



TUTKIMUSEETTINEN
NEUVOTTELUKUNTA

INTERNATIONAL AND NORMATIVE PRESSURES

Secretary General

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National Advisory Board on Research Ethics



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NORMATIVE FRAMEWORK FOR RESEARCH IN FINLAND

Constitution (731/1999)

- Personal integrity (7 §), right to private life (10 §), freedom of expression (12 §), freedom of science (16 §)

Personal Data Act (523/1999)

- General principles of data handling, sensitive data (11-12 §), historical and scientific research (14 §)

Medical Research Act (488/1999)

- Ethics committee evaluation (3 §), informed consent (6-9 §), person in charge of research (5 §), monitoring and reporting



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NORMATIVE FRAMEWORK FOR RESEARCH IN FINLAND

Medical research:

” research involving intervention in the integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of disease in general” (2 §)

Governmental Bill 228/1998:

Research using only register data or e.g. psychological or sport studies excluded from the scope of application.



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NORMATIVE FRAMEWORK FOR RESEARCH IN FINLAND

- Research in humanities and social sciences has been left outside the speciality legislation
 - No legal requirement for ethics evaluation
 - General responsibility to protect personal integrity and private life
 - Present system of hospital district ethics committees does not apply well to evaluation of humanities and social sciences
 - Resources, expertise, different academic standards & methodology
 - Why should we introduce ethics evaluation?



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INTERNATIONAL PRESSURE

- Normative international pressure
 - International treaties that Finland is bound by
- Practical international pressure
 - International research group
 - International funding
 - International publisher



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INTERNATIONAL NORMS

- Biomedicine Convention (ETS 164)
 - Finland signed 1997, ratification preparation
 - Article 4:
 - “Any intervention in the health field, including research, must be carried out in accordance with relevant professional obligations and standards. “
 - ‘Health field’ covers research in psychology and social work (kappale 28).



INTERNATIONAL NORMS

- Biomedicine Convention (cont.)
 - Article 15: Scientific research *in the field of biology and medicine* shall be carried out freely, subject to provisions ensuring the protection of the human being.
 - Article 16:
...“the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the importance of the aim of the research, and multidisciplinary review of its ethical acceptability”



INTERNATIONAL NORMS

Additional Protocol to the Biomedicine Convention (ETS 195)

- Article 2:

“This Protocol covers the full range of research activities *in the health field* involving interventions on human beings.”

Intervention: physical intervention, and any other intervention in so far as it involves a risk to the psychological health of the person concerned.

- Article 9 sets ethics review as prerequisite
- All research in the health field subject to ethics review
- Explanatory report: definition of “biomedical research” follows the definition in the Mother Convention.



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INTERNATIONAL NORMATIVE MODELS

Sweden:

studies that can have a physical or psychological effect to the participant, or where sensitive data is processed.

Norway:

medical and health research

Denmark:

as in Finland – only medical research



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INTERNATIONAL NORMATIVE MODELS

United Kingdom:

Legislation: clinical trials on medicinal products

Administrative: all research in health and social sector

Funding body (ESRC): economic and social studies

United States:

all research on humans (medical, sociological and behavioural studies)



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PRACTICAL INTERNATIONAL PRESSURE

International research group

- Same rules for all

International funder

- E.g. United States or United Kingdom

International publisher

- Distinguished and prestigious international journals



DISCUSSION

- Pressure for setting up ethics committees, but how?
 - All research on humans subject to the same rules? (AUS & USA & CAN)
 - Medical and health research (also behavioural research?) under same criteria? (NO)
 - Review independent from academic disciplines:
 - Research environment – only hospitals or health and social field? (UK)
 - Risks to participants – who evaluates? (SE)
 - Research by students
 - Excluded (SE) or 'light approach' (UK)?
 - Free of formalities and/or voluntary?