-system for biomedicinsk forskning)
- NFA paper on ethical rules for use of biomarkers in research



The interests and welfare of the human being shall prevail over the sole interest of society or science.

Research on a person may only be undertaken if ... there is no alternative of comparable effectiveness to research on human ... the risks which may be incurred by that person are not disproportionate to the potential benefits of the research

Convention on Human Rights and Biomedicine





Benefits $><$ harm/burdens

- Work environment research typically has benefits for the society and rarely for the individual participant
- Thus it is required that participation has negligible risk and minimal burden
- Consequences for purpose and design
- Make the relevant measurable – not the measurable relevant
- Obtain an impartial scientific opinion



Research on a person may only be undertaken if ... the necessary consent as provided for under article 5 (free and informed consent) has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

Convention on Human Rights and Biomedicine





Autonomy

- Voluntariness
- Self-determination
- Informed consent
- Be precise and concrete in the information
- Adapt the information to the recipient
- Do not retain relevant information
- Give time to think it over



Everyone has the right to respect for private life in relation to information about his or her health

Convention on Human Rights and Biomedicine





Integrity

- Participation in a research project must not threaten the participants health, self-esteem or violate their private life
- The right to know
- The right not to know



Anonymity

- If anonymity can not be guaranteed the researcher must refrain from conducting the study
- Voluntariness
- Handling of data
- Publication of results

Handling of data

- Data must be kept confidential
- Do not use identifiable data, use a running number
- Make a back-up – keep it locked both during and after the study
- Perform data-analysis in a room, which may be locked
- Keep the key for linking data to participant locked away
- Present only data in anonymous tables and figures





Publication of results

- DO IT! – also if the results are negative
- Min. 20 subjects in each group
- Send reports to works council (SU or MED-udvalg)
- Personal data only to the person, not to employer.
- Insurance company may not request information obtained in scientific studies in Denmark



Remember to notify:

- Datatilsynet (www.datatilsynet.dk)
- Rigsarkivet (adgang via Statens arkiver: www.sa.dk)
- Videnskabsetisk Komite (www.cvk.im.dk/cvk)



Reference and links

- Simonsen S and Nylenna M. Basic ethical, professional and legal principles of biomedical research. Scand. J. Work Environ. Health Suppl 2006:(2):5-14.
- Den centrale videnskabsetiske komite:
<http://www.cvk.im.dk/cvk>
- NFA og biomarkører:
http://www.arbejdsmiljoforskning.dk/upload/etiske_regler.pdf