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The ethical principles of research with human participants and ethical review in the human sciences in Finland

Finnish National Board on Research Integrity TENK guidelines 2019

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FINNISH NATIONAL BOARD ON
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1. Introduction

In 2009, the Finnish National Board on Research Integrity TENK published the first national guidelines on the ethical principles of research in the humanities and social and behavioural sciences and proposals for ethical review in Finland. By 2019, almost all the universities, universities of applied sciences and research institutions engaged in these fields have undertaken to comply with these guidelines. When the guidelines were first published, they were among the first of their kind produced at national level in Europe. They brought together ethical principles governing non-medical research with human participants and provided guidance in organising the ethical review process.

TENK revised and updated the guidelines in 2019. These updated guidelines should be applied to a wider area than previously, covering all scientific research that involves human participants or research methods used in human sciences (in the sense of social sciences and humanities). Research organisations in Finland can undertake to comply with the guidelines by signing a form. Research organisations that have undertaken to comply with the guidelines also have an obligation to organise ethical review for human sciences research in accordance with these guidelines. The guidelines are part of the scientific community's self-regulation system, monitored by TENK.

The guidelines are divided into two parts. The first part describes the ethical principles of research with human participants. These have been drawn up to cover a wide range of research on human subjects and human behaviour. The second part describes the process of ethical review and the principles underlying ethical review conducted by ethics committees in the human sciences.

TENK's ethical principles in the human sciences concern research ethics. Research with human participants often requires the processing of the participants' personal data. The guidelines have been drawn up so that the ethical principles, where applicable, support the application of the European Union's General Data Protection Regulation (2016/679) (GDPR). These ethical principles do not as such apply as a guide to the application of data protection legislation or other legislation.

The ethical guidelines were updated by a working group formed by TENK, chaired by Development Manager Arja Kuula-Luumi (Finnish Social Science Data Archive). The deputy chair was Professor Erika Löfström (University of Helsinki/TENK) and members were Chief Researcher Kari Hämäläinen (VATT Institute for Economic Research/TENK), Senior Researcher Jyrki Kettunen (Arcada/TENK), Professor Riitta Salmelin (Aalto University/TENK), Professor Risto Turunen (University of Eastern Finland/TENK) and Secretary General Sanna-Kaisa Spoof (TENK). The secretary of the working group was Senior Advisor Iina Kohonen (TENK). Lawyer Antti Ketola (Finnish Social Science Data Archive) was the working group's expert on data protection legislation.

Statements regarding the draft of these guidelines were requested in December 2018 from all universities, universities of applied sciences, research institutions and from other signatories of the 2009 guidelines and key stakeholder groups in Finland. The guidelines were approved at TENK's meeting on 7 May 2019.

2. Scope and compliance

The ethical principles of research with human participants described in these guidelines are applied to research on humans and human behaviour. The ethical principles for research with human participants have been drawn up by the Finnish National Board on Research Integrity TENK, and they serve as a starting point for ethical review work carried out by ethics committees in the human sciences.

The guidelines for ethical review in research with human participants are intended for research designs where ethical review is not regulated separately in the Medical Research Act (488/1999).[29] Besides humanities and social sciences, these research designs include research with human participants in the natural sciences and technology, in artistic research, and in some cases also in non-invasive health or medical research.

In order to distinguish between local medical ethics committees operating under the Medical Research Act, the term human sciences ethics committee will be used below to refer to committees that comply with these guidelines.

An organisation that has undertaken to comply with these guidelines has the responsibility as an employer to ensure that researchers who belong to its scientific community are familiar with guidelines and recommendations on research integrity and ethical review and that they comply with these guidelines and recommendations. The guidelines are also binding upon researchers who operate in joint international projects in Finland or outside Finland's borders. Where applicable, they also apply when working with businesses and other bodies in national and international research collaboration. Researchers comply with the ethical principles described in the guidelines and also promote their application when they teach in higher education institutions and supervise theses. In multidisciplinary research projects which are on the borderline between medical and non-medical research, for example, TENK recommends collaboration between medical ethics committees and human sciences ethics committees in order to clarify the division of work and borderline cases.

Researchers operating in Finland must comply with the ethical principles of research with human participants. Where necessary, they must also request a statement from a human sciences ethics committee before commencing research. Failure to comply with these

29 Studies that fall within the scope of the Medical Research Act (488/1999) in force in May 2019 are evaluated by the local medical ethics committees operating with hospitals. The scope of the Medical Research Act encompasses medical research which involves intervention in the physical or psychological integrity of a person, human embryo or human foetus for the purpose of increasing knowledge of health, the causes, symptoms, diagnosis, treatment and prevention of diseases or the nature of diseases in general. According to Government Bill (HE 65/2010 vp), "this kind of research means scientific research on treatment and health, including into scientific research on exercise or diet. Intervention in the physical integrity of a person includes, for example, taking blood samples, research involving physical strain and research which seeks to influence health or the risk or symptoms of disease. Intervention in the psychological integrity of a person is when the research may cause a risk to the mental wellbeing of the research subject."

guidelines may meet the criteria for a violation of responsible conduct of research (RCR). Where necessary, the matter may be resolved through the process for handling allegations of research misconduct.[30]

These updated guidelines have been in force since 1 October 2019. Research organisations may commit to complying with the guidelines by signing a form to this effect. The form is available on the TENK website, www.tenk.fi. The website also includes a list of organisations that have undertaken to comply with the guidelines.

The previous guidelines still apply to research that has commenced before the research organisation in question signed up to the new guidelines. The new guidelines apply to research which has commenced after the research organisation has signed up to the new guidelines. In both cases, the research organisation's data protection guidelines in force will also apply.

30 Responsible conduct of research and procedures for handling allegations of misconduct in Finland. Finnish National Board on Research Integrity guidelines 2012.

3. Ethical principles for research with human participants

3.1. General ethical principles

"Research is the quest for knowledge obtained through systematic study and thinking, observation and experimentation. While different disciplines may use different approaches, they share the motivation to increase our understanding of ourselves and the world in which we live."[31]

In Finland, researchers in all disciplines are guided by the following general ethical principles:

a) The researcher respects the dignity and autonomy of human research participants. The rights laid down in the Finnish Constitution (1999/731, Sections 6–23) are held by everybody. These include the right to life, personal liberty and integrity, freedom of movement, freedom of religion and conscience, freedom of expression, protection of property and the right to privacy.

b) The researcher respects material and immaterial cultural heritage and biodiversity. In accordance with Section 17 of the Finnish Constitution, the Sami, as an indigenous people, as well as the Roma and other groups, have the right to maintain and develop their own language and culture.

c) The researcher conducts their research so that the research does not cause significant risks, damage or harm to research participants, communities or other subjects of research.

Furthermore, in Finland all scientific research complies with the guidelines on responsible conduct of research (RCR) drawn up by TENK.[32]

Section 16 of the Finnish Constitution safeguards the freedom of science and arts. This freedom must be used responsibly. The ethical principles for research with human participants have been drawn up to support researchers and research groups in protecting the people participating in the research. In research with human participants, ethical questions focus on the interaction between researcher and research participant. This interaction often involves unpredictable factors, and there is not always one single clearly correct solution to ethical questions. These ethical principles for research with human participants provide clear guidance in the consideration of ethical questions. The principles are part of the self-regulation

31 The European Code of Conduct for Research Integrity. Revised Edition. ALLEA – All European Academies 2017.

32 Responsible conduct of research and procedures for handling allegations of misconduct in Finland. Finnish National Board on Research Integrity guidelines 2012.

system of the scientific community in Finland. The ethical principles guide research with human participants alongside the Finnish legislation.

3.2. Treatment and rights of research participants

The fundamental starting point of research with human participants is the participants' trust in researchers and science. Trust can only be retained if the human dignity and rights of the people participating in the research are respected. The same research situations or topics may cause different reactions in different people. Research situations can and may, however, include mental strain and emotional experiences similar to situations of everyday life.

In order to avoid causing unnecessary harm to research participants and the communities they represent, it is important that researchers familiarise themselves with the community they are researching, and its culture and history in advance.

The following principles apply particularly to situations where the participant interacts with the researcher, for example as an interviewee, or through other kinds of participation, such as acting as a provider of information or as a subject of observation.

Informed consent[33] to participate in research is a central ethical principle in research with human participants.

People participating in research have the right

a) to participate voluntarily but also to refuse to participate. It is particularly important to ensure that participation is voluntary if the research participant is in a customer, employee, service or student relationship or in another dependent relationship with the research organisation, or if a person other than the participant decides on their behalf on their participation in the research. The research participant must not feel that participation is compulsory or feel afraid of negative consequences if they refuse to participate in the research. The researcher documents the participant's consent to participate in the research, either orally, in writing, electronically or by other means.

b) to discontinue their participation at any time without suffering any negative consequences. Discontinuing refers to the participant's right to withdraw from the research or an individual phase of the research permanently or for a temporary period. Discontinued participation in the research does not prevent the use of research data that has already been gathered. The research participant does not have to give any particular reason for withdrawing their participation in the research. In some circumstances, the researcher may stop participation in the research on the participant's behalf (see section 3.3(f) and section 3.4(d)).

c) to withdraw their consent to participation in the research at any time. It must be as easy to withdraw consent as it is to give it.

33 Informed consent to participate in research is not the same thing as consent which is used as a legal basis for processing personal data. If the research participant's consent is used as a legal basis for processing personal data, this consent must meet the requirements in the Data Protection Regulation (https://tietosuoja.fi/en/consent-of-the-data-subject). These guidelines do not provide an opinion on choosing the basis for processing that applies to individual research. This is the responsibility of the data controller (see section 3.5(a)).

d) to receive information on the content of the research, the processing of personal data and how the research will be conducted in practice, such as what participation in the research actually means, and what kind of lifespan has been envisaged for processing and preserving the research data. Whenever possible, information is given in a language that the participant understands, in writing or in electronic form. The research participant must be given sufficient time to consider their decision whether or not to participate, and any questions they have regarding the research must be answered.

e) to receive an understandable and truthful view of the aims of the research and any potential harm and risks. The research participant must be given an accurate account of the effects and potential benefits of the research.[34]

f) to be aware that they are participating in research, especially in situations in which the researcher is in a role other than that of a researcher in relation to the participant, for example the participant's superior or teacher. The researcher also informs the research participant of other affiliations relevant to the research.

Irrespective of the law on confidentiality, the researcher has an obligation to report any serious offence being planned that comes to their knowledge and that can still be prevented. There is no obligation under the Criminal Code of Finland to report a crime that has already been committed.[35]

3.3. Research involving minors

Ethical principles must always be complied with when conducting research with human participants, irrespective of the age of the participant. A child should be able to influence matters concerning themselves to the extent commensurate with their level of development. Generally, their parent or carer is informed of the research. Sometimes a child's participation in research is justified without separate consent of the parent or carer.[36]

34 Research participants are not usually paid a separate fee. If, however, the researcher wishes to thank participants for their time and trouble in a tangible way, the gift should be reasonable (such as a movie ticket, a product pack or equivalent). Research participants may also be compensated for reasonable travel and food costs, for example.

35 The Criminal Code of Finland (563/1998) Chapter 15, Section 10: Failure to report a serious offence: "A person who knows of […] 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, trafficking in persons, […], hostage taking, aggravated criminal mischief, aggravated endangerment of health, nuclear device offence, hijacking, […], aggravated impairment of the environment or aggravated narcotics offence, and fails to report it to the authorities or the endangered person when there still is time to prevent the offence, shall be sentenced, if the offence or a punishable attempt thereof is committed, for a failure to report a serious offence to a fine or to imprisonment for at most six months."

36 UN Convention on the Rights of the Child, Article 12(1): "States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child." Article 13(1) reads "The child shall have the right to freedom of expression; this right shall include freedom to seek, receive and impart information and ideas of all kinds, regardless of frontiers, either orally, in writing or in print, in the form of art, or through any other media of the child's choice."

Ethical principles for research involving minors:

a) Minors must be informed about the research in a way that they are able to understand.

b) If the minor is 15 or older, their own consent is sufficient for participation in the research. The parent or carer should be informed of the research also in these situations, if the research design or research questions permit it.

c) The participation of minors under the age of 15 is primarily decided by the parent or carer. For survey-based research involving a large number of respondents, it is sufficient to inform the parent or carer of the research so that they can refuse their child's participation in the research if they so desire. The number of respondents is large if the survey targets at least 400 people. Informing the parent or carer is also sufficient in research that does not involve the processing of the personal data of the minor participant (for example observation without recording devices and processing of personal data).

d) Even if participation in the research requires the approval of the parent or carer or a legal representative, minors primarily give their own consent to participating in the research.

e) Researchers must always respect the autonomy of minor research participants and the principle of voluntary participation, irrespective of whether the consent of the parent or carer has been obtained for the research.

f) If participating in the research is not in the minor's best interests and the minor does not wish to participate in the research, the researcher must discontinue the minor's participation.

The researcher can submit a child welfare notification, if the researcher observes or becomes aware of factors that indicate a necessity to investigate the need for child welfare.[37] If the researcher decides to report to social services under the Child Welfare Act, it is important that they carefully consider the ethical questions involved, such as whether the parties involved should be informed.

3.4. Research involving people with limited capacity

Anyone's capacity may be reduced temporarily or more permanently. Ethical principles must be observed also when conducting research with a research participant whose capacity is limited, e.g. due to illness or age. However, for example physical impairments, sensory impairments or advanced age do not in themselves limit the right of autonomy or thus the right to decide whether or not to participate in research.

However, people who, owing to a mental health disorder, a developmental disorder or other similar reason, do not have the capacity to give their consent to research are defined as being unable to consent in the Medical Research Act (488/1999). According to the same act, written consent may be given

37 Professionals working in particular sectors have a duty to notify the municipal body responsible for social services if, in the course of their work, they discover 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 (Child Welfare Act 417/2007 Section 25). https://www.finlex.fi/en/laki/kaannokset/2007/en20070417_20131292.pdf

by a close relative or other person closely connected with the person or by their legal representative.

Ethical principles for research involving people with limited capacity:

a) People with limited capacity must be informed about the research in a way that they are able to understand.

b) Even if their participation in the research requires the approval of a legal representative, the person with limited capacity primarily gives their consent to participate in the research themselves.

c) Researchers must always respect the autonomy of research participants with limited capacity and the principle of voluntary participation, irrespective of whether the consent of the legal representative has been obtained for the research.

d) If participating in the research is not in the best interests of a person with limited capacity and if they do not wish to participate in the research, the researcher must discontinue the person's participation.

3.5. Processing of personal data in research

The central principles for processing research data containing personal data are that this must be planned, responsible and in accordance with the law. Planning must include appropriate consideration of the risks associated with the processing of research data to the research participants and others. The duty of responsibility applies to the entire lifespan of the research data and the study. The researcher must comply with the legislation in force and with the research-related data protection guidelines issued by their own organisation. Decisions made regarding the processing of personal data must be justified and clearly documented. Decisions made must be able to be checked subsequently by the authorities or the data protection officer of the organisation.

Terms and definitions[38]

personal data means any information relating to an identified or identifiable natural person. Research data contains personal data if it can be directly or indirectly be used to identify a person or persons, taking into account the means that are reasonably likely to be used to do this;

special categories of personal data means personal data in accordance with data protection legislation revealing "racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation";

processing personal data means any operation or set of operations performed on personal data, including, for example, collection, storage, dissemination, use or adaptation of research data that contains personal data;

data controller means the body that determines the purposes and means of the processing of personal data. The data controller for the research study is responsible for decisions regarding its data protection. Depending on the situation, the data controller may be, for example, a research organisation or a researcher. The data controller may be one or more bodies or several organisations, and researchers may act as a joint data controller.

38 The definitions used regarding data protection are intended to correspond with the definitions in the General Data Protection Regulation. The terms are defined in more detail in Article 4 of the General Data Protection Regulation. Regarding personal data, see also recital 26: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN

The following factors must particularly be observed when processing personal data:

a) There must be a legal basis for processing personal data. The processing of special categories of personal data additionally requires a separate legal basis.[39]

b) When processing personal data, the roles of different bodies must be defined so that research data can be processed appropriately. When planning research, particularly the data controller for the research data must be clearly indicated. If there is a joint data controller, the responsibilities of each data controller must be individually defined.

c) When planning research, the purpose for which personal data will be used must be determined in sufficient detail. The purpose of use may be, for example, clearly described scientific research. Research must be planned so that the only type of personal data to be gathered is personal data necessary for the purpose of the research.

d) As a rule, personal data must be removed from research data when it is no longer necessary in order to carry out the research (e.g. the addresses or personal identity numbers of research participants, when these are no longer needed to link the data). If personal data is to be stored solely in order to link the data, the identifiers and information needed to link the data must be stored so that they are protected and separate from the data to be analysed. Only people who have a legitimate basis for processing the research data should be permitted to access it.

e) Research participants are to be informed of their rights and the processing of their personal data in truthful and comprehensible language. Research participants are to be given this information in a manner that is practical and natural in view of the research and those involved. This is to be done no later than when their personal data is collected. Research participants cannot be required to obtain information about the processing of their personal data and their rights themselves. This information must be made available to participants throughout the research process. When personal data is gathered in a way other than directly from the participant, such as, for example, in registry research, the necessity, the content and the time of informing the research participants are to be determined separately in accordance with legislation. For further information about informing research participants, see appendix.

3.6. Protecting privacy in research publications

Factors to be taken into account particularly when publishing research are as follows:

a) The general principle is the protection of the privacy of people who have participated in the research and are mentioned in the

39 See Articles 6 and 9 of the GDPR: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN. Further information is also available from the Office of the Data Protection Ombudsman website: https://tietosuoja.fi/en/when-is-the-processing-of-personal-data-permitted

publication. Decisions are to be made on a case-by-case basis taking freedom of expression into account.

b) When evaluating whether to publish people's names, the copyright of people who have taken part in the research must be respected. In addition, with the consent of people who have provided information or been interviewed, a research publication may include their names and other background information when the research is based on, for example, personal interviews or oral history.

c) Research participants and people who have provided information for the research must not be promised complete anonymity if this cannot be guaranteed. For example, providing anonymity for the participants in research publications does not necessarily prevent their identification by those who are familiar with the activities of the community or organisation that has been the subject of the research.

d) When writing about private individuals who have passed away, the researcher must aim for respectful expression. The need for privacy of the deceased's relatives and others closest to them should be appropriately observed.

It is not generally appropriate to publish the data of people who have participated in the research in a way that allows them to be identified. This does not apply to public figures who exercise or who have exercised significant power and whose privacy is narrower than other individuals. Critical evaluation of the actions of public figures is an important part of the freedom of science enshrined in the Finnish Constitution. In addition, the Data Protection Act which entered into force in 2018 contains special provisions regarding freedom of expression and safeguarding the freedom of information.[40] Irrespective of this, publication of personal data must be founded on consideration on a case-by-case basis and its importance to society. Even public figures have a private life, which must always be respected.

3.7. Openness of research data

Open science is a precondition for critical evaluation and the scientific progress. Preserving the data gathered in research to make it available to other researchers is one way of ensuring open science. The degree of openness is determined on the basis of the data in question, taking into account both freedom of science and freedom of expression, and the protection of personal data and privacy. Alongside completely open data, there may also be data that is open to researchers only. Sometimes the data cannot be made openly available at all for legal or ethical reasons. In such cases, the information describing the data may be open.

Opening the research data must be considered already at the planning stage of the research. Research participants must be informed at the data collection stage that the data will be opened. When data contains or has originally contained personal data, the data controller is responsible for making the data open where applicable and in compliance

40 Finnish Data Protection Act (1050/2018) Section 27: https://www.finlex.fi/en/laki/kaannokset/2018/en20181050.pdf

with legislation. When collecting, preserving and opening research data, reliable services which provide data protection must be used throughout the lifespan of the research.

Opening research data to other researchers reduces the need to gather the same type of data unnecessarily. This reduces research pressure on small population groups, for example. The risk of damage to unique objects, old documents and other objects is also reduced if it is possible to examine these for example in digital form. It is a good idea to check at the planning phase whether data applicable to the research already exists before gathering or obtaining new data.

4. Ethical review in human sciences research

4.1. General ethical review principles

Ethical review in human sciences means evaluating the research being planned in a way that emphasises the anticipation and prediction of any potential harm that may be caused to the people participating in the research due to the research or its results. Ethical review is carried out and a statement issued by a human sciences ethics committee at the request of a researcher.

Ethical review examines the data collection plan and the intended research method from the perspective of avoiding risk and harm. It also examines the documents drawn up for informing research participants and obtaining consent. The review weighs up the potential harm to participants, their families or the researcher themselves as well as the damage resulting from participation in the research in relation to the intended scientific value of the research. The ethical review principles described above serve as a starting point for guidance in evaluation.

The researcher is always responsible for ensuring that their research is ethical. The data controller for the research is responsible for decisions regarding data protection (see section 3.5). The research plan should address ethical risks and the intended methods for avoiding harm and damage, irrespective of whether or not the research undergoes ethical review. Where necessary, more detailed ethical guidelines will be applied in particular disciplines.

If the human sciences ethics committee considers that the plan under review falls within the scope of the Medical Research Act (488/1999), it returns the plan to the researcher and communicates its reasons for this. The committee instructs the researcher to contact the secretary of the local medical ethics committee in accordance with the Medical Research Act.

Factors to be generally taken into account in ethical review in the human sciences:

a) Ethical review is carried out before data is collected. An ethical review statement cannot be issued afterwards.

b) The researcher is always responsible for the ethical and moral solutions in the research, and submitting the research for ethical review never transfers this responsibility to the ethics committee.

c) Theses supervisors are responsible for ensuring that their supervisees are familiar with ethical principles, but the writer of the thesis is responsible for their work being

ethical.[41] If ethical review is necessary, it is recommended that the student request it jointly with their supervisor.

41 On undertaking to comply with the Responsible conduct of research and procedures for handling allegations of misconduct in Finland 2012 guidelines, higher education institutions have undertaken to ensure that familiarity with responsible conduct of research and teaching research integrity are a firm part of the first cycle and second cycle education they provide.

d) If a funding body or publisher requires ethical review for a research which does not require ethical review in Finland and which has not undergone ethical review prior to the commencement of the research, the ethics committee may provide a description of the ethical review practice in Finland instead of issuing a statement.

Ethical review particularly assesses:

the potential risks and harm to research participants, their families and potentially also the researcher themselves as well as their likelihood in relation to the plans drawn up to avoid them described in the request for a statement

sufficiently clear information to research participants on the content of the research, their participation in the research and the processing of their personal data

the data management plan, also containing a description of the processing of personal data throughout the lifespan of the research

the appropriateness of the research participant's written or electronic consent to participate

the way in which the consent of participants is requested and documented if written or electronic consent is not used

the significance of the new information that the research aims to obtain in relation to potential harms and risks.

4.2. Research design elements requiring ethical review

The researcher must request an ethical review statement from a human sciences ethics committee, if their research contains any of the following:

- **a)** Participation in the research deviates from the principle of informed consent,
- **b)** the research involves intervening in the physical integrity of research participants,
- **c)** the focus of the research is on minors under the age of 15, without separate consent from a parent or carer or without informing a parent or carer in a way that would enable them to prevent the child's participation in the research,
- **d)** research that exposes participants to exceptionally strong stimuli,
- **e)** research that involves a risk of causing mental harm that exceeds the limits of normal daily life to the research participants or their family members or others closest to them or
- **f)** conducting the research could involve a threat to the safety of participants or researchers or their family members or others closest to them.

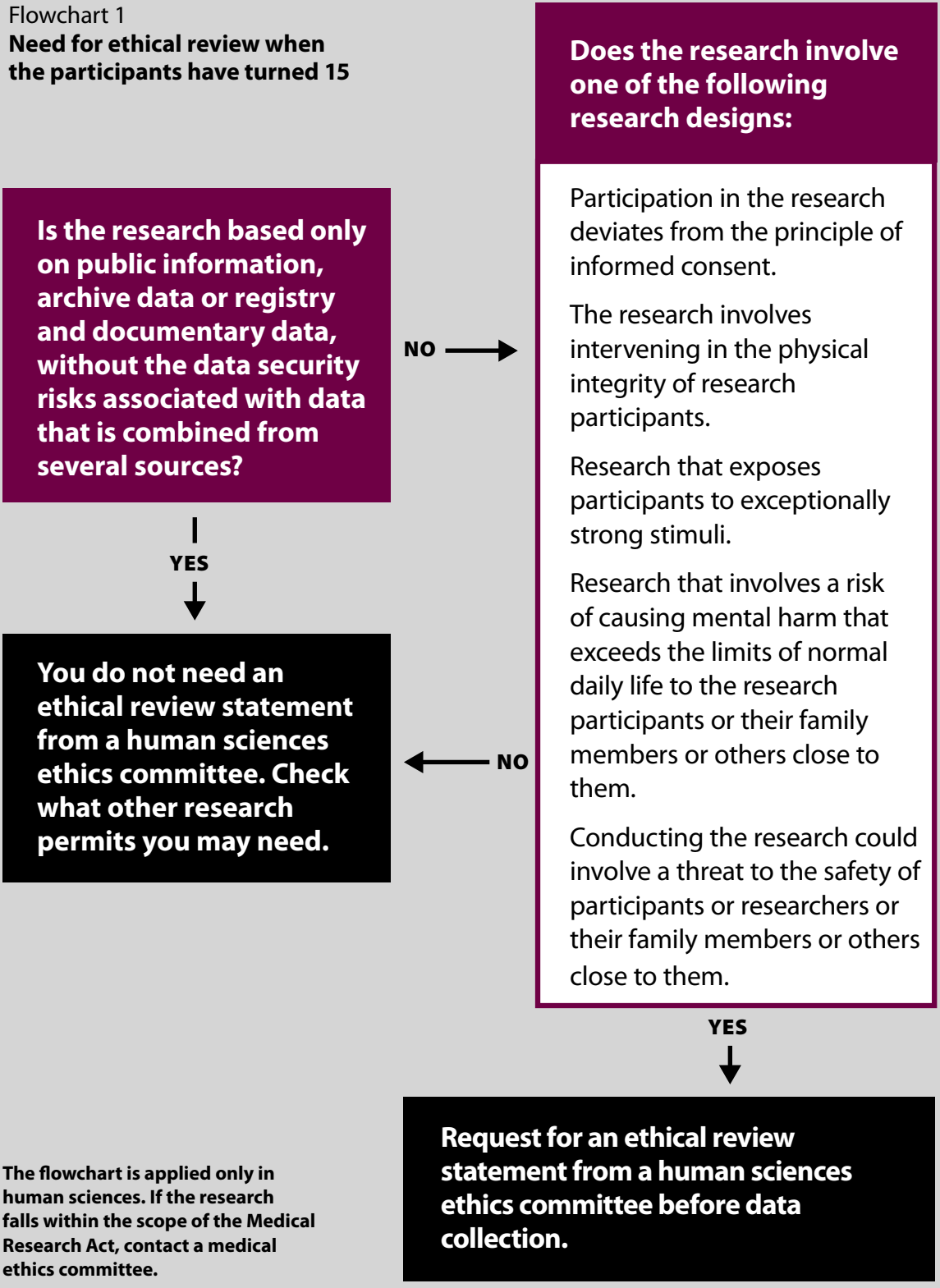
If the research contains any of the factors above and the research has not undergone ethical review, this may constitute a violation of responsible conduct of research (RCR) and, where necessary, it may be resolved through the process of handling allegations of research misconduct.

An ethical review statement may also be requested when a funding body, collaborative partner, research object or publisher so requests. However, it must be noted that a statement cannot be requested once the research has commenced. Where research is carried out or data is gathered outside Finland, the researcher must familiarise themselves with the ethical review practices in the target country.

More specific information on the above elements requiring ethical review:

a) Deviation from the principle of informed consent for participation in research occurs where the participation is not voluntary or the participants are not given sufficient or correct information about the research (if for example the nature of the research demands this kind of research design). The review of the ethics committee is not required for the research of public and published data, registry and documentary data and archive data. Research of registry data and documentary data must be evaluated, if the specification in research design f) on data security risks is applicable to the research in question. When the research deviates from

Flowchart 1
Need for ethical review when the participants have turned 15



The flowchart is applied only in human sciences. If the research falls within the scope of the Medical Research Act, contact a medical ethics committee.

the principle of informed consent, it must be ensured that

- research participants are appropriately informed of the processing of their personal data where the research design so permits
- the research is justified and could not be carried out if participants were asked to consent to participating in the research
- data collection does not cause damage or harm to participants
- the real content and purpose of the study are explained to participants as soon as this is possible in view of the research.

b) Intervening in physical integrity for research purposes may include, for example, measuring physical condition, taking physiological samples, consumption of food or other ingested products. or restricting physical freedom, e.g. using technology, so that research participants have no opportunity to stop their participation in the research of their own free will within a reasonable period of time. When research intervenes in physical integrity, it is necessary to check whether this is a case that must be evaluated under the Medical Research Act or research that falls within the remit of a human sciences ethics committee (see definition in footnote 1).

c) If a participant under the age of 15 participates without the separate consent of a parent or carer and without a parent or carer being informed, it must be ensured that the research does not cause harm to the participant and that the minors asked to participate in the research are capable of understanding the topic of the research and what the research requires of them in concrete terms. In addition, at least one of the following criteria must be met:

- The research focuses on issues of which sufficient research information cannot be obtained if the participation of children requires the consent of the parent or carer (e.g. domestic violence, social problems and similar).
- The research focuses on issues that minor participants do not themselves want their parents or carers to know about (e.g. drug or alcohol use, sexual orientation and similar).

d) Exceptionally strong stimuli for participants may be, for example, data containing violence or pornography which the participants will be shown as part of the research design. Exceptionally strong stimuli may also be involved in research designs in which the participants are deliberately presented with ideas and data that are completely incompatible with their values.

e) A risk of causing mental harm that exceeds the limits of normal daily life to the research participants or their family members or others closest to them may arise, for example, if the research is associated with traumatic experiences of research participants or their family members or others closest to them. Research situations can and may, however, include mental strain and emotional experiences similar to situations of everyday life.

f) A threat to the safety of research participants or researchers or their family members or others closest to them may arise, for example, in research into domestic violence or in research conducted in crisis situations or areas. Data security risks can also form a safety threat, e.g. if the research participants' personal data is collected and combined from several different sources.

If they wish, the ethics committees may make these research design elements requiring ethical review more concrete by sector or organisation.

4.3. Duties of human sciences ethics committees and the statement process

The duty of the human sciences ethics committees is to issue ethical review statements on the ethics of research plans and other risks inherent in the research where researchers so request. The ethical principles contained in these guidelines serve as the starting point for ethical review.

Establishing human sciences ethics committees

TENK recommends that a human sciences ethics committee be established either per organisation or per region, in collaboration between universities, universities of applied sciences and research institutions. TENK recommends that the ethics committees established be named human sciences ethics committees to distinguish them from local medical ethics committees. Cooperation in establishing an ethics committee can also be based on language or the ethics committee may be established for a particular discipline.[42]

When selecting members of human sciences ethics committees, it must be ensured on a case-by-case basis that internal familiarity with different fields is as wide as possible and that there is a wide range of expertise on research methods in the committee. If the ethics committee does not itself have sufficient expertise to evaluate the risks of a research, the committee may call in an expert in the discipline concerned regarding the specific request for a statement or approach an ethics committee for a particular field, where available.

The work of human sciences ethics committees

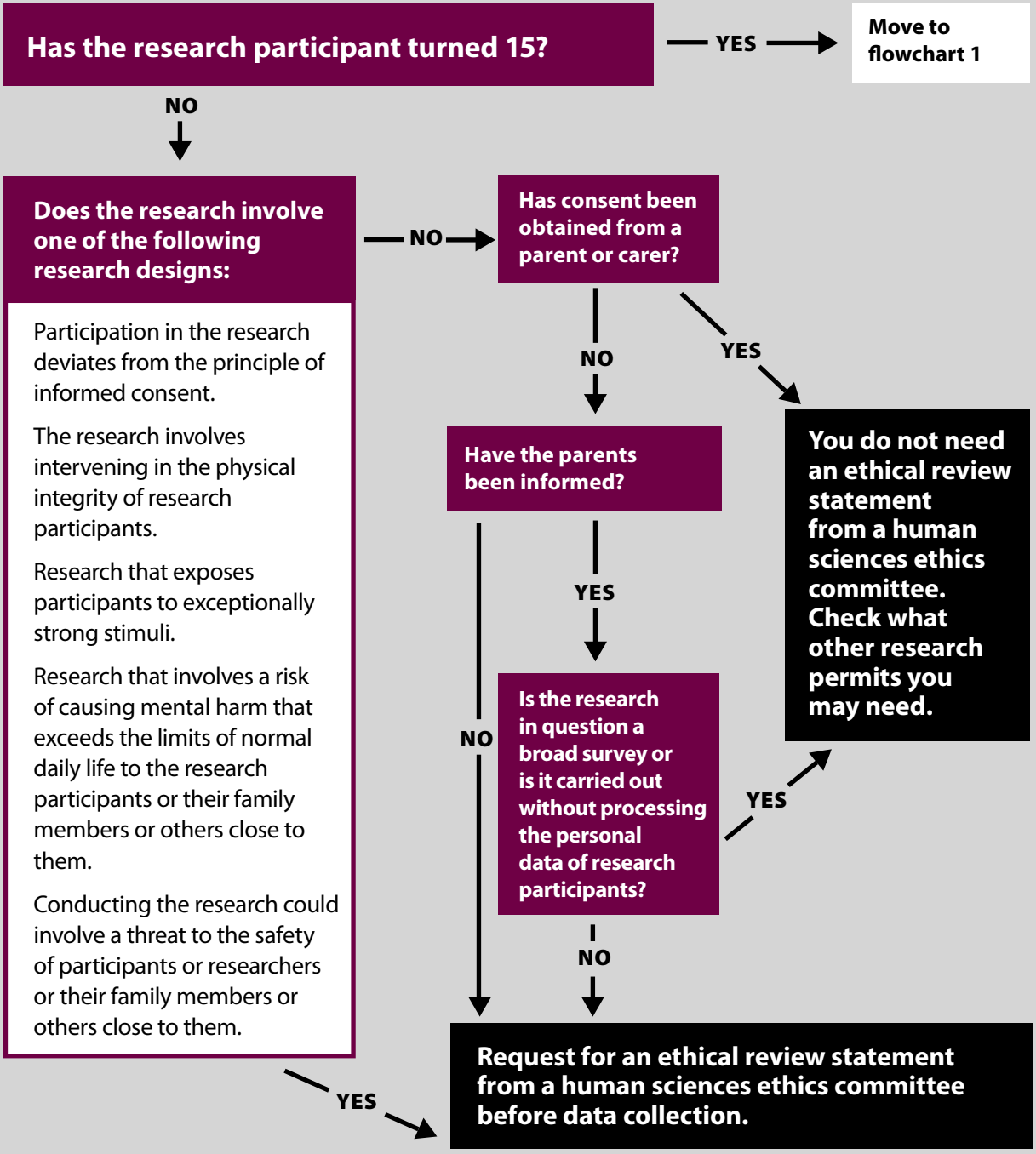
The work of human sciences ethics committees should be as open as possible. Information of the members of the ethics committee, its schedules and instructions for requesting statements should be readily available to researchers.

TENK recommends that the data protection officers or equivalent experts in the organisation take part in the work of the ethics committee where necessary. It is also recommended that the ethics committee works in collaboration with the medical ethics committees in their own region to clarify the division of work and borderline cases.

The task of human sciences ethics committees is to carry out ethical reviews. However, organisations may, if they wish, include other duties in their remit. The work of an ethics committee is demanding in terms of time and resources. TENK recommends that organisations that have signed up to the guidelines ensure that resources are sufficient, for example by ensuring that the ethics committee has at least a part-time secretary at its disposal.

42 For example, the Ethics Committee of Youth and Childhood Studies offers ethical review to those members of the Finnish Youth Research Society and the Finnish Society for Childhood Studies who do not have an opportunity for ethical review of their research in their own organisations. Those requesting a statement must be either a member of the Finnish Youth Research Society or the Finnish Society for Childhood Studies.

Flowchart 2
Need for ethical review in research involving minors



The flowchart is applied only in human sciences. If the research falls within the scope of the Medical Research Act, contact a medical ethics committee.

Applying ethical review statements

To obtain a statement from an ethical review, a researcher must send a request for a statement to an ethics committee. The ethics committee is determined by the researcher's workplace or research organisation. If they wish, ethics committees may also review research taking place outside their own organisation.

Ethical review is free of charge. However, the ethics committee may choose to request a fee, if it for example agrees to evaluate the research plan of a researcher who is not a member in the scientific community of any of the research organisations that have undertaken to comply with these guidelines.

At least the following documents must be appended to the request for an ethical review statement:

- grounds for requesting ethical review
- research plan and summary
- contact details of the person responsible for the research
- assessment of the ethical nature of the research by the person responsible for the research
- information intended to be given to research participants and the possible consent form, as well as other data to be given to participants (e.g. questionnaire, interview outline)
- data management plan
- data protection statement for scientific research (if data containing identifiers is gathered from participants)

If they wish, ethics committees may provide further instructions on the statement process and the necessary annexes to those requesting ethical review.

The ethical review statement provided may be either positive or conditionally positive (requiring changes). The statement may also be negative (requiring changes). If the researcher fails to comply with the guidance in the statement received, this may constitute a violation of responsible conduct of research (RCR).

For more information about the statement process, contact the secretary of the ethics committee or the research integrity adviser of the research organisation.

Request for a statement from TENK

If the person who has requested an ethical review statement does not accept the changes proposed in the statement or the decision of the human sciences ethics committee, they may request a statement on the matter from TENK. The request for a statement, including

Appendix. Information to be given to research participants of the processing of personal data

The General Data Protection Regulation requires that research participants are given the following information of the processing of personal data:

Information required under the obligation to inform	When personal data is obtained directly from the research participant	When personal data is obtained other than directly from the research participant
Identity and contact details of the data controller	x	x
Contact details of the data protection officer (if named)	x	x
Purpose for processing personal data, sufficiently specific	x	x
Legal basis for processing personal data	x	x
If the legal basis for processing personal data is consent (or special categories of personal data are processed namely on the basis of consent), information about the right to withdraw consent at any time without this affecting the lawfulness of the processing of personal data conducted before the withdrawal	x	x
Legitimate interests if processing is based on the legitimate interests of the data controller or a third party	x	x
Storage period of personal data or if this is not possible, the criteria for defining the storage period	x	x
Personal data categories		x
Information about where the personal data was obtained from		x
Information about the rights of the data subject	x	x
Information about the right to lodge a complaint with the supervisory authority	x	x
Recipients or categories of recipients of personal data	x	x
The necessary information relating to the transfer of personal data to third countries	x	x
Information on whether providing personal data is a contractual or statutory requirement and the consequences of failing to provide the data	x	

the grounds for requesting a statement, must be submitted within two months of the ethics committee's decision. All statements issued by the human sciences ethics committee must state that this opportunity is available. Further information: www.tenk.fi/en

Further information about the obligation to inform

In some situations, it is not necessary to inform research participants if personal data is obtained other than directly from the data subject. It is recommended that further information be requested from the organisation's data protection officer or from the authorities before deciding not to inform research participants.

When informing research participants about processing of personal data, it is essential that the participant is informed at the right time. When personal data is obtained directly from a research participant, the participant must be informed no later than the point at which the data is obtained. Different time limits apply to data obtained other than directly from the research participant.

In some cases, complying with the principle of transparency of personal data may also require other information. This may include, for example, informing the participant of the risks associated with processing of the data.

Further information on informing research participants is available on the Finnish Social Science Data Archive website: https://www.fsd.uta.fi/aineistonhallinta/en/informing-research-participants.html

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