The Committee System on Health Research Ethics
History

• The Nürnberg Process 1945
• The Helsinki Declaration 1964++2002
• The Committee System of Biomedical Research Ethics in Denmark 1980
• Good Clinical Practice Guidelines 2004
Committee Act

§1 Section 1:

It is the responsibility of the Committee system to ensure, that health research projects are carried out in a responsible manner. The rights safety and welfare of trial participants is stated as more important than developing new, valuable knowledge.
**Structure**

**DNVK**
- 13 Members

**REC The Capital Reg.**
- Committee A
  - 11 Members
- Committee B
  - 11 Members
- Committee C
  - 11 Members
- Committee D
  - 11 Members
- Committee E
  - 11 Members

**REC Zealand**
- 1 Committee
  - 11 Members

**REC Southern Denmark**
- Committee 1
  - 11 Members
- Committee 2
  - 11 Members

**REC Central Denmark**
- Committee 1
  - 11 Members
- Committee 2
  - 11 Members

**REC North Denmark Reg.**
- 1 Committee
  - 7 Members

- **12 Regional Ethics Committees in five regions**
- **1 national Committee**
The Danish National Committee (DNVK)

- 13 members including the chairman appointed by the Minister of Health
- Board of appeal for REC decisions
- Decides complex projects in 1. instance, e.g. genetic research and gene therapy
- Coordinates the work in RECs
- Focuses on international cooperation
- Gives an opinion in matters of principle
- Provides consultative statements on health research projects in developing countries planned by Danish researchers/ and or founded from DK
Regional Ethics Committees (REC)

- 7-11 members
- Lay members are appointed by the political system
- Medical/research members are appointed after recommendation by relevant professional research forums

- Health research projects
- Inspection of and follow up on approved projects
- Online notification procedure in REC
Health research projects

- Activity planned according to research methods

- Aim at producing new, valuable knowledge about human biological and psychological processes, either in relation to healthy persons or for the purpose of prevention, recognition, relief, treatment or cure of disease, symptoms and pain, including affecting bodily functions
Review by the REC

• Research quality
  - Design, risks, number of participants, new knowledge, publication

• Protection of participants
  - Information, voluntariness, advertising, financial arrangements, vulnerability of the patient category
Protocol
(What is often missing?)

- Expected adverse reactions, risks and disadvantages
- How biological material is handled
- Economic
  - Initiative
  - Sponsor
  - Amount and how payment is done
  - Economic attachment between sponsor and investigator
- Remuneration towards trial participants (must not affect the consent)
- How the results of the project will be made public
- Scientific ethical review
Information of the participants

- First contact to trial participant
- Who, where, how and when
- Written and oral information
- Reflection period
- Opportunity for the participants to have an observer present

- Oral information: responsibility of the investigator – opportunity to delegate
Informed Consent - Vulnerable Patient Categories – Surrogate Consent

- Legally incompetent trial subjects
  - Children (parents)
  - Adults (guardian or next of kin together with family doctor (medical officer))
- Emergency situations
  - Drugs (trial guardian, 2 physicians)
  - No drugs (improve the health both for the individual and for the group of patients § 11, section 1)

Exemption: 15-17 year old if project procedures is low-intervention
Health research projects in other countries

- DNVK can give a consultative statement
  - financed by Denmark
  - under the leadership of Danish researchers (then regardless of the source of financing)
- Statement is made in accordance with the standards of biomedical research ethics under Danish law
- No obligation for the researcher
More information

- DNVK’s homepage
  www.dnvk.dk
- REC’s homepages
  - find them through www.dnvk.dk
- Annual report