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Ethical Control of Social and Behavioral Research in Finland
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THE LEGAL FRAMEWORK

Medical research is regulated by the Medical Research Act and Decree. In the Medical Research Act, medical research is defined as "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". The act thus covers only research involving an intervention and aiming at specifically medical knowledge. The commentary of the government proposal to parliament explicitly states that the act does not apply to experimental psychology or sports science.

The most important piece of legislation regulating social research is the Personal Data Act based on the EU Data Protection Directive (Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data; Rosier & Vereecken, 2003, is a useful survey of the data protection legislation in EU countries). In addition, there are special laws on various person registers.

There are no legal regulations concerning ethical review of behavioral and social research. Four mechanisms have, however, helped to spread administrative ethical control from medical to behavioral and social sciences. First of all, institutions of health care require ethical review of all projects to be carried out in their setting irrespective of whether they are medical or not. In practice, this means submitting behavioral and sociological projects to medical review boards (see sections on Ethics Committees of Hospital Districts and non-medical research and the Department of Psychology of the University of Helsinki).

Second, research institutions with a representation of other disciplines in addition to medicine have started to put all their projects under ethical review (see sections on the Social Insurance Institution of Finland and the National Public Health Institute).

A third mechanism is that many journals that cut across medical and behavioral disciplines require that all submissions have been reviewed by ethics boards. Departments that published articles in such journals have been compelled to submit their project plans to medical committees or to establish ethical committees of their own (see sections on the University of Jyväskylä and the Department of Psychology of the University of Helsinki).

Fourth, interpretations of the Office of the Data Ombudsman have in practice extended to all research requirements that strictly taken concern medical research only (see section on the Office of the Data Ombudsman).

It should be pointed out that the mechanism that from a cross-national perspective is the most powerful one has not played any role in Finland. At least in the United States, Canada and the United Kingdom, most funding agencies now require ethical review of all grant applications. No corresponding regulations exist in Finland. Until recently, U.S. federal requirements also have not affected social and behavioral research in Finland, but the situation may be changing (see section on the University of Helsinki).
NATIONAL AGENCIES

National Advisory Board on Research Ethics

The National Advisory Board on Research Ethics was established in 1991. The board is appointed by the Ministry of Education for a term of three years. It consists of a chairman, a vice chairman and eight members representing key disciplines and administrative bodies responsible for research ethics. The board
1. makes proposals and issues statements to governmental authorities on legislative and other matters concerning research ethics;
2. acts as an expert body working towards the resolution of ethical issues relating to research;
3. takes initiative in advancing research ethics and promotes discussion concerning research ethics;
4. monitors international developments in the field and takes actively part in international cooperation;
5. informs the public about research ethics.

The board issues guidelines for good scientific practice and procedures for handling misconduct and fraud in science. The third version of the guidelines came out in 2002. Alleged cases of misconduct or fraud are handled by the research organization with which the researcher is most closely associated. A researcher dissatisfied with the handling of his or her case can request the opinion of the board. The board has an advisory role and does not issue legally binding decisions.

In 2003–2005, a working group of the board investigated the need for special ethical guidelines for the social sciences and the humanities. At this stage, the working group did not recommend the preparation of a set of guidelines, but instead wanted to stimulate public discussion. To this purpose an anthology of articles on research ethics in the social sciences and the humanities was published under the auspices of the board in August 2006 (Hallamaa et al., 2006).

According to the action plan for 2006 of the board, the requirements of a growing number of international journals have intensified the demand for an ethical evaluation of non-medical projects, and representatives of the ethics committees of the hospital districts have argued that they do not have enough resources nor the required expertise to accomplish the task. It is against this background the board wants to launch a discussion of the possible need for new ethics committees that would take over the task of evaluating non-medical research projects involving humans.

(National Advisory Board on Research Ethics et al., 2006)

Advisory Board on Health Care Ethics and the Sub-Committee on Medical Research Ethics

The Advisory Board on Health Care Ethics was established in 1998. The Government appoints the board for a four-year term. The board consists of a chairperson, a vice chairperson and 18 members representing healthcare service users and providers, healthcare professionals, and various disciplines such as law, medicine, nursing science and ethics. At least four members must be members of parliament. The board meets six times a year. The board
1. takes initiatives and makes recommendations on ethical issues in health care,
2. acts as an expert body on health care legislation;
3. collects and disseminates information about ethics in health care and about international ethical discussion on health care;
4. follows the development of health care and health technologies from an ethical point of view.

The National Advisory Board on Health Care Ethics has a Sub-Committee on Medical Research Ethics. The sub-committee consists of a chairperson, a vice chairperson and nine members. The members represent pharmaceutical research, various medical specialties, genetic research, epidemiology, jurisprudence, ethics and patients. The sub-committee meets once a month.

The sub-committee reviews international multi-centre clinical trials on medicinal products or delegates the task to ethics committees of hospital districts. The sub-committee considers more than 200 applications each year. Opinions given by the sub-committee are not appealable, but it can reconsider an application after the requested changes have been made.

Other medical research and clinical trials on medicinal products to be conducted only in Finland are reviewed by the ethics committee of the hospital district within which the person in charge of the investigation is operating or within which the trial is mainly to be carried out.

The sub-committee provides support to the ethics committees of hospital districts and assists in arranging training in ethical issues concerning medical and other health care research. For example, the sub-committee has prepared a model consent form and a detailed checklist for applicants and members of ethics committees.

The sub-committee also functions as an instance of appeal. When a regional ethics committee gives a negative opinion on a project and the applicant resubmits an unchanged research proposal, the ethics committee has to apply for an opinion from the sub-committee. Appeals are rare, only 1–3 cases each year.

(National Advisory Board on Health Care Ethics, 2005; National Advisory Board on Research Ethics et al., 2006; Konttinen, 2006)

Academy of Finland

The Academy of Finland is the most important funding agency for university research in Finland. It has a board, four research councils and an administrative office. The councils are: Research Council for Biosciences and Environment; for Culture and Society; for Health; and for Natural Sciences and Engineering. The councils and the board are appointed by the government for a three-year term. The Academy operates under the administration of the Ministry of Education. Annually the Academy issues funding decisions worth around 200 million euros.

In the application guidelines of the Academy of Finland, the focus of the research ethics page is on misconduct and fraud in science. Relationships to research subjects are mentioned in passing only and on a very general level: Researchers funded by the academy have to comply with prevailing legislation and to use ethically sustainable methods of data collection. However, ethical review of medical research is taken for granted. The statement of an ethics committee is listed among the most common appendices to research plans, "if such a statement is necessary".

There are no special guidelines concerning social and behavioral studies, but the section on "objectives and methods" of the model outline of the research plan includes a sub-section on "ethical questions and/or data protection issues". No information is available on how much attention is paid to this section in the review process.

(Academy of Finland, 2006)
Office of the Data Protection Ombudsman

The Office of the Data Protection Ombudsman is an independent authority operating in connection with the Ministry of Justice. The office is run by the Data Protection Ombudsman, appointed by the Government for a term of five years. The total number of staff is 20. The Data Protection Ombudsman guides and controls the processing of personal data and provides related consultation. The ombudsman sees to the distribution of information related to data protection and participates in international co-operation. (Office of the Data Protection Ombudsman, no date.)

The office has adopted an extremely strict interpretation of the Personal Data Act. The booklet prepared by the office on scientific research purports to apply to all types of research involving humans, but some of its requirements clearly are based on the Medical Research Act and not on the Personal Data Act (Tietosuojavaltuutetun toimisto, 2001; Kleemola, 2000). The same is true of other guidelines prepared by the office.

The Personal Data Act (section 10) requires that the controller shall draw up a description of the personal data file and keep the description available to anyone. The office has prepared two model descriptions, one for research data files and another for other data files. Much more detailed information is required in the case of research files. For example, in the case of research files, the description has to identify all individuals who are authorized to process the data. For files collected for other purposes, it suffices to identify a person responsible for processing the data and/or contact person. The Personal Data Act contains no stipulation that could motivate this additional requirement with regard to research files.

More importantly, the instructions for the description form stipulate that the study for which the file will be used has to be defined very narrowly and in a way that excludes all secondary analyses. Moreover, the description has to characterize the study by selecting one of two alternatives, as an "on-off project" or as a "follow-up study". Once again, it is impossible to fit ethnographic studies, for example, into this dichotomy.

The likely explanation for the more stringent requirements for research files is that they are based on the Medical Research Act and on medical research practice. They are, however, presented as universally valid requirements based on the Personal Data Act.

The office also has prepared a model consent form for research subjects. The instructions require that the consent always be given in writing. This goes against even the Medical Research Act, which makes allowance for oral consent "when giving personal data would be in contrary to the research subject's interests and the research will only involve minor stress to the research subject and is not harmful". The commentary of the government proposal to parliament on the Personal Data Act explicitly condones oral consent.

Moreover, the instructions formulate categorical and detailed requirements concerning the information to be presented to the participants. For example, information has to be provided about the benefits the research will bring to the participants and to the society. This and other requirements have no basis in the Data Protection Act but can perhaps be based on the Medical Research Act. The line adopted by the Office of the Data Protection Ombudsman is, however, echoed in a recent monograph on research ethics focusing on social research, where a long and detailed list is presented of items that "always have be covered by the information provided to the subjects" (Kuula 2006, 121).
ETHICS COMMITTEES OF HOSPITAL DISTRICTS

In Finland, the first ethics committees were established in medical faculties in the late 1960s (Immonen, 1992, 26). By the late 1970s, all medical faculties and a number of hospitals and other health care units had ethics committees. In 1979, the National Board of Health issued a circular on research ethics committees of hospital districts. Ethics committees were also established in a number of research institutes.

The present system is based on the Medical Research Act. A medical research project may be started only after an ethics committee has given a favorable opinion on the research plan. Each hospital district shall have at least one ethics committee. There are 21 hospital districts and 25 ethics committees. Projects shall be considered by the ethics committee of the region where the person in charge of the research is based or of the region where the research is to be principally conducted.

Ethics committees consist of a chairperson and at least six other members. Apart from medicine, ethics committees shall also contain representatives for other areas. At least two members shall be laypersons. The committee shall include both men and women; at least 40 per cent of both genders.

The ethics committees evaluate research projects based on provisions of the Medical Research Act, data protection legislation, the international obligations covering the status of research subjects and the rules and guidelines that govern medical research. The most important of these are the Convention of Human Rights and Biomedicine by the Council of Europe (CETS 164) and the Directive 2001/20/EC on the implementation of good clinical practice on clinical trials on medicines.

An opinion on the clinical trials on medicinal products that are carried out as international multicentre research shall be given by the relevant sub-committee of the National Advisory Board on Health Care Ethics, unless the task has been delegated to a regional ethics committee.

If the opinion of the ethics committee is negative, the matter can be brought before the committee for reconsideration. The ethics committee shall then seek the opinion of the Sub-Committee on Research Ethics of the National Advisory Board on Health Care Ethics.

An application that has been given a negative opinion may be resubmitted when the changes requested by the ethics committee have been made.

The following excerpt from the guidelines of the Ethics Committee of the Hospital District of Northern Savo gives a good picture of the review process:

"The verdicts of the committee generally belong to the following formats:
Positive opinion: the research plan fulfills the legal requirements.
Positive opinion, on condition that the following further information is supplied to the secretary or the working committee of the committee. (Usually small technical defects.)
The application was tabled for further information. (Important defects in the research plan or the appendices.)
The application was tabled and the researchers will be invited to the next meeting of the committee. (Ethical issues are related to the research plan that need discussion.)
The application was transferred to the Sub-Committee on Research Ethics of the National Advisory Board on Health Care Ethics. (General ethical issues that require national discussion.)
The application cannot receive a positive opinion. (It is always question of a serious ethical problem. Before this decision the researcher has been invited to present his comments..."
In the review process, ethical, scientific and administrative aspects are closely intertwined. According to the commentary of the government proposal to parliament, ethical review of research protocols requires scientific expertise. It is unethical to submit research subjects to any risk, if the research cannot possibly provide answers to the research questions posed, for example, if the statistical power of the study design is not adequate. It is similarly unethical to carry out repetitious studies of problems that already have been adequately investigated. Issues like these require scientific expertise. When deemed necessary, the committee may also consult outside experts to assess the scientific value of a proposal.

In theory, practical and administrative considerations should not be part of the ethical review process. A positive ethical review of a proposal is not in itself a guarantee that it can be carried out. Suitable research subjects are a scarce resource, and it is up to the administrative leadership of each health care unit to control the access to patients and personnel. In actual practice, it is difficult to keep apart scientific, ethical and administrative considerations, since the expected scientific value of a proposal has a bearing on both ethical review and administrative decision-making. These issues are particularly salient in the review of qualitative social science proposals.

Both applicants and committee members have difficulties in distinguishing between ethical and administrative considerations. Representative of a hospital district are often annoyed when the ethics committee of another district "interferes in our affairs", and social scientists in particular do not always understand the difference between ethical review and administrative decision-making.

*(Medical Research Act; National Advisory Board on Research Ethics et al., 2006; interviews with members of the Sub-Committee on Medical Research Ethics)*
ETHICAL REVIEW OF NON-MEDICAL RESEARCH

The research organizations described in this section have been selected to represent various contexts of the ethical control of social and behavioral research. The ethics committees of hospital districts review a lot of non-medical projects carried out under the auspices of health care units. The Social Insurance Institution and the National Public Health Institute both undertake social as well as medical research and have institutional ethics boards of their own. The A-Clinic Foundation is the leading substance abuse service provider in Finland. The National Research and Developmental Centre for Welfare and Health is the only organization focusing on social research that has an institutional ethical review board of its own. The University of Helsinki is the largest and oldest among Finnish universities, and the Department of Psychology and the Department of Sociology represent two different arrangements in a university context. The University of Tampere is a large university with a special emphasis on social and behavioral sciences. Finally, the University of Jyväskylä has a review board mainly for projects in physiology and sports sciences that do not meet the legal definition of medical research but nevertheless contain similar interventions and risks.

Ethics committees of hospital districts and non-medical research

The Medical Research Act covers only research involving an intervention and aiming at specifically medical knowledge. This differs from the guidelines issued by the British Central Office for Research Ethics Committees (Tinker, 2004). Paragraph 3.1 of Governance Arrangements for National Health Service’s Research Ethics Committees states that ethical advice from the appropriate NHS REC is required for any research proposal involving:

a. patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user’s past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions;

b. individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;

c. access to data, organs or other bodily material of past and present NHS patients;

d. fetal material and IVF involving NHS patients;

e. the recently deceased in NHS premises;

f. the use of, or potential access to, NHS premises or facilities;

g. NHS staff recruited as research participants by virtue of their professional role.

In actual practice, the difference between the British and Finnish systems is smaller than on paper, since most Finnish health care units require an opinion of an ethics committee for all projects carried out under their auspices irrespective of whether they meet the legal criteria for medical research. The interpretation of the hospital district committees of their mandate varies, but most hospital district committees sometimes review projects not covered by the Medical Research Act. Sometimes this leads to rather artificial arrangements. According to the Medical Research Act, "medical research may be undertaken only under the responsibility of a medical doctor or dentist with the adequate professional and scientific qualifications", and ethics committees tend to apply this requirement also to projects that are not medical research as defined by the act. This means that a linguist and a social psychologist carrying out a conversation analytic study of doctor patient interactions may have to find a pro forma dentist to supervise their work or that an
internationally well-known specialist in brain research may have to work under the protection of a less experienced medical doctor. All may go smoothly if the pro forma project director refrains from intervening in the research process, but problems arise if he wants to share authorship.

Qualitative studies are particularly problematic. One the one hand, research plans of inexperienced qualitative researchers are often inordinately vague. One the other hand, it is outright impossible to describe in advance the qualitative research process in the degree of detail required for clinical trials.

Social Insurance Institution of Finland

The Research Department of the Social Insurance Institution has 68 personnel. Of these, 25 persons work in social research, 25 in health research, 11 in research services and 7 in research administration. It should be pointed out that all projects carried out as health research are not necessarily medical research. The main part of the department is located in Helsinki but there is a smaller unit in Turku.

The social science projects carried out at the research department are predominantly based on survey and register data.

Before the Medical Research Act, the Social Insurance Institution was one of the institutes that had a medical review board of their own. After 1999, all medical projects have to be submitted to a hospital district committee, but the institution decided to uphold its own board for the purpose of reviewing non-medical research.

The Research Ethics Committee is appointed for a period of three years. It consists of one outside member (presently a professor of medical ethics at the Department of Philosophy of the University of Turku), three representatives of the research units and one representative of the administrative unit of the research department. The committee meets 1-2 times and reviews 1-2 applications a year. The committee keeps minutes of its meetings, but there is no annual report. The decisions of the committee are recorded in the minutes, and committee members convey more detailed information to the applicants on the deliberations of the committee.

There are no detailed guidelines on what projects have to be submitted for review. Judging from the following formulations on the home page of the committee, the criteria are quite inclusive: “A large proportion of research projects deal with individual human beings and must therefore be preceded by an ethical review.” The committee reviews non-medical projects “dealing with individual human beings and their personal integrity ... . The majority of interview and survey studies can potentially infringe on personal integrity and therefore are subject to ethical review.”

The committee is not, however, an instrument of administrative control. Its task is to offer service and advice, and it is up to the researchers to decide whether their research needs to be reviewed. The unit in Turku carries out rehabilitation surveys of, for example, the opinions of the respondents of the treatment they have received. The unit represents a clinical research tradition, and all studies including non-intrusive questionnaire surveys are brought under review. In Helsinki, not all projects are brought to the committee, but ethical issues connected to a project are often discussed informally with members of the committee.

In reviewing research plans, the committee pays particular attention to:
– the appropriateness of the research
– the potential for harm or discomfort to the research subjects
– the adequacy and comprehensibility of the information provided to the subjects
– privacy protection considerations.
As a general rule, the request for an ethical review must include at least the following information:

- Title of the research
- Main objectives of the research
- Research plan or a summary thereof
- Estimate by the researcher (or the research team) about the potential risks and benefits to the subjects and an outline of measures designed to minimize the risk
- Estimate by the researcher (or the research team) about the potential ethical or privacy protection problems associated with the research and a plan for reducing these problems
- A model informed consent form (if applicable to the research) and an outline of the information to be communicated to the subjects either orally or in writing and of the ways intended to ensure informed consent
- Copies of the letters to be sent to the subjects. The informed consent process must set aside sufficient time for the subjects to inform themselves about the issues involved before indicating their consent.

One may doubt the relevance of estimating the benefits to the subjects of non-medical research projects. As a rule, one might expect that a competent adult is able to decide on his or her consent without taking extra time.

The committee has never denied approval to a project, but it often requires changes in the research protocol. The researchers usually comply with the demands of the committee without protests. The only serious disagreement was several years ago concerning an internal questionnaire about the conditions of work in the Social Insurance Institution. There is no formal appeal procedure, but a researcher disagreeing with the committee could raise the issue at a meeting of the research department.

(Social Insurance Institution of Finland, 2006; interviews with members of the Research Ethics Committee)

National Public Health Institute

The National Public Health Institute is a research institute and expert body under the Ministry of Social Affairs and Health. The mission of the institute is to "provide decision makers, health care personnel and the public with the best available information on health for making their choices". The institute "promotes actions for health at all levels of society and government". At the end of 2005, the institute had a staff of 887 persons, of whom 367 (40 per cent) were scientists or experts. The majority of the researchers have a background in medicine or natural science, and only less than 5 per cent represent behavioral and social sciences.

The institute has a 120-page handbook of good research practice and detailed regulations on how research plans are processed and approved. All research has to undergo an ethical review. Medical research is reviewed by the ethics committee of the appropriate hospital district. Other projects are evaluated by the institute's own research ethics committee. The committee is appointed by the director general for a period of 3 years. The committee consists of a chairperson, five members and a secretary. One member represents the National Agency for Medicines; the rest are institute staff. The committee had 11 meetings in 2005. The committee keeps minutes of its meetings but has no annual report.

According to the standing order on the processing and approval of research plans, the ethics committee reviews the information to be given to participants in non-medical research following the guidelines of the committees of hospital districts "as appropriate". According to the
handbook of good research practice, the ethics committee "evaluates the study plan according to
the same ethical guidelines as the regional ethics committees". There is no discussion of to what
extent the guidelines based on the Medical Research Act can and should be applied to social and
behavioral research.

The handbook of good research practice contains an important passage on secondary use
of research materials: "It is important that the study materials can be utilised for research needs
arising at a later stage. Material already collected can often provide answers also to new research
problems more quickly, more easily and more economically than by carrying out a completely
new study. Research work is also made more efficient when previous investments into research
materials can be utilised." A little later it is pointed out that "it may also be open to interpretation
whether or not the consent obtained originally also covers further use". It is not clear whether
the committee has adopted a liberal or a strict line of interpretation.

(National Public Health Institute, 2001 & 2006; Aromaa et al., 2006; interviews with members
of the Research Ethics Committee)

National Research and Development Centre for Welfare and Health

The National Research and Development Centre for Welfare and Health was established in
1991 as a sector research institute under the Ministry of Social Affairs and Health. The centre's
"statutory function is to monitor and evaluate activities and developments in social welfare and
health care, to produce and acquire information and expertise at the national and international
level and to make relevant information and expertise available to users." (National Research and
Development Centre for Welfare and Health, 2006)

The centre has about 500 personnel of whom a large number (around 40 per cent) on short-
term contracts. The research and development activities are organized in four divisions: welfare
policy, municipality services, social services and health services research. Separate divisions handle
information, publications and international development collaboration. The research ranges from
large projects to small-scale investigations on topical questions. Projects often involve several
researchers and collaboration with partners from the outside.

The centre is also a statistical authority. Statistics on social and health services, alcohol and
drugs, and social and health expenditure are compiled for national and international purposes.
Some are freely available on the net (including statistical summaries and the databases of the
Care Registers for Social Welfare and Health Care). Other registers contain personal data and
are confidential.

Researchers need to submit their project plans to the head of their division, who then asks
the head of the centre's research activities for a statement. Large projects will be discussed by the
research committee or by the board of the centre.

As a register authority the centre is entitled to process its personal data files even when the
data have been collected for other purposes than the research project in question. An individual
researcher or project will, however, always need a new permission for each new project that
collects or uses confidential data.

If the research processes sensitive or in other respects confidential data from registers kept
by more than one authority or more than one municipality, permission must be sought from
the Ministry of Health and Social Welfare. The same holds for data from private health care
providers.

Before getting started, projects should "as a rule" be reviewed by an ethics committee (National
Research and Development Centre for Welfare and Health, 2006). Medical projects are reviewed
by the ethics committee of the hospital district. Non-medical projects are reviewed by the centre's
own ethics committee. In actual practice, it is up to the individual researchers or the heads of the divisions to decide whether a non-medical project raises ethical issues that need to be reviewed.

The ethics committee of the centre was established in 1993. The present guidelines for the committee were adopted in January 2003. The committee consists of 10 persons with expertise in social and health care research, ethical questions and data protection. The committee is appointed by the Director General of the centre for a period of three years. Of the present members, 8 are researchers and one is a legal expert. The head of the research activities of the centre acts as chair. At least one member must represent an external expert organization and one member has to be a layperson. Presently the University of Helsinki, the National Public Health Institute and the Finnish Institute of Occupational Health are represented on the committee.

The tasks of the committee are to review the centre's research and development projects, to produce statements on ethical questions on behalf of the centre and to attend to and discuss ethical issues in the field of social and health care. The opinions of the committee are formulated as recommendations as they are not binding in a legal sense although the staff of the centre has to comply with them.

The committee is entitled to discuss the scientific adequacy of the research design as well as ethical problems during the research process.

In addition to the centre's own projects, the committee may review external projects using the centre's data and on request external projects that have no connection to the centre, for example if the funding agency requires ethical review.

The committee meets at least three times a year (seven times in 2005). The committee will usually arrange an extraordinary meeting if a project needs a quick review. The annual number of projects reviewed has varied from five to ten. The committee has organized yearly seminars on ethical topics.

(National Research and Development Centre for Welfare and Health, 2003 a & b, 2003-2005 & 2006; interviews with members of the Research Ethics Committee)

A-Clinic Foundation

The A-Clinic Foundation is the leading substance abuse service provider in Finland, with a staff of 700 and 19 outpatient and inpatient service units. The foundation is a non-profit, non-governmental organization. The treatment services are mainly funded by municipalities. Training, research and information activities are funded through national funding sources, such as Finland's Slot Machine Association and the Ministry of Social Affairs and Health. The volume of research in the strict sense is limited but the foundation carries out a number of development projects to test the applicability of new prevention, treatment and rehabilitation methods in the context of the current alcohol and drug situation in Finland.

The Research Ethics Committee of the foundation was established in 1985. In 1992, it was re-established as the Treatment and Research Ethics Committee in the hope that this would be closer to the interests of the personnel and to treatment as the basic task of the foundation. The committee is appointed by the board of the foundation for a period of two years. It consists of a chair and 12 members representing research, treatment, public authorities and patient organizations.

Medical projects should presumably be reviewed by the ethics committee of a hospital district. Other projects are reviewed, "if need be", by the foundation's own ethics committee (A-klinikkasäätiö, 2006d). In actual practice, no research plans have been reviewed by the committee in 2004-2006. In 2006, 27 projects were granted permission to collect data in foundation settings. Five were classified as medical and 22 as non-medical. However, none of the projects had been
submitted to an ethics committee but all were reviewed by foundation executives. Most projects had limited scientific ambitions. The great majority were Bachelor’s theses (17) or Master’s theses (5). One study aimed at a doctoral dissertation, and four were general scientific projects.

(Ahonen, 2005, 316–317 & 321; A-klinikkasäätiö 2006a–d; minutes of the Treatment and Research Ethics Committee; interviews with members of the Treatment and Research Ethics Committee)

University of Helsinki

The University of Helsinki was established in Turku in 1640 and transferred to Helsinki in 1828. It has 11 faculties, 38,000 degree students and 7,600 staff. The number of doctorates taken each year is 400.

In June 2004, the rector of the university appointed a working group with the task of drafting an action program for the university in the field of research ethics. The working group submitted its report in October 2005. The working group found that the regulation of both animal and human research in Finland was in good order and limited therefore its recommendations to issues of misconduct and fraud in science.

The research ethics guidelines of the university provide links to sites presenting the regulations governing animal experiments, medical research of humans and research based on registers. The guidelines also claim that committees exist for the review of non-medical research of humans but add that these have no legal mandate and are just advisory bodies.

The university has submitted a Federalwide Assurance (FWA) to the U.S. Department of Health and Social Services. The assurance commits the university to the principles of the Declaration of Helsinki in all research involving humans and to the U.S. rules of protection of human subjects in all research funded by the U.S. federal government.

The university assures "that all of its activities related to human subject research, regardless of funding source, will be guided by the ethical principles” in the Declaration of Helsinki. The formulation is not limited to medical research but covers all human research. It is not clear how the phrase "guided by the ethical principles” should be interpreted, but it may be meant as a programmatic declaration. Many institutions in a number of countries have submitted similar assurances although their non-medical research with humans does not meet all detailed requirements of the Declaration of Helsinki or other corresponding codes. The assurance would thus not imply that all human research has to be put under ethical review, although the Declaration of Helsinki so requires. The fact remains, however, that psychological and sociological research complying with Finnish legislation does not meet all the detailed requirements of the Helsinki declaration. The assurance may thus be one more mechanism by which psychological and social research is put under pressure to follow medical codes.

The assurance categorically specifies that projects receiving funds from the U.S. federal government must be submitted to the coordinating ethics committee of the Hospital District of Helsinki and Uusimaa. This means that the ethics committee of the Department of Psychology, for example, cannot any more review project carried out on federal money. It also means that the hospital district committee has to review projects that are outside its field of scientific competence.

The ethics pages of the university web site contain special guidelines for research funded by the U.S. federal government. According to these guidelines, the assurance commits the university to the principles of the Belmont Report in all research involving humans despite the fact that the report is not mentioned in the assurance. Here the web site probably is mistaken. The terms of the federalwide assurance (FWA) for international institutions (U.S. Department of Health and Social Services, 2006) designate the Declaration of Helsinki and the Belmont Report as two of the
alternative codes among which institutions may choose, and the University of Helsinki decided to comply with the Declaration of Helsinki.

In projects receiving funds from the U.S. federal government, the university pledges to comply with the terms of the federalwide assurance for international institutions as well as the May 1, 1996, International Conference on Harmonization E-6 Guidelines for Good Clinical Practice (ICH-GCP-E6), Sections 1 through 4.

(Helsingin yliopisto, 2005, 2006a, 2006b; U.S. Department of Health and Social Services, 2006)

Department of Psychology

In 2004, the department had close to 450 undergraduate students majoring in psychology or cognitive science and close to 170 postgraduate students. In August 2006, the number of personnel was approximately 200.

Several of the research groups at the department publish in journals that require ethical review of all submissions. To meet this demand, the department established its own review committee in 1999. The committee consists of five psychologists, one medical doctor, one representative of the laboratory and technical personnel, one student representative and one layperson. In 2005, the committee met 8 times and reviewed 16 applications.

Ethical review is not mandatory but researchers can submit their proposals for review when they need an ethical opinion. Researchers often put their proposals under review even in cases where the results end up in journals not requiring ethical review. This is because of the so called Nature effect. High quality groups often submit their reports to top journals such as Nature or Lancet just to try their luck, and these journals require ethical review (Nature, 2006; Lancet, 2006).

Experiments using equipment of any of the hospitals of the Hospital District of Helsinki and Uusimaa have to be reviewed by the ethics committee of the hospital district irrespective of whether the project is medical research as defined by the Medical Research Act. This can bring about complicated and paradoxical situations.

In 2007, the ethics committee of the department will be superseded by a new committee to be established by the Faculty of Behavioral Sciences.

(Department of Psychology, 2005; minutes of the Research Ethics Committee; interviews with members of the Research Ethics Committee)

Department of Sociology

In fall 2006, the department had close to 600 undergraduate students majoring in sociology, demography or anthropology, close to 140 postgraduate students and some 20 personnel.

The department does not have an ethical board. Most of the research results are published in monographs or in journals that do not require ethical review. Projects carried out at the department have not received funding from the U.S. federal government. Health-related projects are reviewed by the ethics committee of relevant hospital district. Projects based on data in public registers require special permission and are reviewed by the register authorities.
The University of Jyväskylä was established in 1934 as Jyväskylä College of Education. In 2005, it had 7 faculties, 15,400 degree students and 2,500 personnel. The university offers cross-faculty training on research ethics, and its researchers have to follow the Guidelines for Good Scientific Practise of the National Advisory Board on Research Ethics.

The Ethical Committee of the university was established in 1991, with the Faculty of Sport and Health Sciences and particularly at the Department of Biology of Physical Activity playing key roles. In 1975, an amendment in the Declaration of Helsinki had introduced mandatory committee review of biomedical research projects involving humans. Medical journals started to require that all submitted articles include an assurance of ethical review, and journals in neighboring fields, such as physiology and sport sciences, soon followed suit. In the beginning, Jyväskylä sport scientists submitted their projects to the regional medical review committee, but soon the need was felt for a committee directly connected to the university.

The Ethical Committee is appointed by the rector for two years at a time. The committee spreads information on and promotes discussion of research ethics, for example by organizing courses and seminars. In addition, the committee reviews research protocols.

The 12 members of the committee and their deputies represent a broad spectrum of fields from musicology and philosophy to health sciences and information technology. One of the committee members represents medicine and another biology of physical activity. These two members share the main responsibility for reviewing the projects submitted to the committee.

The committee is somewhat indecisive about its remit. In June 2006, the main page of the committee spoke of research "where humans are studied in such a way that their health may be endangered". In June 2005, the formulation was narrower: "research where human participants were used as experimental subjects in such a way that their physical health may be endangered". The page giving more detailed instructions to applicants uses a third, somewhat different formulation and speaks of projects which "may cause physical or psychological harm to the participants or to endanger their legal rights". These nuances are not important, however, since ethical review is never mandatory but "an opinion can be sought if carrying out the project so requires".

The committee gives an opinion on 6-10 applications annually. About 80-90 per cent of the applications come from the Faculty of Sport and Health Sciences, and the rest are psychological experiments involving nutrients or medical compounds. Some applicants have been advised that ethical review is not required of straightforward surveys, for example. In at least one such case the committee nevertheless gave an opinion, when the applicant insisted on it.

(Jyväskylän yliopisto, 2006; University of Jyväskylä, 2006a, 2006b; interviews with members of the Ethical Committee)

The University of Tampere was established in 1930 in Helsinki as the School of Social Sciences and transferred to Tampere in 1960. It has six faculties, some 15,400 degree students and 2,100 staff. The university has "a special commitment to the critical scrutiny of social phenomena and the formation of civic society". Research activities are "focussed on society, its economy, administration and culture and on the health and welfare of individuals". (University of Tampere, 2007a)

The university adheres to the Guidelines for Good Scientific Practise of the National Advisory Board on Research Ethics. In April 2005, the university initiated a six-month project with the aim of mapping out the coverage of research ethics in graduate and post-graduate studies. The
recommendations presented in the project report are of a very general nature. They do not discuss the ethical review of research projects.

The university has no ethical review board. When social and behavioral researchers need ethical review, they submit their project plans to the ethics committees of the hospital districts, the Treatment and Research Ethics Committee of the A-Clinic Foundation or other relevant committees. Researchers at the Department of Sociology and Social Psychology have discussed the need for an institutional review board, and the issue will in all likelihood be put on the agenda of the Faculty of Social Sciences in the near future.

(Sahlander, 2005; Tampereen yliopisto, 2007; University of Tampere, 2007; interviews with representatives of the Department of Psychology and the Department of Sociology and Social Psychology)
CONCLUDING REMARKS

In the field of research ethics, agencies of research funding and administration such as the Academy of Finland and the universities focus on misconduct and fraud in science. This is mainly because the relationships to research subjects can either be taken for granted or is regulated separately by special legislation.

Register authorities keep a tight control of the use of personal data for research purposes. In some cases the regulation may be exaggerated. In the main, however, researchers have reasonable access to Finland’s multifaceted and reliable personal data files.

The system for ethical control of medical research is in good order.

In social and behavioral research, no serious cases of misconduct with respect to human subjects have been reported. This of course does not mean that no mistakes or wrongs are committed, but education and control based on the spontaneous morality of the research community and on the Personal Data Act probably are the most effective means to prevent transgressions.

Several mechanisms have helped to spread administrative ethical control from medical to behavioral and social sciences. This often means submitting social and behavioral projects to medical review boards or leads to other forms of mechanical application of medical review criteria to other branches of science.

There is no acute need for mandatory ethical control of social and behavioral research. There is a need, however, for separate ethical committees with special expertise in social and behavioral research. These committees need no legal mandate but should serve researchers who want to put their projects under ethical review because of the requirements of their funding agencies or of journals publishing their results.

Such committees will need codified criteria for review, to be based on international codes and to be developed by the relevant Finnish learned societies. It is important to keep in mind that the ethical issues of social and behavioral research often are of a different nature than those met in medical research.

In making plans for a legal or administrative regulation of any life arena, it pays to pose a few simple questions (cf. Tala, 2005):

- How commonly does misbehavior occur and how serious are its consequences?
- What proportion of the ills can be remedied by administrative regulation?
- What are the economic and other costs of the proposed administrative system?
- What unintended consequences are likely to surface?
- What alternative measures are available to prevent unethical practices?
- It is not easy to collect empirical evidence that helps to answer these questions. However, it is striking that in the discussion so far, questions like these have not even been formulated.

Advocates of administrative control simply argue that some problems are likely to exist and that no clear line can be drawn between all medical research and all other types of research. If similar arguments would be applied to other kinds of legislation, the outcome would be a tremendous increase in legal regulation. The fact that the borderline between legally regulated and unregulated cases is gliding does not mean that all cases should be regulated. Grey areas belong to the very nature of all legislation and all social life. The lack of unequivocal borderlines is in itself no argument for including all research under administrative review.
REFERENCES


Table 1. Chronology of ethical control of research in Finland

<table>
<thead>
<tr>
<th>Year</th>
<th>Event Description</th>
</tr>
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<tbody>
<tr>
<td>Late 1960s</td>
<td>The first research ethics committees were established in medical faculties</td>
</tr>
<tr>
<td>Late 1970s</td>
<td>All medical faculties had established a research ethics committee</td>
</tr>
<tr>
<td>1979</td>
<td>The National Board of Health issued a circular on research ethics committees of hospital districts</td>
</tr>
<tr>
<td>1985</td>
<td>The Research Ethics Committee of the A-Clinic Foundation was established</td>
</tr>
<tr>
<td>1988</td>
<td>The Personal Data File Act came into force</td>
</tr>
<tr>
<td>1991</td>
<td>The National Advisory Board on Research Ethics was established</td>
</tr>
<tr>
<td>1991</td>
<td>The Ethics Committee of the University of Jyväskylä was established</td>
</tr>
<tr>
<td>1993</td>
<td>The Research Ethics Committee of the National Research and Development Centre for Welfare and Health was established</td>
</tr>
<tr>
<td>1998</td>
<td>The Advisory Board on Health Care Ethics and the Sub-Committee on Medical Research Ethics were established</td>
</tr>
<tr>
<td>1999</td>
<td>The Research Ethics Committee of the Department of Psychology of the University of Helsinki was established</td>
</tr>
<tr>
<td>1999</td>
<td>The Personal Data Act replaced the Personal Data File Act</td>
</tr>
<tr>
<td>1999</td>
<td>The Medical Research Act came into force</td>
</tr>
<tr>
<td>2004</td>
<td>The Medical Research Act was amended</td>
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