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## Ethics Review in Finland

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# Finland: normative framework for ethical evaluation

- Act on Medical Research (488/1999)
- Research in humanities, social and behavioral sciences has been left outside the legislation
- In November 2007, the National Advisory Board on Research Ethics appointed a working group to look into the need for ethics review in the humanities and social sciences
- Ethics review system has been enforced from the beginning of 2010


# The need for an ethics review system in Finland

- Researchers themselves need the evaluation for the moral basis of their study
- Research subjects need protection
- International publications, foreign sponsors, or foreign research partners require the review
- Competence and capacity of medical ethics committees are not adequate




# Proposals

- The new system for ethical review is not based on legislation, but universities and research institutes have joined the organization on a voluntary basis adhering to the principles and arrangements laid down by the Advisory Board.
- The goal is that the committees have a regional mandate so that all researchers can submit their project plans to a committee irrespective of where they work.



Researchers must submit their research plan to ethical review if a study contains any of the following features:

1. The study involves intervening with the subjects' physical integrity.
2. The study deviates from the principle of informed consent
3. The subjects are children under the age of 15 and the study is not part of the normal activities of a school or an institution of early childhood education and care and the data are collected without parental consent and without providing the parents or guardians the opportunity to prevent the child from taking part in the study.



# Researchers must submit their research plan to ethical review if a study contains any of the following features:

4. The study exposes research subjects to exceptionally strong stimuli and evaluating possible harm requires special expertise.
5. The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond similar risks encountered in normal life.
6. The study can pose a security risk to subjects.

A researcher can also request an ethical review if the research subject, the funding agency or a cooperation partner so requires or if the results are to be published in a scientific journal which requires ethical review. The reason for requesting an ethical review must always be specified.



# Ethical principles related to data archiving and re-use

- If the study deviates from the principle of informed consent it should be evaluated
  - BUT ethical review is not required if the research is based on public documents, registries or archived data.
- Research ethics principles concerning the protection of privacy aim to find a balance between confidentiality and the openness of science
  - Research in the humanities and social and behavioral sciences is not always repeatable, but the scientific community should have the possibility if necessary to verify research findings from the data analysed in a study.
  - Openness is a key defining characteristic of science and also a precondition for testing the validity of scientific information, critically evaluating information and advancing science.
  - Data which is carefully archived for secondary research reduce the need to collect undue research data containing identifiers.
  - Archiving data reduces the pressure to research small population groups.
  - It is especially important to archive research data which are significant from a cultural, a historical or a secondary research viewpoint.



# Privacy and confidentiality

- Data containing identifying information can be collected and used when it is appropriate from a research viewpoint.
- With the consent of the subject data with identifying information can also be archived for secondary research.
- It is important to respect the autonomy and own judgment of the research subjects. In social research, participants are usually fully competent to assess the risks involved without outside expertise.
- The protection of subjects' privacy should be ensured by setting strict conditions for the secondary use of data.





# Privacy and confidentiality

- The limits of the sensitivity and privacy of the matters that are dealt with in studies depend primarily on the research subjects.
- By giving consent the subjects have demonstrated their willingness to participate in a study while being aware of the study's scope and methods.
- If the subjects participate in a study by writing about their experiences or filling in a questionnaire, they regulate their own participation by avoiding matters and questions that they consider damaging, harmful or too intrusive.



# Ethical review

- The review process should put special emphasis on adequate data management.
  - Information given to research participants, data security, plans to remove or protect identifiers, data archiving plan
  - Specific consent with regard to the use of data in only one project without an archiving plan may be justified only on the grounds that data cannot be anonymized and the archiving of data with identifiers for secondary research would in all likelihood be detrimental to subjects.

# Ethics review in the University of Tampere

- Finnish Social Science Data Archive was invited to participate in planning how to organise ethics review in the University of Tampere and in creating guidelines for the review
- When making guidelines for researchers special attention was paid to data management
- Ethical guidelines have several links to data archive's web pages ('informing research participants', 'anonymisation', 'data security')
- Starting point of the committee: the research project to be evaluated will have a detailed plan on how to archive the data at the end of the project
- Since Tampere University was the first one to implement ethics review, it has been a model for other universities
- In the forthcoming large seminar on ethics review, half of the time available will be given to FSD to lecture about data management

# Further information



- Ethical principles of research in the humanities and social and behavioural sciences and proposals for ethical review (National Advisory Board on Research Ethics, Helsinki 2009)
- <http://www.tenk.fi/ENG/ethicalreview.htm>