

Ethical principles of research in the humanities and social and behavioural sciences and proposals for ethical review

National Advisory Board on Research Ethics

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THE NATIONAL ADVISORY BOARD ON RESEARCH ETHICS' PROPOSALS

1 Ethical review and its organizational framework in the humanities and social and behavioural sciences¹

Science should be practiced primarily with the help of the scientific community's own critical review and joint ethical rules. The National Advisory Board on Research Ethics proposes an ethical review system for the humanities and social and behavioural sciences. The review system would follow the same principles as the guidelines published by the National Advisory Board on Research Ethics entitled "Good scientific practice and procedures for handling misconduct and fraud in science" (2002). The scientific community (universities, research institutions, universities of applied sciences and funding agencies) has broadly made a commitment to comply with those guidelines.

With the new proposal, this commitment would also include the obligation to arrange ethical review in the manner proposed by the National Advisory Board, and applying the ethical principles published by it. The commitment model provides a flexible possibility to alter the ethical review system and ethical guidelines on the basis of experience if this is necessary.

2 Establishment of ethics committees

The National Advisory Board on Research Ethics proposes that universities and research organizations that have made a commitment to comply with the guidelines arrange ethical review in the way they consider best. If no organs exist to deal with ethical issues, ethics committees can be established within the organization or through regional cooperation. Cooperation can also be based on language (Finnish or Swedish).

The National Advisory Board on Research Ethics recommends the establishment of regional committees particularly if, in addition to a university, smaller research organizations or universities of applied sciences operate in the region. The initiative to establish regional ethics committees should be taken by university rectors.

Since ethical review examines a study's research methods, committees' composition should ensure familiarity with the content of research fields and broad expertise in research methods as opposed to electing representatives of every possible subject in the humanities and social and behavioural sciences. If necessary, the committee can ask for an expert in a particular field to evaluate an application if it considers its own expertise inadequate for risk evaluation.

The National Advisory Board on Research Ethics considers it important that no fee should be charged for an ethical review. However, committee work requires time and money. The National Advisory Board on Research Ethics was not asked to propose a financing model for the system. It should be noted that some secretaries of ethics committees established on the basis of the Medical Research Act are employed full-time, for example.

The ethics committee can request an ethical review from an outside expert if a planned study will intervene in a subject's personal integrity and if it considers its own expertise inadequate for risk evaluation.

¹ This also includes nursing science, health sciences and other sciences insofar as they use social and behavioural science research methods.

3 Scope of ethical review

The National Advisory Board on Research Ethics considers that researchers must submit their research plan to ethical review if a study contains any of the following features:

1. The study involves an intervention in the physical integrity of subjects,
2. The study deviates from the principle of informed consent (ethical review is not required if the research is based on public documents, registries or archived data),
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,
4. The study exposes research subjects to exceptionally strong stimuli and evaluating possible harm requires special expertise (for example, studies containing violence or pornography),
5. The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life,
6. The study can signify a security risk to subjects (for example, studies concerning domestic violence).

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 review does not mean transferring the ethical responsibility for the conduction and implementation of the study from the researcher to the ethics committee. Which ethics committee will conduct the review will depend on the location of the organization where the researcher works.

The National Advisory Board on Research Ethics proposes that the ethics committees to be established should also evaluate studies that are conducted in health-care institutions that do not fall within the category of medical research as defined in the Act on Medical Research.

The guidelines for ethical review are intended to cover post-graduate research. Thesis supervisors are responsible for ensuring that thesis work complies with the ethical principles. If the planned thesis research includes any of the features requiring ethical review, the student, together with his/her supervisor, must ask the ethics committee for an ethical review.

4 Ethics committees' work

The evaluation carried out by the ethics committees should be based on the ethical principles prepared by the National Advisory Board on Research Ethics.

Ethics committees will give a statement on the ethical acceptability of a planned study. The permission to actually conduct the study will be given by the organization/research target

where the research is conducted, and individual research subjects will give their consent to participate in the study.

A researcher can ask for a statement on an ethics committee's statement from the National Advisory Board on Research Ethics if he/she does not approve the changes recommended by the ethics committee.

The National Advisory Board on Research Ethics considers it important that the work of ethics committees should be as transparent as possible within the framework of the Act on the Openness of Government Activities. This will prevent major policy differences between regional committees. The board recommends that requests for ethical reviews received by the committees and the statements they issue should be published on the websites of the committees.

The National Advisory Board on Research Ethics will prepare a sample statement form for committees.

In addition to ethical review, ethics committees can also handle other tasks that they deem necessary, such as the coordination of education in research ethics.

5 The National Advisory Board on Research Ethics' other proposals

1. A proposal to take measures to amend the Act on Medical Research so that it would cover all health research that involves an intervention in the physical integrity of subjects and so that the person in charge of the study could also be a scientifically qualified expert in some other field than medicine or dentistry.

2. A proposal to take measures to amend legislation so that the right guaranteed to children in the Constitution of Finland and in the UN Convention on the Rights of the Child to influence matters pertaining to themselves to a degree corresponding to their level of development is also implemented in matters regarding participation in research.²

3. The National Advisory Board on Research Ethics recommends that education in research ethics be promoted and given a permanent place in undergraduate and post-graduate education. The importance of ethics education has repeatedly come up in the Advisory Board's own discussions, in the feedback from the scientific community to the Advisory Board, and in articles and seminar presentations on ethical review. Ethical issues in the humanities and social and behavioural sciences also essentially concern the research relationship and the possible consequences of research publications. Therefore, in addition to separate courses, ethics education in these fields should form an integral part of methodology training and research supervision. Since ethical issues in the humanities and social and behavioural sciences research cannot always be predicted and depend on the situation, graduate schools in particular should make sure that researchers are given opportunities to discuss any problematic situations with experienced researchers and with other post-graduate students.

² See also Liisa Nieminen, *Lapset tutkimuskohteena: Kuka päättää lapsen osallistumisesta tutkimukseen?* Lakimies 2/2009, pp. 226-253.

4. The National Advisory Board on Research Ethics considers it important that the functionality of the proposed new system and the ethical review guidelines, as well as any problems that may arise, are evaluated by the end of 2011. For this purpose, information should be collected on the composition and activities of the ethics committees. Basic information on requests for ethical review should be collected 1) by discipline, 2) according to the reasons for requests, 3) according to the main data collection method and 4) on applications that have to be reconsidered and changes recommended by the committee along with the reasons for suggested alterations. The National Advisory Board on Research Ethics will draft a form for collecting information.

ETHICAL PRINCIPLES OF RESEARCH IN THE HUMANITIES AND SOCIAL AND BEHAVIOURAL SCIENCES

All research must comply with the guidelines prepared by the National Advisory Board on Research Ethics entitled "Good scientific practice and procedures for handling misconduct and fraud in science" (2002).

Ethical principles of research in the humanities and social and behavioural sciences are divided into three areas:

1. Respecting the autonomy of research subjects,
2. Avoiding harm and
3. Privacy and data protection.

1 THE AUTONOMY OF RESEARCH SUBJECTS

1.1 Voluntary participation

Participation in research should be voluntary and based on informed consent. An exception from the principle of voluntary consent can be made when research is conducted on published and public information and archived materials. Research concerning official registries and documents and carried out without the consent of research subjects is governed by legislation.

Research subjects can give consent orally or in writing, or their behaviour can otherwise be interpreted to mean that they have given consent to participate. For example, assenting to a polite request for an interview or responding to a questionnaire or request for a written response indicates that the subject has consented to be studied.

In institutional settings (prisons, child protection institutions, hospitals, homes for the elderly etc) it is important to make sure that consent is given voluntarily by each and every subject. In evaluating the matter, attention must also be paid to the nature of the study, i.e. the degree to which personal matters are dealt with (need to protect privacy). If the research intervenes in personal integrity, it is particularly important to ensure the genuineness of consent. On the whole, researchers should always take into account the constitutional rights guaranteed to each individual.

If research intervenes in the physical integrity of subjects, consent must always be given in writing or in some other certifiable way, unless this is contrary to the interests of subjects.

For example, a person with AIDS may not want his or her name registered on a written consent.

Consent can be specific or general. General consent applies to research use in general. General consent can include conditions regarding the form in which data are recorded and archived and conditions set for the use of data in secondary research.

If information obtained from subjects is combined with information in official registers, subjects must be given detailed information on the registers that will be used.

Specific consent concerns the use of information in a particular study. Specific consent with regard to the use of data may be justified on the grounds that data cannot be anonymized and that archiving the data with identifiers for secondary research would in all likelihood be harmful to subjects.

Subjects have the right to withdraw from a study at any stage, but this does not mean, however, that their prior input (interviews etc) cannot be used in the study.

1.2 Autonomy and research involving minors

According to section 6 paragraph 3 of the Constitution of Finland, children must be treated equally and as individuals and must be allowed to influence matters pertaining to themselves to a degree corresponding to their level of development. The same right is also ensured in Article 12 of the UN Convention on the Rights of the Child. On the other hand, according to section 4 paragraph 1 of the Child Custody and Right of Access Act (361/1983), a guardian has the right to decide on a child's personal matters. Balancing this right and the above-mentioned principles in the Constitution and the UN Convention on the Rights of the Child is not always easy. Consequently, the National Advisory Board on Research Ethics has called for legislation to be clarified in this respect.

In practice, it cannot be assumed that researchers should always request separate consent from a guardian when research involves minors. First, according to the above-mentioned principles children should be able to influence matters pertaining to themselves to a degree corresponding to their level of development. Second, there are situations where there may be differences in values and interests between a guardian and a minor, and requesting the guardian's consent may endanger the collection of comprehensive research data on the conditions and behaviour of minors, thus restricting the freedom of science, which is guaranteed by the Constitution. Third, there are studies which do not include risks and where requesting consent from the guardian would be difficult.

1.3 Autonomy and age limits

Many studies that are conducted in schools and institutions of early childhood education and care can be carried out as part of the normal work of the institution or school. It is not necessary to request a guardian's permission if the director of an institution of early childhood education and care or the head teacher of a school has evaluated that the study would produce useful information for the institution or school and can be carried out as part of the normal activities of the institution or school. For example, observations, broad questionnaires and open interviews which do not collect directly identifying information

(names, ID's, addresses) for research purposes can be carried out without the consent of parents or some other guardian. In other cases they must be informed of the study.

When studying minors outside an institution of early childhood education and care or school, researchers must themselves evaluate when it is necessary to ask for a guardian's separate consent or inform a guardian of the study so that the guardian can forbid the child from participating in the study. A study involving children under the age of 15 can be conducted without a guardian's separate consent or informing a guardian if this is justified from the viewpoint of 1) the age and development level of subjects, 2) the subject and research method or 3) the need for information. If a study is to be conducted without a guardian's separate consent or informing a guardian, an ethical review must be requested for studies involving subjects under the age of 15.

Researchers must always respect a minor's autonomy and the principle of voluntary participation, regardless of whether a guardian's consent has been obtained or not.

1.4 Information for subjects

The information that must be provided to research subjects depends on the nature of data collection methods. In studies based on observation, interviews or questionnaires, subjects must be told what the study is about and what participating in the study means in concrete terms and how long it will take.

Information regarding a study should include at least the following: 1) the researcher's contact information, 2) the research topic, 3) the method of collecting data and the estimated time required, 4) the purpose for which data will be collected, how it will be archived for secondary use, and 5) the voluntary nature of participation.

Subjects may ask for additional information regarding the study and researchers should prepare for this in advance. Additional information can concern, for example, 1) a study's scientific or doctrinal orientation, 2) how confidential data will be protected and where data will be archived after the study, 3) how and when the results of the study will be published.

In experimental studies sufficient information must be provided concerning the design of the experiment. Experimental designs vary considerably from one field to another. Determining the adequacy of information is always up to the researcher according to the guidelines in the particular field.

If a study intervenes in the physical integrity of subjects, the information given to subjects must comply with the guidelines issued on the basis of the Act on Medical Research as far as these apply.

Regardless of how data are collected, requests by the subjects for additional information must be answered truthfully. Research personnel should be trained to answer questions. In some studies, such as studies based on participant observation, the research relation deepens over time, and it is natural to provide increasingly detailed information on the objectives and content of the study along the way.

1.5 Exceptions from informed consent: an ethical review must be requested from the ethics committee

If a study deviates from the principle of informed consent, an ethical review from the research ethics committee is always required.

An exception from the principle of informed consent can be made if advance information would distort the results of the study. As a matter of principle, studies on the use of power should be allowed without the consent of those in power. There are also groups and subcultures that researchers cannot approach without using an assumed identity for the sake of their own safety.

Data collection can deviate from the principle of informed consent in a number of ways:

1. Research subjects may be given all the relevant information but participation is not voluntary (e.g., a study based on participant observation of military conscripts or the observation of work processes where the organization's management has given permission for the research).
2. Research subjects may be given insufficient or misleading information about the role of the researcher. For example, the researcher may not identify him/herself as a researcher but does not give misleading information (e.g., observational data collected from an emergency room or riding with a police squad) or the researcher may work under a covert role (e.g., to mislead research subjects in a field study of discrimination).
3. The researcher identifies him/herself but gives misleading information about the content of the study.

Observing subjects in a public place does not require their consent or an ethical review from the ethics committee. Technical recording equipment can be used in a public place provided the principles regarding privacy and data protection are observed in the use, storage and archiving of data.

2 AVOIDING HARM

An important task of historical and social research is to produce information on the improper functioning of social institutions and problems regarding the use of power.

Possible harm resulting from research can stem from the collection of data, the storage of data and consequences following the publication of studies.

2.1 Avoiding mental harm

Avoiding mental harm includes treating subjects with respect and reporting findings in a respectful way in research publications.

How sensitive a subject matter is and what the limits of privacy are depend primarily on the research subjects themselves. If the subjects know what matters will be dealt with on the basis of the information that is supplied to them, by giving consent they have demonstrated their willingness to participate in the study while being aware of the study's scope and methods. If subjects participate in a study by writing about their experiences or answering a questionnaire, they regulate their own participation by avoiding matters and questions that they consider damaging or harmful.

People experience things in different ways. The same research questions or topics can arouse different reactions in different people. Research situations can and may include the same kind of mental strain and feelings (disappointment, joy, sadness, hate, shame, frustration etc) as in everyday life in dealing with different aspects of human life.

If a study includes interaction with subjects (participant observation, experimental study, interviews), subjects must be treated politely and with respect for their human dignity.

A researcher must make sure that the principle of voluntary participation is also observed in situations where there is interaction with subjects. A subject's annoyance, embarrassment, fearfulness or physical fatigue can be sufficient grounds for the researcher to discontinue the study as far as the subject is concerned, even if the subject does not expressly refuse to continue. It is essential to ensure that subjects are participating voluntarily when studying people in institutional settings (hospitals, prisons, child protection institutions, homes for the elderly etc). Unnecessary mental strain can be avoided by testing in advance how much time subjects' participation will take.

2.2 Avoiding financial and social harm

Financial and social harm to subjects is more likely if a study does not observe the ethical principles concerning privacy and data protection. According to the principles, systematic care must be shown in handling and storing confidential information. Furthermore, the duty of confidentiality must be observed regarding subjects' private matters (see ethical principles regarding privacy and data protection).

Research publications can have harmful consequences for subjects. The risk of harm is greatest if results are presented judgmentally, in a prejudiced way or disrespectfully. Harm can also be caused by publishing results giving a negative picture that are not based on comprehensive data or the systematic analysis of data.

Researchers should avoid any damage or harm to subjects that may be caused by research publications. However, this principle should not prevent the publication of research findings that may not be pleasing to subjects in all respects. A researcher's task is to produce new information without having to fear the reaction of authorities or other research subjects. Particularly research concerning the use of power and the functioning of social institutions must not be restricted on the grounds that results can have negative effects for subjects. The best way to ensure freedom of research is to conduct research carefully and systematically and to publish results with proper arguments and shedding light on different perspectives in a balanced manner. Researchers and editors are responsible for compliance with ethical principles in research publications.

2.3 Studies containing risks of harm: an ethical review must be requested from the ethics committee

Studies entailing possible risks that cannot be evaluated by research subjects themselves, and studies with potential to cause harm beyond the limits of normal life, must be evaluated in advance. This includes studies that 1) intervene in the physical integrity of subjects or 2) in which subjects undergo exceptionally strong stimuli and evaluating possible harm requires special expertise (for example, studies containing violence or pornography). In addition, studies in which the researcher is aware that there is a risk of causing long-term mental

harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life or studies that can signify a security risk to subjects (for example, studies concerning family violence) must be evaluated in advance.

3 PRIVACY AND DATA PROTECTION

The protection of privacy is a right protected by the Constitution of Finland. It is also an established and important principle in research ethics. Data protection forms the most important area of privacy protection regarding the collection and processing of research data and the publication of results.

Research ethics principles concerning the protection of privacy fall into three categories: 1) protecting research data and confidentiality, 2) storing or disposing of research data and 3) research publications. The goal is to find a balance between confidentiality and the openness of science and research.

Principles concerning the protection of privacy do not apply to materials that are in the public domain or to published data, which can concern individuals and their activities in the fields of politics, business, official activities and culture. Guidelines concerning privacy and principles concerning data protection must be observed with regard to court sessions and court decisions, however.

The Personal Data Act (523/1999) contains provisions on the processing of personal data. According to section 3, personal data means "any information on a private individual and any information on his/her personal characteristics or personal circumstances, where these are identifiable as concerning him/her or the members of his/her family or household".³

According to the main principle in the Act, personal data can be processed with the consent of the subject. A basic principle regarding the collection and storage of personal data is the need for personal data in a study. Personal data may not be collected and stored unnecessarily. If research data can be reasonably analysed without direct identifiers and there are no research grounds for storing identifiers, only data from which identifiers have been removed may be produced for research purposes and stored for secondary research.

Data with identifiers can be collected and used when this is appropriate from the viewpoint of that particular research. With the consent of the subject data can also be stored for secondary research with identifiers. Research in the humanities and social and behavioural sciences may require the processing and storage of identifiers. This may be based on the need to analyse data, later contacts with subjects or the historical and cultural significance of data. All contemporary data may also have historical and cultural significance.

3.1 Protecting research data and confidentiality

³ With regard to identifiability the most significant thing is whether a particular individual can be identified from data easily and without unreasonable costs. Identifiers in research data have traditionally been divided into direct and indirect identifiers. Direct identifiers are name, address, data of birth and a person's voice and picture. Indirect identifiers are, for example, place of residence, neighbourhood, education, job and family composition.

The protection of data with identifiers must be carefully planned. The protection of subjects' privacy may not be jeopardized by the careless storage of data or unprotected electronic data transfers.

Data security solutions for data with identifiers include decisions regarding where paper materials containing identifiers will be stored, at what stage unnecessary data will be destroyed or how their storage and archiving will be arranged for secondary research. Decisions must also be made regarding how electronic data containing identifiers will be protected (back-up copies, user names, processing if necessary on computers not linked to a network), and to what extent identifiers will be deleted or stored in connection with the data to be analysed.

If necessary, researchers or other research personnel handling data with identifiers can be required to sign a pledge of confidentiality. The research director or the principal investigator is responsible for written pledges. The confidentiality of data containing identifiers also applies to anyone using data, even if written pledges are not used.

If subjects' personal data are not needed for data analysis, and there are no research grounds for storing them, paper materials containing identifiers must be destroyed, and identifiers must be removed from electronic files or else recoded, categorised or otherwise masked. Identifiers that are stored for the purpose of further contacts with subjects must be protected and stored separately from analysed data.

If research data have been collected from official documents and registers without asking for subjects' consent, both identifiers and sensitive information must be destroyed as soon as they are unnecessary for conducting the research.

The confidentiality of research data relies on restrictions on the processing, use and storage of data. Research data may not be used or handed over for other uses besides research. It is particularly unacceptable to reveal information on research data or hand over data in such a way that it could influence the evaluation, treatment or position of individual subjects. Research data may not be handed over to the media or for commercial purposes.

Protecting privacy as a constitutional right protects citizens particularly against measures taken by public authorities. A researcher's task is to produce scientific information to help understand social problems or society and culture in general. This task does not include revealing information about individual subjects to authorities. For example, information concerning crimes is considered to be sensitive information that is subject to and restricted by the researcher's obligation of confidentiality. Information regarding individual subjects in research data may not be revealed to tax authorities, social welfare authorities or the police.

An exception to the obligation of confidentiality is every citizen's obligation to report an imminent *serious* offence that can still be prevented.⁴ The deciding factor is the possibility to

⁴ Chapter 15 section 10 of the Penal Code (563/1998): "A person who knows of imminent genocide, preparation of genocide, breach of the prohibition of chemical weapons, breach of the prohibition of biological weapons, compromising of the sovereignty of Finland, treason, aggravated treason, espionage, aggravated espionage, high treason, aggravated high treason, rape, aggravated rape, aggravated sexual abuse of a child, murder, manslaughter, killing, aggravated assault, robbery, aggravated robbery, kidnapping, hostage taking, aggravated criminal mischief, aggravated

prevent an offence. A researcher does not have an obligation to reveal information regarding crimes that have already been committed, unless revealing information helps to prevent an imminent serious crime.

According to section 25 of the Child Welfare Act (417/2007), the obligation to confidentiality can be inapplicable if in the course of work a researcher discovers that "there is a child for whom it is necessary to investigate the need for child welfare on account of the child's need for care, circumstances endangering the child's development, or the child's behaviour".⁵ The primary starting point in a researcher's work is to ensure confidentiality and remain in the role of researcher. In studying children and young people one must respect their own opinion if they are mature enough to form an opinion. If a researcher decides on the basis of the Child Welfare Act to make a report, it is good practice to inform the subjects in question of this intention.

3.2 Storing or destroying research data

Research in the humanities and social and behavioural 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 characteristic of science and also a precondition for testing the validity of scientific information, critically evaluating information and advancing science.

Data that are carefully archived for secondary research reduce the need to collect research data containing identifiers. Archiving also reduces the research pressure on small population groups. It is particularly important to archive for secondary research data that have cultural, historical and/or scientific value.

When necessary, the protection of privacy should be ensured through anonymisation measures and through the regulation of access to data for secondary research.

If it is necessary to remove identifiers from data stored for secondary use, the goal of the anonymisation measures undertaken should be that secondary users of data cannot immediately identify individual subjects. In addition to direct identifiers (name, address, ID), indirect identifiers (workplace, school, place of residence, age, profession etc) can be removed from archived data or be recoded, categorised or otherwise masked.

The protection of subjects' privacy should be ensured by setting strict conditions on the secondary use of data. Data can only be used for research purposes. In addition, secondary users of data should be requested to sign an agreement on the conditions set for secondary research and if needed also a pledge of confidentiality.

endangerment of health, nuclear device offence, hijacking, an offence committed with terrorist intent referred to in chapter 34 a, section 1(1)(3), aggravated impairment of the environment or aggravated narcotics offence, and fails to report it to the authorities or the endangered person in time to prevent the offence, shall be sentenced, if the offence or a punishable attempt is committed, for a failure to report a serious offence to a fine or to imprisonment for at most six months."

⁵ In this connection cf. the judgement of the European Court of Human Rights, 2.12.2008 (*Juppala v. Finland*).

If data containing identifiers are sensitive, and cannot be anonymized, and research subjects have not been asked to give permission to store the data, the datasets should be destroyed after the study has been completed. If data are of scientific value or historically unique, a request for permission to archive data can be submitted to the National Archives.

3.3 Protecting privacy in research publications

Unlike research data, research publications are in the public domain. The need to protect privacy in publications must be evaluated on a case-by-case basis.

For most studies, there is no need to present subjects in an identifiable way in published findings. The results of quantitative research are reported statistically, which means that there is no risk of identification even when the publication is based on data containing identifiers.

In the case of qualitative data, the risk of identification must always be evaluated before any samples/quotations from the data are published: what indirect identifiers (workplace, school, place of residence, age, profession etc) will be left in the sample as such, what will be masked and what will be omitted altogether.

In studying organizations or other social actors (institutions, associations, work communities, public bodies etc), the identifiability of the organization and its individual representatives must be evaluated separately in each case. Subjects generally participate in a study as individual representatives of their social or professional role. Anonymity in research publications does not necessarily prevent identification among those who are familiar with the unit or organization in question, however. Subjects should not be promised complete anonymity unless it can reasonably be guaranteed. Research publications should strive to treat individual subjects and the research target in a respectful manner. Critical findings regarding the research target should be explained analytically, avoiding a labelling attitude.

In research, particularly in the humanities but also in the social sciences, it may be justifiable for research purposes and also ethically to present subjects by name in research publications. For example, a study based on interviews with experts can be published without removing the names of subjects or other identifiers. Agreement about this must be reached with research subjects in advance.

If research concerns archived materials, the identifiability or non-identifiability of subjects in research publications depends on the conditions the distributing archive has set on the use of the data.

4 ETHICAL REVIEW

In preparing a request for an ethical review and in evaluating the possible negative effects and risks of a study, the point of departure should be the ethical principles in the humanities and social and behavioural sciences (the autonomy of research subjects, avoiding harm, privacy and data protection). Evaluation never shifts responsibility for research ethics to the committee. In research in the humanities and social and behavioural sciences, ethical questions focus on the encounter between the researcher and the subject, which can include unanticipated factors. The researcher is always responsible for the ethical and moral solutions in a study.

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

1. The study involves an intervention in the physical integrity of subjects.
2. The study deviates from the principle of informed consent (ethical review is not required if the research is based on public documents, registries or archived data).
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 forbid the child from taking part in the study.
4. The study exposes research subjects to exceptionally strong stimuli and evaluating possible harm requires special expertise (for example studies containing violence or pornography).
5. The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life.
6. The study can signify a security risk to subjects (for example studies concerning domestic violence).

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.

For example, according to the guidelines issued by the Academy of Finland, it is sufficient if a review is submitted after a positive funding decision.

4.1 Guidelines for reviewing studies

An ethical review examines the plan for collecting data, how the study will be carried out, the information that will be given to subjects and the plan for processing and storing data from the perspective of avoiding risks and harm. *The review weighs possible negative effects or harm to subjects resulting from participation in the study in relation to the intended scientific value of the study.* The starting point is always the ethical principles in the humanities and social and behavioural sciences (the autonomy of research subjects, avoiding harm, privacy and data protection).

If necessary, ethical guidelines in the particular research field should also be applied.⁶

In the humanities and social and behavioural sciences, evaluating scientific value and risks is not a utilitarian cost-benefit analysis but rather a question of normative evaluation of values that are in themselves incommensurable. Evaluation ensures that a study does not contain unnecessary risks that could be avoided without reducing the scientific value of the study. Next, one must decide whether risks on the whole are morally acceptable. Research which entails higher risks may be morally acceptable if the scientific value of the study is very high, and the study does not cause harm to subjects (studies that are not based on informed

⁶ There are separate ethic codes in psychology and economics, for example. In addition research institutions keeping statutory registers have ethical guidelines concerning register data.

consent), or the people participating in the study can evaluate possible harm themselves on the basis of the information that is supplied to them.

If a study does not have the features listed above (1-6) and does not present a risk of causing long-term mental harm beyond the risks encountered in normal life, this should be mentioned in the request for an ethical review. In this case, the committee will primarily evaluate the information supplied to subjects as well as matters concerning privacy and data protection. If a study entails any of the features listed above (1-6), the ethics committees must also evaluate the proposed research methods in relation to research questions and the value of the new information that the study is intending to provide.

Information for subjects

The committee will check that the informing of research subjects is planned appropriately. Information regarding a study includes at least the following: 1) the researcher's contact information, 2) the research topic, 3) the method of collecting data and the estimated time required, 4) the purpose for which data will be collected, used in secondary research and archived, and 5) the voluntary nature of participation.

In experimental studies, sufficient information must be provided concerning the design of the experiment. Experimental designs vary considerably from one research field to another. Ethics committees will determine whether the proposed level of information is adequate.

If a study intervenes in the physical integrity of subjects, the information given to subjects must comply with the guidelines issued on the basis of the Act on Medical Research, as far as these apply.

Privacy and data protection

An ethical review examines a study's data management plan and ensures that technical data security solutions have been planned. The data management plan must describe 1) how data containing identifiers will be protected or identifiers removed, 2) whether signing a pledge of confidentiality will be required from persons using or processing the personal data and 3) the plan for archiving the data for secondary research or alternatively destroying personal data after the study has been completed.

Ethics committees do not review the protection of privacy in research publications. Researchers and editors are responsible for compliance with ethical principles in research publications.

4.2 Special review guidelines regarding different research designs:

a. The study involves an intervention in the physical integrity of subjects

The ethical guidelines for medical research can be applied in planning and reviewing studies that involve an intervention in the physical integrity of subjects (see <http://www.etene.org/tukija/dokumentit/Muistlco.pdf>). The committee will evaluate anticipated negative effects (risks, harm and their probability) in relation to the intended scientific value of the study. Studies must be conducted in a manner that minimizes any negative effects and risks to subjects.

Evaluating physical risks requires expertise and background information based on empirical studies. The ethics committee can if necessary request an ethical review from an outside expert if it considers its own expertise inadequate for risk evaluation.

b. The study deviates from the principle of informed consent

With regard to a study that deviates from the principle of informed consent, the ethics committee will evaluate whether conducting the study is ethically acceptable. Conducting the study is ethically acceptable if the following preconditions are met:

1. the research is justified, and it would not be possible to conduct the research if subjects were informed of the study and their consent asked for,
2. the data collection does not involve risks to participants,
3. if possible, research subjects will be informed afterwards of the nature and purpose of the research,
4. adequate attention is paid to the privacy of the research subjects and data protection issues.

c. 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 forbid the child from taking part in the study

A study involving children aged under 15 can be conducted without the consent of a parent or other guardian and without informing the parent or guardian if it does not involve risks to subjects, and the research design is justified by one or more of the following preconditions:

- 1) On the basis of subjects' age and level of development:

The minors who are intended subjects are able to understand the research topic and what participating in the study requires of them in concrete terms.

- 2) On the basis of the research area and method:

The research topic is not sensitive and asking for a parent's or guardian's consent is difficult in practice (for example, studies of youth clubs or school pupils' voluntary clubs etc).

- 3) From the viewpoint of the need for information:

The subject matter of the study will prevent the collection of comprehensive data if parents' consent must be requested for children's participation (for example, domestic violence, social problems etc), or the research covers issues which minors may not want their parents to know about (for example, use of intoxicating substances, sexual orientation etc).

d. The study exposes research subjects to exceptionally strong stimuli and evaluating possible harm requires special expertise (for example studies containing violence or pornography).

e. The study may cause long-term mental harm (trauma, depression, sleeplessness) beyond the risks encountered in normal life.

f. The study can entail a security risk to subjects (for example studies concerning domestic violence).

The researcher must describe possible negative effects and risks so that the ethics committee can evaluate whether the study is ethical, weighing possible risks to subjects against the intended scientific value of the study. Studies must be conducted so as to minimize any negative effects and risks to subjects.

The intended scientific value will be weighed against possible negative effects and the measures that are taken to reduce negative effects to subjects during or after the study (physical and mental harm) or to prevent them altogether (data protection). The evaluation must take into consideration subjects' free will and autonomy. After all, subjects themselves are always able to evaluate to some extent their own risks of participating in a study.

In evaluating experimental studies, the ethical guidelines in the particular field can be applied in a supplementary manner.