Proposal for Ethical Guidelines for Sámi Health Research and Research on Sámi Human Biological Material
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Abbreviations

FEK The National Research Ethics Committees
NEM The National Committee for Medical and Health Research Ethics
NENT The National Research Ethics Committee for Science and Technology
NESH The National Research Ethics Committee for Social Sciences and the Humanities
REC Regional Committees for Medical and Health Research Ethics
SAMINOR Study of Health and Living Conditions in Areas with Sámi and Norwegian settlement
SSHF Centre for Sámi Health Research/Sámi dearvvašvuodadutkama guovvdáš
STN The Sámediggi/ the Sámi Parliament’s subsidy schemes for economic development

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DISCUSSION OF CHALLENGES RELATED TO HEALTH RESEARCH AMONG INDIGENOUS PEOPLES

1. At the international level........................................................................................................................... 33
2. Norway ......................................................................................................................................................... 35
3. Methods for identifying ethnicity.............................................................................................................. 36
4. Surrogate measures .................................................................................................................................... 37
5. Methodological and ethical challenges involved in using ethnicity in health research ......................... 37
6. New legislation and regulations on health research .................................................................................... 38
7. Communication ............................................................................................................................................. 39

RELEVANT INDIGENOUS PRINCIPLES................................................................................................................. 40
1. ILO Convention No. 169 and the UN Conventions of 1966 ........................................................................... 40
2. The UN Declaration on the Rights of Indigenous Peoples ............................................................................ 41

ETHICAL GUIDELINES FOR SÁMI HEALTH RESEARCH....................................................................................... 39
1. Values ............................................................................................................................................................ 39
2. Sámi self-determination and health research .............................................................................................. 40
3. Collective consent ........................................................................................................................................ 41
4. Acknowledgement and recognition of Sámi affiliation .............................................................................. 41
5. Ethical guidelines for Sámi health research ................................................................................................. 41
6. Partnership between research institutions and the Sámi communities ......................................................... 41
7. Knowledge about Sámi conditions .............................................................................................................. 41
8. Respectful and responsible treatment of human biological material and genetic research .................... 42
9. Securing collective consent for population studies with previous broad consent .................................... 42

References ......................................................................................................................................................... 43

Appendix 1: The Committee’s working methods ............................................................................................ 49

Appendix 2: Mandate and clarification of the mandate ..................................................................................... 50
Summary

The purpose of this proposal for Ethical Guidelines for Sámi health research and research on human biological material is to provide guidance to individual researchers, research institutions, Sámi communities and private individuals about which principles of research ethics should be applied as the basis for Sámi health research.

This report offers an overview of principles established to ensure that research is experienced as safe in a cultural perspective, that it is respectful and responsible, of good quality, and useful to the Sámi communities as well as to individuals. The guidelines are intended to ensure that research on the Sami population and local Sámi communities, or their biological material, takes into account and respects the diversity and distinctive character that distinguishes Sámi culture and the Sámi communities, and ensures full equality and reciprocity throughout the research process.

The Committee understands Sámi health research to be research that is intended to gain new knowledge about disease or health in the broad sense. This also includes research on health services and research on human biological material.

In this sense, Sámi health research may include:

1) questions/research issues that include the Sámi as a group, and/or
2) questions/research issues in municipalities/regions in which the Sámi are in the majority or account for a substantial percentage of the population, and/or
3) questions/research issues which include Sámi language, culture, traditions and/or history.

Such research can be performed by Sámi or non-Sámi researchers/research groups. It can feature different research designs and can be performed using different research methods.

Sámi self-determination is a right pursuant to the international rights of indigenous peoples, as laid down in Article 1 and Article 27 of the International Covenant on Civil and Political Rights (OHCHR) and ILO Convention No. 169 on Indigenous and Tribal Peoples in Independent Countries, as well as the UN Declaration on the Rights of Indigenous Peoples. In connection with health research, Sámi self-determination can be enshrined in two basic principles for the purposes of the ethical guidelines:

1 Collective consent

To ensure compliance with the principles for ethical guidelines in Sámi health research, the Committee is of the opinion that collective consent must be obtained for all research that directly or indirectly involves the Sámi communities or people. Approval from the Sámediggi/ the Sámi Parliament or the body designated by the Sámediggi would be considered a collective consent.
2 Acknowledgement and recognition of Sámi affiliation

As a people, the Sámi are entitled to learn about their own health. The registration of ethnic affiliation is a prerequisite for knowledge of ethnic groups’ health situation and living conditions. Ethnic registration has previously been misused, also by researchers. Consequently, as a variable, ethnicity must be used in all contexts in a balanced and responsible manner to ensure that research contributes to knowledge and not to stigmatisation.

Sámi ethnicity shall be recognised and acknowledged in a culturally safe and responsible manner that preserves Sámi values and the standards associated with Sámi affiliation.

In addition to the principles of collective consent and acknowledgement and recognition of Sámi affiliation, the Committee proposes the following ethical guidelines:

1 Insofar as necessary, the researcher must explain how a partnership with the Sámi communities will be carried out and safeguarded.

2 The researcher must render visible/document his/her expertise in the field of Sámi culture, Sámi health and Sámi living conditions based on the requirements that have been laid down.

3 In examining human biological material, researchers shall behave respectfully and explain:
   a) their reason(s) for collecting the material,
   b) the method of collection, storage, sharing, exporting, typing of analyses of the material and its destruction.

4 Also, in cases of broad consent, researchers must seek to obtain collective consent for new projects.
1 Introduction

1.1 Background

Research on the Sámi's health and medical conditions has been performed for different purposes and with different methods since the early 1800s. Skeletal material from archaeological excavations and autopsies at the Department of Anatomy were the starting point for early medical research on the Sámi.

Race research was a key part of these research activities. Using cranial indices and skull measurements, the intention was to distinguish ethnic groups, e.g. to tell Sámi and Norwegians apart. In the 1920s and 1930s, the Anatomist Kristian Emil Schreiner from the Department of Anatomy at the University of Oslo was especially focussed on the distinctive physio-anthropological features of the population of Norway. Like colleagues in the neighbouring country of Sweden, he was especially interested in measuring the skulls of the Sámi population.

In the past, research was carried out not only with a lack of knowledge about and focus on the Sámi’s lifestyle and culture, but also with a discriminatory, racist view of the Sámi as being primitive and inferior. This view of the Sámi was prevalent in several disciplines, leaving a deep impression on many, and causing Sámi communities to distrust researchers.

Growing political awareness among the Sámi since WWII, a generally higher level of education and a growing number of Sámi health care workers and researchers have been decisive for the mounting interest in Sámi health research in recent decades. In 1984, the Sámi Medical Association submitted the first proposal for a separate Sámi health study to the University of Tromso (UiT) but got no response. In 1995, the Ministry of Health and Social Affairs published its report “A Plan for Health and Social Services for the Sámi Population in Norway” (Norwegian Public Report 1995:6). The report surveyed problem areas for Sámi patients in their encounters with the Norwegian public health service. More research on Sámi health problems was identified as a prerequisite for understanding those problems and led to a study of ethnic medicine made by the University of Tromso, and to the establishment of a separate Centre for Sámi Health Research at UiT - The Arctic University of Norway (1).

The establishment of the Centre for Sámi Health Research at UiT - The Arctic University of Norway, in 2001, was in response to Sámi health workers’ persistent efforts and the pressures they exerted over an extended period of time. The Centre has helped facilitate a substantial increase in publications and reports on the health of the Sámi and the rest of the people who live in Sápmi (Sámi territory). Sámi health research carried out by other health research communities has also expanded substantially in recent years. In addition, contact and collaboration with research groups in other indigenous areas has helped improve Sámi health research.

The Sámediggi/ the Sámi Parliament has been instrumental in dealing with questions of research policy. In 1997, in its recommendation on Sámi research, the Sámediggi pointed out that a separate Sámi body was needed to deal with research ethics issues. This was never brought to fruition. However, growth in health research has resulted in a greater need for ethical guidelines. Consequently, in 2016, the Sámediggi appointed a working committee to draw up a report, including a proposal for ethical guidelines for Sámi health research and research on Sámi human biological material. This report is a result of the Committee’s work.
1.2 The composition and work of the Committee

The Sámediggi/ the Sámi Parliament appointed the following members to the Committee:

- Professor Siv Kvernmo, Department of Clinical Medicine, UiT - The Arctic University of Norway (chair).
- Professor Emeritus Kirsti Strøm Bull, University of Oslo.
- Academic Director Ann Ragnhild Broderstad, dr. med., Centre for Sámi Health Research, UiT - The Arctic University of Norway.
- Office Manager May Britt Rossvoll, Regional Ethics Committee, UiT - The Arctic University of Norway.
- Bengt-Martin Eliassen, post-doctoral research fellow, Centre for Sámi Health Research, UiT - The Arctic University of Norway.
- Jon Petter Stoor, PhD student, Sámi National Competence Center for Mental Health Services (SANKS), Finnmark Hospital and the Centre for Sámi Health Research, UiT - The Arctic University of Norway/University of Umeå, Sweden.
- Heidi Anita Eriksen, municipal physician, Utsjohki Municipality, Finland.
- Isalill Simonsen Kolpus, Sámi Nuorrat.

Members Eriksen and Kolpus have not been able to participate in the Committee’s work.

1.3 Mandate

In case 058/16, the Sámediggi Executive Council in Norway adopted the following mandate for the Committee’s work:

- Draft ethical guidelines for Sámi health research, including research that involves Sámi human biological material;
- Identify and discuss challenges associated with the storage and right of disposition of Sámi human biological material;
- Discuss the ethical issues that must be covered by the ethical guidelines;
- Discuss the legal status of the guidelines;
- Consider further treatment of the guidelines at the national and international levels.

Indigenous rights enshrined in ILO Convention No. 169, the United Nations Declaration on the Rights of Indigenous Peoples, and other relevant international conventions form the basis for the work.

Read the entire mandate in Appendix 2

1.4 The Committee's interpretation of key concepts

1.4.1 The Sámi

1) Individuals who either identify themselves as Sámi, and/or who can be considered to be Sámi based on linguistic affiliation, their ancestors’ ethnic affiliation and/or geographical affiliation.

2) Dead people who satisfy the criteria in point 1), or who are identified as Sámi by other means.
1.4.2 Sámi health research

Sámi health research is research intended to gain new knowledge about disease or health in the broad sense. This also includes research on health services and research on human biological material. In this sense, Sámi health research may include:

1) questions/research issues that include the Sámi as a group, and/or
2) questions/research issues in municipalities/regions in which the Sámi are in the majority or account for a substantial percentage of the population, and/or
3) questions/research issues that include Sámi language, culture, traditions and/or history.

The research can be performed by either Sámi or non-Sámi researchers/research groups. The research can feature different research designs and can be performed using different research methods.

1.4.3 Sámi human biological material

Sámi human biological material is defined as organs, parts of organs, cells and tissue, and parts constituted of such material from Sámi individuals. This means that all types of physical material from the human body constitute human biological material, including skeletal material from Sámi people.

2 Research Ethics in Norway: overview over current regulations

2.1 Act no. 23 of 28 April 2017 on the Organisation of Ethical Research

The agencies that deal with questions about research ethics are currently governed by the Act on Organisation of Ethical Research (the Research Ethics Act).¹ The following is a list of agencies that are anchored in the Act, and how they are described in the legislative history of the Act².

2.1.1 The Norwegian National Research Ethics Committees (NEM, NENT and NESH)

NEM – The National Committee for Medical and Health Research Ethics is responsible for medical and health research. NEM is the appellant body for decisions adopted by REC (Regional Committees for Medical and Health Research Ethics). NEM performs advisory and coordinating duties for the seven regional committees.

NENT – The National Research Ethics Committee for Science and Technology is responsible for science and technology, manufacturing, agriculture and fisheries research and the parts of biotechnology and gene technology research that are not covered by NEM.

NESH – The National Research Ethics Committee for Social Sciences and the Humanities is responsible for the social sciences, humanities, law and theology.

¹ The Act entered into force on 1 May, superseding Act No. 56 of 30 June 2006 on Ethics and Integrity in Research.
² Prop. 158 L (2018–2019)
**Skeleton Committee** – The Norwegian National Committee for Evaluation of Research on Human Remains is an advisory committee under the auspices of NESH. The Committee gives advice on ethical issues involving research on human remains stored in public museums and collections.

The Norwegian National Research Ethics Committees are intended to be advisers on research ethics issues. The committees’ remit is to inform and provide advice to researchers, administrators and the general public. They are to provide legal opinions on questions of principle and to draw up ethical guidelines in their particular areas of expertise. The committees are to keep informed on issues involving relevant and potential research ethics questions at the national and international levels alike.

The Norwegian National Research Ethics Committees used to operate under the auspices of the Research Council of Norway, but the Research Ethics Act of 2006 separated it from the Research Council in an effort to enhance the committees’ legitimacy and independence. The Ministry of Education and Research appoints the national committees, cf. §9 of the Research Ethics Act. The Norwegian National Research Ethics Committees constitute what is known as the Norwegian National Research Ethics Committees (FEK).

### 2.1.2 The administrative agency: The Norwegian National Research Ethics Committees (FEK)

FEK is currently assigned the following routine responsibilities:

- **FEK shall work to promote good, ethical research and contribute to the efforts to prevent scientific misconduct.**
- **FEK is to be a central source of communication that targets researchers, research institutions, the authorities and the general public on questions of research ethics, and it shall be a driving force for debate in this area.**
- **The committees shall stay informed on issues involving relevant and potential research ethics questions at the national and international levels alike.**
- **FEK is responsible for the guidelines for ethical research being a useful tool for promoting good, ethical research. In addition to general guidelines for ethical research, there are to be guidelines for ethical research in various disciplines, as needed.**
- **FEK is to collaborate with and be a resource for research institutions and to be socially engaged on questions of research ethics.**
- **FEK is to collaborate with international research ethics committees and organisations on questions of research ethics, and strive to promote international cooperation on common research ethics values, etc.**

### 2.1.3 Regional Committees for Medical and Health Research Ethics (REC)

To ensure ethical medical and health research that involves humans, we have regional committees (REC). The regional committees were established in 1985 as a follow-up to the Helsinki Declaration. Today, the committees are established by law pursuant to §10 of the Research Ethics Act.

There are seven REC committees. Administratively, they are affiliated with the faculties of medicine at the universities in Oslo, Bergen, Trondheim and Tromsø. The committees’ spheres of responsibility are laid down in Act No. 44 of 20 June 2008, the Health Research
Act. Pursuant to this Act, medical and health research on human subjects, human biological material or health information shall be approved in advance by REC, cf. the Health Research Act, Chapter 3. Other tasks may be assigned to the REC committees pursuant to other legislation, cf. §10, second subsection, of the Research Ethics Act. NEM is an appellant body for decisions adopted by REC.

2.2 Act No. 44 of 20 June 2008 on medical and health research

The Health Research Act governs medical and health research on human subjects, human biological material or health information, cf. §2. The terms used here are defined in more detail in §4.

**Medical and health research:** activity conducted using scientific methods to generate new knowledge about health and disease, cf. §4, litra a.

Research projects covered by the Act must be pre-approved by REC, the Regional Committee for Medical and Health Research Ethics, cf. §9. The requirement for advance approval covers not only experiments on human subjects, but also research on human biological material and health information.

**Human biological material:** organs, cells and tissues and components of this kind of material from living and deceased human beings, cf. §4, litra b.

**Personal health data:** confidential information pursuant to §21 of the Health Personnel Act, that is, data on people's health and medical issues. The term ‘personal health data’ also covers other data and evaluations of health conditions or information of significance for health conditions, and which can be linked to individuals, cf. §4, litra d.

§§10 to 12 of the Health Research Act contain rules that apply to applications to REC. We will not go into more detail about these provisions in this context.

One important principle for medical and health research is enshrined in §5:

“Medical and health research must be organised and carried out in a responsible manner. Research must be based on respect for the research participants’ human rights and dignity. The participants’ welfare and integrity shall have priority over scientific and social interests. Medical and health research must take into account ethical, medical, health, scientific and privacy factors”.

One important consequence of this principle is that medical and health research requires consent from the participants. This is laid down in §13, which also states that consent must be informed, voluntary, express and documented. Consent must be based on specific information about a concrete research project.

Research participants may consent to human biological material and personal health data being used for specific, broadly defined research purposes, cf. §14. REC may specify conditions for the use of broad consent and may order a project manager to obtain new consent if the committee deems it necessary. In the event of substantial changes, the research project
must obtain renewed consent if the changes are believed to be significant for the participant’s consent, cf. §15. If it is difficult to obtain renewed consent, REC can approve a new or amended use of previously collected human biological material or health data without obtaining new consent. This can only take place if such research is of significant interest for the community and consideration is taken for the participants’ welfare and integrity. REC can set conditions for use. Consent is not required to use anonymous biological material and anonymous information, cf. §20. Consent is required to collect material that is subsequently anonymised.

REC can also determine that material collected by health and care services can be used for research purposes without obtaining the patient’s consent, cf. §28. The patient must be informed in advance that human biological material may, in certain cases, be used for research, and must have had an opportunity to reserve him/herself against research on human biological material, see §28, second subsection.

Consent to participate in a research project can be withdrawn at any time, cf. §16. Withdrawal of consent implies that research on the person’s biological material or health data must cease. The person in question can also demand that the biological material be destroyed, and that the health data be deleted or surrendered.

However, there is an important exception from what is stated in this context. The destruction, deletion or surrender cannot be required if the material or health data is anonymised. The same exception applies if, after processing, the material becomes part of another biological product, or if the data has already been used in analyses that have been carried out. However, further use is not allowed.

§16, last subsection, allows an apparently broad exemption from the right to withdraw consent. There, it states that if strong societal or research interests so require, REC can allow continued research on the material and postpone the destruction, deletion or surrender until the research project has been completed. However, the legislative history of the Act indicates that this exception shall be practised restrictively. According to the provisions of the Health Research Act, the Act does not apply to the establishment of health registries, cf. §2, second subsection. Health registries are regulated by Act No. 43 of 20 June 2014 on Personal Health Data Filing Systems and the Processing of Personal Health Data (Personal Health Data Filing System Act). On the other hand, the establishment of research biobanks is governed by the Health Research Act, cf. §§25 to 31 of the Health Research Act, and it requires approval by REC and, in many cases, also a licence from the Norwegian Data Protection Authority.

Each research biobank must be under the supervision of a person who has an advanced degree in medicine or biology, cf. §26. The Ministry may decide, by issuing regulations, that certain research biobanks must have a board, in addition to the person responsible for the biobank. No such regulations have been issued as of today. REC can always set conditions for approval, even though no regulations have been issued. Sámi representation on the boards of biobanks containing Sámi human biological material has not been practised up to now.

Human biological material from a research biobank can be transferred out of the country once the transfer has been approved by REC. The general rule is that the person who has provided the material gives consent for this, cf. §28, but REC can also make exceptions that
would allow biological material to be sent out of the country without consent. Health data can be transferred to countries within the EEA. Transfer to countries outside the EEA can only take place if the person in charge of data processing abroad follows the same rules as in the EEA, cf. § 37.

Anonymised data can freely be transferred out of the country. The data are anonymous when information cannot be linked to individuals. Anonymised health data on groups – also on small groups – can freely will be transferred out of the country as long as the data cannot be traced back to individuals. Approval from REC is always required for biological material.

2.3 Act No. 100 of 5 December 2003 relating to the Application of Biotechnology in Human Medicine, etc.

The Biotechnology Act distinguishes between genetic testing to pose a diagnosis for a patient in need of treatment, and genetic testing to learn something about a patient’s hereditary predisposition for a disease and proneness to the disease later in life.

Health care personnel who require genetic testing in connection with diagnoses or treatment can always ask the patient for consent.

As regards tests for whether or not a person is a carrier of a hereditary disease, there are strict rules about this in the Biotechnology Act. The Ministry of Health must approve which diseases can be tested for using such methods. Before the Ministry decides whether permission will be granted for testing genetic material for a particular disease, the application must be submitted to the Norwegian Biotechnology Advisory Board (§5-3). What is more, such genetic testing can only be performed at institutions approved by the Ministry of Health. The subject of such a test must give written consent (§5-4) and shall receive genetic counselling before, during and after the test (§5-5).

Only institutions approved to perform genetic tests on DNA to identify diseases are authorised to receive data on such tests. Others, e.g. insurance companies or employers, are not allowed to ask for or receive such data. Nor are they allowed to ask that such tests be performed (§5-8).

In the wake of the enactment of the Biotechnology Act of 1994, there were questions about the exact scope of the Act. Many researchers believed that the strict rules in the Act regarding genetic testing did not apply to medical basic research that was not intended to inform the treatment of a specific subject of an experiment. In 1998, the question was put to the Department of Legal Affairs at the Ministry of Justice, which concluded that the rules of the Act also apply to dedicated research. This resulted in a legislative amendment in 1999, defining more precisely that the rules of the Act involving genetic testing did not apply to research that did not have consequences for the diagnosis or treatment of the subjects of the experiments, and where the data could not be traced back to the individual.

This provision was carried through in §1-2, second subsection, of the Biotechnology Act of 2003.
2.4 In particular about testing of ethnic groups

The above review indicates that individuals' privacy is well protected in connection with medical research. However, the situation is entirely different when a test cannot be traced back to individuals but is undertaken on anonymised material. The law imposes far fewer restrictions in this context. Nonetheless, ethical questions may also arise in connection with genetic testing of anonymized material, not least if it involves material associated with a narrow, specific geographical area or a demographic group.

As mentioned, medical and health research on anonymised biological material always requires the approval of REC – regardless of how the material has been obtained. For biological material obtained in the context of medical treatment or diagnostics after the Health Research Act entered into force, there is also a requirement that patients be informed before the material is used. There is also a public, although not very well-known, registry of reservations, against which the list of participants is to be edited.

As regards the use of biological material collected in connection with medical treatment or diagnostics before the Health Research Act entered into force, it also requires an exemption from the duty of confidentiality/consent from REC. REC can set conditions for the exemption. The Health Research Act must be understood to mean that human biological material and health data obtained pursuant to the Health Research Act cannot be made available for research that is not intended to obtain new knowledge on health or disease. However, the collection of human biological material for a purpose other than to acquire new knowledge about health or disease appears to fall outside purview of the Health Research Act and REC’s pre-approval. The view is that genetic testing that is not intended for such a purpose is not covered by the Biotechnology Act either.

In the early 1990s, an ambitious project was launched to identify different demographic groups’ DNA profiles, i.e. the Human Genome Diversity Project. The project met with strong resistance from indigenous groups, who feared that past negative research on them was now going to be continued through genetic research. Even across the generations, the skull measurement research of times past evokes collective memories of abuse perpetrated on the Sámi people.

Some years ago, the National Geographic Society wanted to perform genetic testing on the Sámi population of Finnmark County. The testing had no medical purpose but was intended to be part of ‘The Geographic Project: Molecular Genetic Analyses of Western/Central European Populations’. Naturally, each individual who participated in the project had to consent. However, the project had nothing to do with the individual participant, but rather with all the Sámi communities collectively, since the testing was aimed at members of a particular ethnic group. Several institutions in the Sámi community protested the testing.

There were divided views on whether such tests were covered by the provisions of the Biotechnology Act. One opinion was that such testing fell outside the scope of the Act pursuant to the provision in §1-2, second subsection, which states that the Act does not apply to “research that has no diagnostic or therapeutic consequences for the participant or where data about an individual person are not linked to that person”.

Others were of the opinion that such testing was not allowed under §5-2 of the Biotechnology Act, which states that genetic testing shall only be “carried out for medical purposes if it has a diagnostic or therapeutic objective”. An identical provision was included in the Biote-
chnology Act of 1994 and the legislative history of this Act states that genetic testing cannot be used to distinguish certain groups of people based on genetic material if doing so has no medical purpose.

However, today many would maintain that such testing does not fall under the scope of the Biotechnology Act, with reference to §1- 2, second subsection. Such testing will not be covered by the Health Research Act either.5

3 Research Ethics in Sweden and Finland: overview over current regulations

3.1 Sweden

3.1.1 Acts of legislation
In Sweden, health research ethics has been regulated since 2004 through the Act on Ethical Review of Research Involving Humans (2). The Act covers research on living and deceased human beings, biological material from human subjects, and research that entails the handling of sensitive personal data.

The Personal Data Act (3) defines the following information as sensitive: race or ethnic origin, political opinions, religious or philosophical convictions and membership of trade unions. It is also prohibited to process personal data relating to health or sexual life.

3.1.2 Ethical approval
There is one national ethics committee in Sweden, and six regional ethics committees located at the faculties of medicine. The objective of the ethical reviews is to protect individuals and to preserve respect for the value of human life in research. The risk to the individual must be weighed against the potential acquisition of knowledge, the quality of the research must be high (research of low quality is considered unethical), and the participants must understand and accept the conditions for participation.

3.1.3 Ethics in Sámi Health Research in Sweden
There are currently no guidelines for general or specific research (such as health research) on indigenous peoples, the Sámi or Sámi-related issues in Sweden. Sámi ethnicity is considered sensitive data and, as research subjects, the Sámi can also be viewed as being a vulnerable population. The extent to which ethical evaluations take account of or manage to preserve Sámi perspectives in research is unknown (4). A survey of applications for research projects on Sámi issues (including Sámi health research) shows that there are huge differences in how different researchers deal with general or specific ethical requirements related to Sámi issues and Sámi contexts. Some do not call attention to any particular ethical issues related to the Sámi context, while others apply ethical guidelines used for indigenous research in other countries (5).

The absence of ethical guidelines for Sámi health research has been criticised by the Sámediggi/ the Sámi Parliament on the Swedish side(6), which has pointed out that one has no guarantee that the general guidelines adequately protect Sámi perspectives, or that the ethical review committees (consisting of 15 individuals, i.e. 10 researchers and five lay people, and chaired by a judge) have sufficient expertise as regards the Sámi. Within scientific communities, certain quarters have been critical about introducing ethical guidelines on Sámi research because they might make it more difficult to carry out research on Sámi conditions.

The Sámediggi in Sweden has established an ethics council to deal with ethical issues, e.g. with a view to returning Sámi skeletal material.

3.1.4 Reviews
In theory, the circumstances for ethical reviews of Sámi health research coincide in the Swedish and Norwegian regions of Sápmi. However, the ethics councils could conceivably have different practices and different review routines, and there may be differences in their (Sámi) expertise. Differences may also be ascribable to sheer coincidence. There could even be major differences within Sweden, since it is not required that all Sámi health research be processed by the same ethics committee. The establishment of ethical guidelines for Sámi health research on the Norwegian side of Sápmi can most certainly strengthen the protection of the Sámi perspectives in health research on the Swedish side as well.

3.2 Finland

3.2.1 Acts of legislation
Ethical reviews of health research in Finland are regulated through the Medical Research Act (7) and the Act on the Medical Use of Human Organs, Tissues and Cells (8). The Biobank Act (9) governs the establishment and operation of biobanks. Medical research is defined as an encroachment on a human being’s, a human embryo’s or a foetus’ integrity, the purpose of which is to acquire knowledge about health, the causes of diseases, symptoms, diagnostics, care, the treatment of diseases or the nature of a disease in general. The handling of sensitive personal data, including information about race or ethnic origin, is prohibited by the Personal Data Act (10), unless the data is going to be used for historic or scientific research.

3.2.2 Ethical approval
All medical research shall be considered from the ethical perspective and be approved in advance by an ethics committee. Which of the regional committees will give its approval, depends on the primary applicant’s place of work or where the research will primarily be performed. The regional committees are located at the faculties of medicine. If a research project fails to be approved by an ethics committee, an appeal can be filed with the national committee. The national committee is also responsible for the ethical evaluation of clinical testing of pharmaceutical drugs. The purpose of ethical evaluation is to ensure the value and inviolability of human life through a balancing of interests in which the subject of the research project is given priority. In other words, his or her best interest and welfare will always take precedence over scientific and societal interests.
3.2.3 Etikk i samisk helseforskning i Finland

Finland has no ethical guidelines for research on Sámi-related topics, neither generally nor specifically (e.g. Sámi health research). Sámi ethnicity or research on the health of the Sámi are not mentioned in legislation or regulations related to health research in Finland. The lack of ethical guidelines for Sámi research in Finland may be because the State has not recognised and taken responsibility for its colonial practices. Some of the most important aspects of such guidelines involve repairing damaged relations between academia and the Sámi (11). Trust, understanding of Sámi culture, language and contexts, as well as the inclusion of Sámi in the research process, will be important for ensuring appropriate and ethically correct methods for health research cooperation with the Sámi in Finland (12).

3.2.4 Review

Due to the absence of established practice and recognised guidelines, it is not known how much account is taken of Sámi ethical needs in Sámi health research in Finland. The situation appears to be quite similar to the situation in Sweden, and there are probably also different practices for how ethical approval is reviewed in Sámi health research. Accordingly, there is reason to expect that the establishment of ethical guidelines for Sámi health research in Norway will have favourable ramifications in Finland.

4 Sámi health research and research on Sámi human biological material

4.1 Sámi health research in Norway – an historical perspective

Social Darwinism as a philosophical and ideological influence was predominant during the interim from 1850 to 1950; it made its mark on both research and politics at the time. Social Darwinism outlined a scenario in which a society either develops or perishes in the struggle for existence and in competition with other societies. While strong, adaptable types of societies survive the struggle for existence, it was assumed that the weaker, less adaptable societies would perish (13). It was this idea that largely motivated the assimilation of and research on the Sámi and Kven populations of Norway (14-16).

The assimilation policy was inextricably linked to the emergence of strong nation states. It was considered crucial to assimilate indigenous peoples and, linguistically and culturally, to homogenise the general population in order to make it easier to promote feelings of identity and self-esteem in a nation state. This was also the case in Norway.

The authorities viewed Norwegianisation as an act of mercy and as a necessity for security policy. Through the Norwegian language and culture, the Sámi could be saved from imminent doom, at the same time as it was considered essential to document and demonstrate Norway’s presence in the areas along the border with Finland and the Soviet Union (14). Norway feared a Russian/Finnish invasion, and the Kven people were seen as a threat, as well as a Russian/Finnish incentive for laying claim to territory in Finnmark County (17).

The direction within social Darwinism was the anthropo-sociological school (16). It studied racial characteristics based on people’s physical anthropology and afforded importance to body height, head shape and skin, eye and hair colour. The shape of the skull was especially
important, because it allowed human subjects to be divided into two main categories: "elongated skulls" and "short skulls". Based on average skull measurements, along with many other characteristics, categories of main races and sub-races were defined. The categorisation was understood, among other things, as an evolutionary scale and a theory of evolution, and blond long skulls - that is, "the Nordic race" - were considered to be the very top rung of the evolutionary ladder (16). In other words, social Darwinism rendered possible a notion of an evolution on a continuum from the primitive towards the civilised, and indigenous peoples – the Sámi included – were considered underdeveloped races. From the beginning of the 1900s, strong racist currents began gathering in Europe, and several large-scale surveys were initiated for the purpose of mapping the population’s racial distribution and the various races’ physical and mental characteristics. In Norway, a national committee for surveying the country’s anthropology was set up in 1904 at the Academy of Science in Christiania (now Oslo) (16). Talking about distinct races among mankind is now considered rather passé (18).

Norwegian museums and collections possess the remains of 12 000 to 15 000 individuals from interment and cremation graves from prehistoric and historic times (19). The remains are stored in the archaeological storage magazines of designated museums and in the Schreiner Collections, the skeleton collection at the Department of Basic Medical Sciences, Anatomy Section, University of Oslo (19). From about 1850 and far into the 1900s, large volumes of Sámi skeletal material were collected from pre-Christian and Christian grave sites.6 This was primarily done in Finnmark County.

Kristian Emil Schreiner was a professor of Anatomy at the Department of Anatomy, University of Oslo, and he focussed intently on questions related to the origins of the Sámi. From 1914 to 1939, he collected skeletal material from Sámi grave sites. Most of the material originated in the 1600s, 1700s and 1800s and comes from cemeteries in Finnmark County. Some of the material originated from the Skolt Sámi area in the 1900s (16). The Protestant cemeteries that were excavated are located in the municipalities of Kautokeino, Karasjok, Nesseby, Kistrand, North Cape and Alta. In Sør-Varanger municipality, orthodox Skolt Sámi grave sites were excavated in Pasvik and Neiden. Many hundred skulls were sent to Oslo, and local protest demonstrations were largely ignored (16). Grave site excavations also took place south of Sápmi in Norway, but those graves were much older (Middle Ages) and they were in imminent danger of being destroyed due to development. These excavations were not carried out by physicians, but by archaeologists (16).

At the same time as skeletons and skulls were being collected, studies were being carried out on the general public. Schreiner managed to secure funding for a major data collection effort in northern Norway from 1913 to 1929 (15).

Anthropometric measurements of heads were taken on roughly half the population of Kautokeino and on a large part of the Sámi population in Tysfjord (15). Although Schreiner’s approach was far from the Nazi racial ideology of the time, his conviction that the Nordic race was superior and the Sámi race was more primitive was fundamental to much of what he did as

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6 The term ‘Sámi skeletal material’ refers to parts of skeletons that are highly likely to originate from pre-Christian Sámi grave sites, Sámi cemeteries or other grave sites that generally accommodated individuals of Sámi heritage. (Temporary guidelines for the use and administration of the skeletal material at the University of Oslo, Institute of Basic Medical Sciences (The Schreiner Collections) up until the collection is audited [1999]).
a skilled expert. The connection between culture and race, the notion of original and "pure" races and the conviction that certain ethnic groups were more primitive than others, were scientific “truths” at that time (16).

According to unofficial oral history from several Sámi areas, skull measurements were carried out in the name of science until long after World War II, but there is no written documentation for these stories.

4.1.1 The State’s X-ray studies
At the same time as Schreiner was measuring Sámi skulls, tuberculosis was rampant in Norway, especially in Northern Norway and Finnmark County. In 1900, tuberculosis was the cause of about 20 per cent of all deaths in Norway, and mortality and the incidence of tuberculosis in the years up until 1950 were twice as high in Finnmark County as in the rest of the country (20). In 1943, the State’s X-ray programme was established as part of tuberculosis control, and everyone of school age and older was screened up until 1963 (21).

From the introduction of the Tuberculosis Act in 1900 and up until 1914, tuberculosis prevention in both Finnmark County and the rest of Norway was based on an infection prevention strategy. Institutions were established for the most contagious individuals, and emphasis was attached to public education about contagion and disinfection (22). The State focussed intently on fighting the disease in Finnmark County, not least by providing support for the operation of tuberculosis sanatoriums. The operation of such institutions was usually a local responsibility, but it was of so-called ‘national interest’ for the State to be especially concer-
ned about Finnmark County; besides, support for tuberculosis work was not only disease prevention, it was also considered part of the endeavours to integrate Finnmark County more closely into the Norwegian nation state and thus also to secure Norway’s borders (22). Tuberculosis prevention was characterised by the view of humankind prevailing at the time. A large majority of the children in Finnmark County attended boarding schools. The boarding schools in northern Norway were crucial in a Norwegianisation perspective, because they removed Sámi and Kven children from their cultural and linguistic environments. The children were not merely taught Norwegian and how to be Norwegian at the boarding schools, they were also taught Norwegian hygiene and culture. Many of the agencies of the government perceived the Sámi – yes, actually the entire population of Finnmark County, Norwegians included – as unhygienic and uncivilised. This was also identified as the main reason for the high incidence of disease and mortality in the county. In keeping with this, the schools and the state boarding schools were defined as being among the most central arenas for disease prevention in Finnmark County and in the rest of Northern Norway (22).

Norway’s anti-tuberculosis efforts shifted during the interim between the wars. In the 1920s, infection prevention was supplemented by a socio-hygienic-oriented strategy that attached importance to strengthening organic resistance to infections, especially among children. In the early 1930s, there was, however, more concern about tracking down and treating recently infected tuberculosis patients. This was done among other things, by X-ray screening at diagnostic stations and with the help of surgical intervention (22). This scheme was made official in 1942 and it was continued after the war, in combination with BCG vaccinations. In Finnmark County, contagion prevention was carried out on a large-scale in the post-WWII era. In 1952, conditions in the county in the wake of the ‘scorched earth’ damage were considered good enough with a view to diagnostic stations and personnel that mass screenings and the first mandatory X-ray campaign could be implemented. Due to the high mortality rate, the citizenry of Finnmark County was tested more frequently than the rest of the country all the way up until 1966. Subsequent to the first study, it became apparent that if the work really was to be effective among the Sámi population as well, it was necessary to make information available in the Sámi’s own language. As from 1953, Sámi, and to a somewhat lesser degree, Finnish, was systematically used in connection with information about BCG vaccinations and X-ray testing. This was in contravention of the one-language policy that had dominated anti-tuberculosis efforts in the county ever since 1914 (22).

4.2 Medical examinations: from 1974 up to the present

Norwegianisation as a political strategy and ideology was slowly but surely brought to an end during the years from 1960 to 1980 (14). A shift also took place in health research. Now the hypotheses changed from being based on Social Darwinism to focussing on lifestyle. From being concerned with origin and race, scientists began exploring ethnicity as a social phenomenon to a greater extent.

A changing public health profile also influenced the research efforts. Eventually, as the incidence of disease and the mortality rate declined from 1945 to 1960 thanks to a higher standard of living, the incidence of chronic lifestyle diseases like cardiovascular disease (23) began to rise. This is a development that characterises a society undergoing rapid change and growing affluence (24). Mortality due to cardiovascular disease peaked in Norway in the 1970s and has subsequently declined, not least as a result of combating the most important risk factors: high blood pressure, high cholesterol and smoking (25). In 1970, the mortality
rate in Norway was the highest in the north, and the highest rate of all was in Finnmark County (25). As a consequence of the high cardiovascular mortality rate, the first cardiovascular surveys under the auspices of the National Health Screening Service (formerly the State’s X-ray Surveys) were conducted in Finnmark County, Sogn & Fjordane County and Oppland County (1974–1988). From 1985 to 1999, all 40-42-year-olds across the country were invited to a cardiovascular screening. The screenings took place at three-year intervals (23). Questions about ethnicity were included in the population studies in Finnmark County, the so-called Finnmark Studies. The Finnmark Studies did not focus on factors that could be specific for health and lifestyle in Finnmark County or among the Sámi.

The Tromsø Study has been carried out seven times between 1974 and 2016. Four of the studies also included questions about Sámi ethnicity (26). The Centre for Sámi Health Research was established in 2001 because of the lack of quantitative data and knowledge about Sámi health. In 2003–2004, the SAMINOR 1 Study was therefore conducted as a cooperative effort between the Centre for Sámi Health Research and the Norwegian Institute of Public Health (formerly the National Health Screening Service) (27). Originally, this was intended to be a new county study in Troms County and Finnmark County, but it was extended to include more municipalities with Sámi populations in Finnmark County, Troms County, Nordland County and North and South Trøndelag Counties.
SAMINOR 1 included a separate questionnaire that covered linguistic and cultural affiliation, a factor that had previously only been done on the same scale in the Youth Health studies of the 1990s. 2012–2014 marked the advent of SAMINOR 2, focusing on cardiovascular disease and diabetes, and including the same questions about linguistic and cultural affiliation. All these surveys are epidemiological (cf. Chapter 3) and contain data obtained through questionnaires, clinical examinations and blood tests.

The research project "Everyday life of reindeer herding" was conducted by the Sámi National Competence Center for Mental Health Services (SANKS) and the Sámi Reindeer Herders’ Association in Norway in 2013. It was a questionnaire survey administered to Sámi reindeer herders in Norway about living conditions and mental health (28).

The above-mentioned population surveys have been limited exclusively to the adult population (> age 19). In 1994–1995 and 1997–1998, the youth health study "Young in the North" was carried out, while "Youth and Health in the North" was conducted in 2003–2005. These questionnaire surveys emphasised the multi-cultural youth demographic in northern Norway and were especially concerned with the health and development of young Sámi. The surveys addressed mental health, physical health, dental health, the use of intoxicants, education, etc. Young in the North was the first survey of Sámi health that contained questions about Sámi ethnicity, the Sámi language, Sámi identity, Sámi traditions and cultural adaptation. The subsequent survey "Youth and Health in the North" also included such questions (29).

The Norwegian Mother and Child Survey (MoBa) is one of the world’s largest health surveys, encompassing 114 000 children, 95 000 mothers and 75 000 fathers. The survey is being conducted by the Norwegian Institute of Public Health, and recruitment began in 1999. Both biological material and questionnaire data have been collected from the 17th week of pregnancy. The survey is designed to determine the causes of different diseases.

The survey includes questions about Sámi language skills and covers about 480 Sámi children, as defined by the Sámi language skills of their parents and grandparents. The study would probably include far more Sámi children if one were to use a broader definition of a Sámi affiliation based on self-defined ethnicity. The data are linked to a number of health registries. The Norwegian Institute of Public Health has close cooperation with several research groups in the USA, which also provide funding for the study. This cooperation also includes exchanges of biological material. Thus far, no specific surveys have been carried out on the group of Sámi children.

Population studies like the County Surveys, The Tromsø Study, SAMINOR, Young in the North, and Youth and Health in the North give a unique picture of public health in northern Norway and contribute a great deal to improving expertise and knowledge among health care workers, researchers and health administrators.

Population studies give a snapshot of living conditions and the spread of disease. When the studies are repeated, the way studies such as the Tromsø Study and SAMINOR were, this also give a picture of trends over time.

It is not currently allowed to register ethnicity in registries or on patient charts (cf. Chapter 5.2). Accordingly, it is only through studies like SAMINOR, MoBa and the youth studies that knowledge can be obtained about public health among the Sámi. Population studies must always be carried out in close cooperation with the community and the people who are invited to participate.
When it comes to human biological material, this has been collected through the Tromsø Study, the earlier Finnmark Study, SAMINOR and the MoBa Study.

4.3 Epidemiological research

Epidemiology is the study of the distribution and variation of disease among the members of the general public and the factors that determine the variation. This science gives insight into the treatment and control of diseases and other health problems (30). Epidemiology can be both descriptive and analytical. Descriptive epidemiology involves describing the incidence of disease and factors that have an impact on health in a population. It provides an important platform for planning health services and for preventive health initiatives. Analytical epidemiology is applied when trying to determine the cause of a disease (31). Data from health registries (e.g. the Norwegian Patient Registry, the Cancer Registry of Norway and the Cause of Death Registry) and medical surveys are used in both descriptive and analytical epidemiological studies.

In epidemiological studies, it is common to divide the general public into groups, e.g. by gender, age or ethnicity. Such methodologies are important to understand how and why health and disease vary in a population. For example, in a population with a high average age, one might expect a higher incidence of type 2 diabetes than one would expect in a young population. If one does not take account of such age differences, one can easily draw the wrong conclusions about the risk of disease (31).

In health research, it is crucial to distinguish between causes and risk markers. Ethnic background can be a risk marker, but not a risk factor for (cause of) disease. For example, daily smoking may be more common in one ethnic group than in another. Such factors are related to social conditions and lifestyle, not to an individual’s DNA (32).

It is important that ethnicity be a marker and a variable that is considered for inclusion in all epidemiological studies to make it possible to discover possible ethnic differences in health and disease.

The Tromsø Study, the Finnmark Studies and SAMINOR, Young in the North, and Youth and Health in the North are all population studies that have included data on Sámi ethnicity and cultural variables in their data collections. All in all, said population studies have shown few health differences between Sámi and non-Sámi individuals. However, the youth surveys have documented less use of alcohol and other intoxicants among Sámi youth and their parents or guardians compared with non-Sámi, yet there were no significant differences in the incidence of mental or physical problems compared with non-Sámi young people. That being said, there is variation within the Sámi group, e.g. Sámi youth who live in areas where there are few Sámi and little support for Sámi culture experience the most problems.

Data from the SAMINOR studies have shown that the incidence of obesity and type 2 diabetes is alarmingly high in northern Norway. Both SAMINOR 1 and SAMINOR 2 have shown that Sámi women have a somewhat higher incidence of obesity and larger waistlines than non-Sámi women (33, 34). Data from SAMINOR 2 also shows that type 2 diabetes is more common among Sámi than non-Sámi (33). The Centre for Sámi Health Research published two reports in 2015. The first summarises health research in Norway from 1985 to 2015 that
has included information on Sámi ethnicity. The summary is exclusively based on research carried out using quantitative methods (35). The other summarises research at the Centre during the period from 2001 to 2015 (36). A comprehensive summary based on the population studies mentioned in Chapter 4.2 has been published in “Sámi figures reveal 2+” (37). These sources give a detailed introduction to epidemiological research based on the Sámi population of Norway. The Young in Sápmi Report from the Centre for Sámi Health Research summarises findings from the youth health study ‘Youth in the North’, a research project designed to study health and lifestyles among young people in northern Norway, where nearly all of the Sámi and non-Sámi 10th graders in northern Norway were invited to participate during the period from 2003 to 2005 (29).

4.4 Qualitative Sámi health research

Qualitative scientific Sámi-related health research is relatively new, and it has been carried out only to a limited extent. Qualitative health research focuses on how health, the body, disease, symptoms and treatment are experienced and communicated about by the party experiencing them, be it as a patient, relative or health care personnel. Health research can often be combined with the humanities and/or social sciences, and often uses qualitative methods for data collection, mainly interviews/focus group interviews, or participatory observation/field work. Qualitative studies usually specify that the informants’ ethnic identity is determined by self-identification.

Qualitative Sámi health research rests on the perception that Sámi social conditions, including Sámi language and culture, may have an influence on the Sámi’s experience of and communication about health, disease and care services. The goal is to shed light on the Sámi’s experiences and reflections as expressed in their own words. The purpose is to identify phenomena that point out something new or to look at familiar phenomena from a new perspective. The method does not lend itself to generalising findings and results. Examples of topics that have been explored through qualitative Sámi-related health research include understanding diseases that affect the Sámi, Sámi religion, Sámi cultural norms, the Sámi way of communication, ethnic identity, the Norwegianization process, the meeting between Sámi patients and the public health service, Sámi language and Sámi cultural appreciation. The participants in the studies are mainly health care personnel and, to a lesser extent, Sámi patients/users/relatives.

Several studies have shown that the Sámi may have their own understanding of health, disease and treatment, often linked to quality of life and to Sámi language, culture and understanding of reality (38-46). Some studies have focussed on Sámi cultural norms, which are alleged to limit communication about health and disease, and to prevent Sámi from seeking and receiving medical assistance (46-52). Other studies have focussed on “the Sámi way of communication”, maintaining that the Sámi can communicate in an indirect manner, usually through hints or silence (48, 49). This is, however, highly individual and context-dependent (53, 54). Other studies have focussed on how historical, collective experiences, ethnic discrimination and ethnic conflicts can influence the meeting between Sámi patients and health and care services and result in linguistic and cultural needs remaining unnoticed and unsatisfied (55-60).

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7 This sub-chapter is based on a number of articles, books and book chapters published during the period from 1999 to 2017. The references are mainly to peer-reviewed research, but some seminal masters’ theses are also mentioned.
A couple of studies have shown that Sámi patient’s choice of language and language preference are complex, and that it is coincidence whether a Sámi patient’s language is identified and followed up with a linguistically appropriate offer of services (53, 54). However, there is a lack of Sámi-language studies in this field.

All in all, the studies indicate that knowledge of Sámi language and culture, combined with knowledge of history and political processes, play a key part in adapting the offer of healthcare services to the Sámi population. Importance should also be attached to the studies being based on a dynamic understanding of culture and on exploring what language and culture mean for the individual Sámi respondent, while also reflecting the researcher’s point of view (61-66). For a detailed description of qualitative Sámi-related health research, the reader is referred to the following references: (6, 55, 67).

There are ethical challenges related to the use of cultural concepts and cultural perspectives. Health research that includes ethnic identity and an ethnic cultural perspective is often based on cultural theory from socio-anthropology. Please note that while the socio-anthropological use of the concept of culture has become more cautious and nuanced, the concept of culture has improved its position in other disciplines, including health-related disciplines (61). It is, however, not clearly defined what the terms Sámi culture and cultural competence actually mean in a health-related context. There are few descriptions of how health care personnel should integrate Sámi culture into their provision of health care because there is a lack of knowledge about the "effect" of health care personnel’s cultural competence and cultural adaptation, and one has limited knowledge about Sámi patients’/users' needs and wishes.

Caution should be exercised to avoid a simplified, narrow and static view of culture in which particular cultural characteristics are presented as representative of the Sámi as a group. General opinions about a people’s culture cannot be accepted as objective truths, and that leads to the danger of generalisation, essensialisation and the creation of stereotypes as regards individual wants and needs. This means there is a danger that individual needs and preferences will be overlooked in a medical consultation (63, 65, 66). There is also a danger that culture will be presented as something that only the Sámi ("the others") have, while the influence on the culture of the majority population and the public health service’s ("our") culture remains invisible and is not reflected. By concentrating unilaterally on culture, other significant factors, e.g. gender, age, occupation, finances, structural or practical obstacles, could be overlooked.

The inclusion of a cultural perspective in Sámi health research appears to be absolutely essential, but must be applied in a nuanced manner.

4.5 Partnership research

In the debate about research in collaboration with indigenous peoples, in several contexts, emphasis has been attached to involving indigenous peoples in every step of the research process. Such community-based participatory research is based on the principle of close, equal cooperation and partnership between the researchers and the target group for the re-

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8 Otherwise, please see: https://www.etikkom.no/FBIB/Temaer/Forskning-pa-bestemte-grupper/Etniske-grupper/
search. Equal participation applies to every step in the research process, from the initial idea for the choice of issue to be studied, to the design and method for the interpretation of the results and how they are communicated. So far, very few studies have entered into active, equal partnerships with the participants and the Sámi communities.

Partnership research is not exclusively intended for ethnic minorities or indigenous peoples, but it is considered to lend itself especially well for groups that have been abused. Among other things, studies have shown that research projects that apply this design have greater participation than other types of studies (68, 69). Studies like this often call for more extensive planning, but in return, they guarantee that the Sámi stakeholders are protected.

**Everyday life of reindeer herding – a Sámi example of partnership research**

‘Everyday life of reindeer herding’ is a research project that began as an initiative taken by the Sámi Reindeer Herders’ Association in Norway (NRL) in 2008.

The NRL wanted a study that identified psycho-social stress and strains in reindeer husbandry. In the autumn of 2010, the NRL and the Sámi National Competence Center for Mental Health and Substance Abuse (SANKS) entered into discussions, setting up formal cooperation in 2012. SANKS was chosen since they had knowledge about the Sámi communities. Both the project development period and the research project itself have been carried out according to the guidelines issued by the Canadian Institute for Health Research (2007), Guidelines for Health Research Involving Aboriginal People. Their ethical principles are based on equal participation and respect for indigenous people’s cultures and values (Community-based participatory research). In ‘Everyday life of reindeer herding’, the NRL and the reindeer herders themselves have been leading and participating every step of the way in the research project, from the original idea to the interpretation and presentation of the results.

### 4.6 Clinical research

Clinical research covers a broad range of health research whose common goal is to promote direct improvements in the diagnosis, treatment and the care of patients (70). There was also a desire that clinical research be used to ensure that resources were used more effectively in the health care sector. Research provides the basis for scientific, practical medicine. Applied clinical research takes its point of departure in theories from other research and clinical experience and issues, aiming to generate correct, verifiable knowledge about the effect of prophylactic measures, diagnostic procedures and therapeutic intervention. The research also covers safety and efficacy related to medicine, equipment, diagnostics and treatment regimens for people with a view to prophylactic measures, treatment and diagnose, or for the relief of symptoms associated with illnesses.

Norway is well-suited for clinical research. The country has a clear offer of treatments, a coordinated, uniform health service, good contact between the various levels, a good system of health registries and a population that is motivated for clinical research (71).
Clinical research provides answers to:
The causes of diseases, which is the motivation for all health research. One overriding question in terms of both the prevention and the treatment of disease is: “Why do we fall ill? What is more important, nature or nurture?” There is probably significant interaction between genetic predisposition and environmental factors. However, questions like these pave the way for research, not least, clinical research.

For example, noise, indoor climate, and certain substances in foods and chemicals both cause and trigger illness or damage. Meanwhile, the genetic characteristics of each individual help determine how we are influenced by the food we eat, and the environment in which we live.

Different designs for clinical research
Clinical research often involves two groups of participants: one group of patients with a type of disease, and one group of participants who do not have the disease. Another design involves two groups of patients with the same type of disease, where a drug versus a placebo (an inactive treatment often referred to as leading to ‘the placebo effect’ in clinical trials) is used to test the efficacy of the treatment. Regardless of design, the groups must match well with a view to number of participants, age distribution and gender. It is important to match the groups so that no significant gender or age differences between the groups lead to the wrong conclusions. Such a design is called a randomised clinical study and it is the most common type of clinical study. There are also several other varieties of clinical studies.

According to the Research Council of Norway, clinical research goals are attained through three types of research:

- **Basic research.** When basic research addresses epidemiological causal research and basic biological and psychological research, providing it is of immediate relevance for routine clinical activities, it is classified as applied clinical research. Usually, however, this type of research will not be categorised as applied clinical research.
- **Clinical research** in the usual sense. The optimal is to have a controlled, randomised clinical study, preferably on large samples of patients. Such projects call for both time and resources. Observational studies, the use of health registries and medical development of methods are other types of clinical research.
- **Research on health services.** This refers to research that takes its point of departure in established offers of treatment or standards, and which studies needs, distribution, organisation and the use of resources to improve efficiency, quality and social justice.

Applied clinical research is necessary to assess efficacy and side effects, both in connection with established routines that are not well documented, and in connection with new diagnostic and therapeutic services. Research is also a prerequisite for maintaining and renewing expertise in the Norwegian public health service. The research is to be independent and it is to give priority to projects that have medical and social value. Clinical research shall therefore form the basis for the choice of medical treatments, where clinical decisions are based on knowledge gleaned from clinical research and experience.

Although there are few clinical studies in Sámi health research, there are two examples of studies on Sámi patients with Bechterew’s Disease (72-74) and cardiovascular disease (75, 76).
4.7 Stordata (big data)

Big data is a designation for copious amounts of digital data. Big data is often described in the form of several 'Vs', the three best-known of which are volume (amount of data), velocity (speed) and variety (how different are the data in the collection) (77). In health research, this can refer to data from major population studies involving human biological material, different medical examinations and questionnaire data.

There are growing demands that it be mandatory for research data to be shared with others through large databases, and there is considerable interest in doing research on human biological material. Indigenous people’s wish to maintain control of and have influence on the research process and research data may come into conflict with requirements for sharing research data in large databases, allowing less control over how the data are used.

Journals and sources of funding for research are increasingly requiring that the documentation underlying the data be made available through large databases, e.g. for the verification of findings or other research (78).

Human biological material is stored in biobanks. In Norway, biobanks are regulated by the Health Research Act. One challenge is that the material may be analysed in other countries that may have different statutory regulations (78).

One important assumption for giving collective consent is that one is guaranteed a say in what happens to the data and biological material, and about how it is shared. How data might be shared with others in future can be difficult to envisage at the onset of a research project, meaning that it is crucial to ensure that a dialogue is established between the Sámediggi/ the Sámi Parliament and researchers.

If there is a fear that the data will be misused, it is possible to completely refuse to allow the data to be used in large databases, or that the data be shared, but then the publication and use of Sámi research will be severely limited. One must not necessarily refuse to share databases, but it is important to have a mindful attitude to it.

In an article published in the journal Cancer Forum, health researchers in Australia pointed out some challenges related to health research on indigenous peoples and sharing data in large databases. In that context, they report that the possibility of identifying and thereby addressing health risks through the use of big data is well documented (79). In Australia, indigenous peoples have their own guidelines for health research. One challenge is that it is time-consuming to get permission to use health research data, meaning that indigenous peoples may get medical assistance later than others. Meanwhile, it is emphasised that simpler consent processes must be balanced with a view to respecting cultures, giving enough information to the indigenous peoples, and ensuring that the research is used to improve indigenous people’s health and status (79).
5 Discussion of challenges related to health research among indigenous peoples

5.1 At the international level

The Centre for Sámi Health Research (SSHF) has drawn up a report that provides a general overview of selected ethical guidelines for health research on indigenous peoples in Canada, Greenland, Australia and New Zealand (80). This sub-chapter gives a brief summary of this report. The reasoning behind the inclusion or exclusion of countries and regions appears in the report’s preface and introduction (80). The countries and regions that have been included are smoothly-functioning states based on the rule of law, or regions within such states, with considerable affluence as measured by gross domestic product. This makes them comparable with each other and comparable with Norway.

Nonetheless, there are differences between them, and between them and Norway, when it comes to indigenous people’s legal status and/or public health services, rules of law and systems for funding and making ethical reviews of research. The principles applied in said guidelines may nevertheless be relevant and inspirational for drafting ethical guidelines for health research on the Sámi in Norway.

The guidelines summarised in the report suggest different scenarios for how indigenous peoples can or should be included in the research process. This report focuses on the documents’ guidelines for collective consent and for the storage of and indigenous people’s control over the use of human biological material and other data. The report does not describe the countries’/region’s respective ethical review processes and systems for research funding. In other words, the practical application of the guidelines included were not discussed, since that would be beyond the scope of the report and it would have delayed its completion significantly. The purpose has been to compile a knowledge base for drafting guidelines for health research on the Sámi in Norway.

The term ‘free and informed collective consent’ (henceforth ‘collective consent’) refers to a consent given without coercion or pressure by a local community or an indigenous group that is directly or indirectly impacted by the suggested research. Such consent will also require free, informed individual consents, as described e.g. in the Helsinki Declaration. This definition is based on a summary of the documents presented in said report.

Research that directly affects indigenous peoples refers, for example, to research in which indigenous peoples are explicitly included in a hypothesis or an issue, and where the intention is to generalise findings to apply to one or more indigenous peoples.

Indigenous peoples are indirectly affected, for example, in projects that cover geographical areas that are readily associated with particular indigenous peoples. This may be epidemiological population studies that include districts or municipalities with significant Sámi population density. One example of research that neither directly nor indirectly affects indigenous peoples may be a study based on interviews of a limited number of individuals of indigenous extraction, regardless of whether or not they identify with indigenous peoples, and which is not intended to generalise findings to indigenous peoples in general or in specific indigenous territories (81). It is underlined that small, non-representative studies can obviously impact
indigenous peoples. A project’s issues and/or hypotheses must also be considered when assessing the influence it will have on indigenous peoples.

Three methods were used to search for documents: systematic searches of the literature through Google, searches on relevant websites and the use of research networks. The report discusses five documents featuring ethical guidelines that apply in Canada, four in New Zealand, three in Australia and one in Greenland, as well as the World Health Organization’s guidelines entitled "Health Research involving Indigenous Peoples". No guidelines that apply in Alaska were found in the searches of the literature.

The documents can be ranked and classified as being ‘minimum standards’, ‘good practice’ or ‘best practice’, as the terms apply to ethical health research on indigenous peoples (82). The classification may, for example, determine the extent to which indigenous peoples are consulted, involved or given determinative roles and a high degree of control of the research that involves them (cf. Chapter 2.4 of the report).

Except for one document containing guidelines that apply in Australia, all the documents feature provisions relating to collective consent. A total of eleven documents (all in said countries/regions) contained guidelines relating to the storage of and control over indigenous data in general, and six documents (in Canada, Greenland, Australia and New Zealand) included specific descriptions of the storage and control of human biological material derived from indigenous peoples. Only two documents (from Canada and Australia) had guidelines that might possibly be considered ‘best practice’ (83, 84). Such guidelines pose an absolute requirement for collective consent and basically afford indigenous peoples full control of research that affects them directly or indirectly.

Characteristic of the majority of the documents that can be considered ‘good practice’ and ‘best practice’ is that they directly or indirectly include references to indigenous people’s right to self-determination. This right is a principle that establishes that indigenous peoples, insofar as possible, have decision-making authority in matters that involve them. Indigenous people’s right to self-determination is therefore a question of being allowed to freely promote their political position and their own financial, social and cultural development (85). Indigenous people’s control over and possibility to give collective consent to research can help bring such a right to fruition, since the research may form the basis for financial, social and cultural development.

The report concludes that good research practice requires indigenous people’s collective consent when the research will affect them either directly or indirectly. A process that results in a collective consent can make it easier to identify and render more concrete a project’s implications for the indigenous people and community involved (86). Such a process may also make it easier for researchers and local communities to establish respectful relationships and to negotiate culturally meaningful ethical parameters for the project (86).

Ethical reviews and evaluations of health research projects are based on principles and values embodied inter alia in the Helsinki Declaration. These values are considered to be fundamental and universal ethical points of reference. However, it might be asserted that ethics and the notion of what is ethically responsible also depends on culture (86). Introducing a requirement for collective consent can stimulate a discussion on local ethical considerations. It should not be thought that indigenous peoples do not support the Helsinki Declaration, for instance, but rather that indigenous peoples may have ethical convictions that are additional
to those appearing in the Helsinki Declaration. Several of the documents urge that local ethical convictions be respected.

Seven documents with guidelines that apply in Canada, Australia and New Zealand assume that a formal research agreement between researchers and an indigenous people must be signed to define indigenous people’s involvement in health research. Five of these documents in the same countries point out that the agreement shall state specific rules for the storage of and indigenous people’s control over their human biological material and/or other indigenous data. Yet other documents contain guidelines associated with the storage of data without any explicit requirements for a research agreement.

5.2 Norway

This chapter focuses on epidemiological research in particular. Ethical challenges related to qualitative Sámi health research are discussed in Chapter 4.4.

Current legislation does not allow ethnicity to be registered in national registries, patient record systems or other health databases that can be used in epidemiological research. Accordingly, it is not possible to use these databases to find health data about different ethnic groups in Norway. On the other hand, it is allowed to ask participants in research projects about their ethnic background. Consequently, it is only through research projects that data on Sámi health and living conditions can be obtained.

Ethnicity is an important variable in epidemiological research. In terms of methodology, ethnicity can be measured using subjective, objective and/or surrogate measures (see sub-chapter 5.4). The concept of ethnicity originates from the Greek word ethos, meaning “people, nation or tribe”. Ethnicity is a multi-faceted phenomenon that categorises people who belong to or are believed to belong to a particular group, based on certain distinctive
social and cultural characteristics (32). What provides guidance for ethnic categorisation varies from community to community and is often situation dependent, and how ethnicity is measured and defined will necessarily also vary from one health study to the next. Usually, language, culture, customs, traditions and/or religion are of significance for ascribing or self-ascribing ethnic status (32).

Ethnicity has no direct connection with biology and is not, in the epidemiological sense, a source of causal knowledge per se. On the contrary, ethnicity is associated with factors which to a greater or less degree have an impact on behaviour and lifestyle, and thus also on the risk of disease. This may refer to customs and traditions (e.g. food traditions), but may also include the use of and access to health services and school and educational programmes (32).

In the context of research, ethnicity is challenging to measure. Different ways of defining ethnic groups may also affect research results. There are currently two ways of collecting information about Sámi ethnicity in research: Ethnicity can be registered by questioning research subjects directly about their ethnic background or by characteristics or qualities that distinguish the Sámi (such as language or industry). An example of this is shown in Figure 1.

### 5.3 Methods for identifying ethnicity

The questions in Figure 1 are both of an objective and subjective nature, and they are excerpted from the SAMINOR Study (27, 87). Asking research subjects about the ethnic backgrounds of their parents (and grandparents) can be considered an objective measure (88). In the same way, asking about the home language of participants and their families can be considered an objective measure.

Culture and society are in constant flux, and the distinctive features that are assigned importance when ethnic affiliation is ascribed and self-ascribed may vary from place to place and from one generation to the next in one and the same ethnic group (88). A subjective measure of ethnicity is more flexible and gives research subjects an opportunity to define their own ethnicity based on what must be a relevant reference (88). As mentioned, this can be culture, industry, language, etc. This measure is often referred to as self-perceived ethnicity. Here are some examples of subjective measures of ethnicity:

- "What is your ethnic background?"
- "What do you consider yourself to be?"

![Figure 1. Questions about ethnic affiliation in the SAMINOR Study](image-url)
5.4 Surrogate measures

Surrogate measures or proxy measures specify something comparable to what is to be measured. Typical surrogate measures are domicile or a geographically limited area. The language administration area (89) and the area of the Sámi Parliament subsidy schemes for business development (the STN area) (90, 91) have been used as surrogate measures of Sámi ethnicity in research projects. Consequently, individuals domiciled in these areas are considered to be Sámi.

5.5 Methodological and ethical challenges involved in using ethnicity in health research

Sámi, Kvens and Norwegians have lived and continue to live side by side in northern Norway. Many families in the region have a multi-cultural history in which Sámi, Kven and Norwegian are closely interwoven. In carrying out research, it is therefore difficult to operate with absolute ethnic categories. In some cases, it is possible to get a completely erroneous idea of people’s identity and self-understanding. Certain people see themselves as more Kven than Sámi, or as more Norwegian than Sámi or Kven. The questions in Figure 1 give no information about this. Another way to measure ethnicity is to classify ethnic affiliation on a scale, as illustrated in Figure 2. According to this model, it is possible to have a strong affiliation to several ethnic groups, or to have different degrees of affiliation to the individual ethnic groups. The degree of ethnic affiliation can vary with age, over time and with social contexts. Sámi affiliation can also change during a life cycle and be influenced largely by the majority society’s attitudes to an ethnic group such as the Sámi. It is important that the research does not promulgate unfortunate generalisations, no matter how a questionnaire is worded.

This problem is not as serious in qualitative research, since the ambition is not to generalise findings and results. Qualitative research can adequately safeguard consideration for people’s perceptions of their own complex family history and identity. In a multi-cultural landscape, people can only to a limited extent operate with stringent perceptions of their own ethnicity. As a result, the research must accommodate individual variations in the categorisation of ethnicity. Medical research has a clear scientific tradition. In this research, quantitative data is often used to generalise findings. In epidemiological research, for instance, the intention is often to measure the distribution or the causes of disease among the general public. Health research that originates from the humanities or social sciences commonly uses qualitative methods to identify social patterns within a limited area. Qualitative health research is concerned, among other things, with how diseases and symptoms are experienced and communicated. Qualitative and quantitative research usually address different research issues, meaning that ethnicity is measured and operationalised in accordance with the point of departure for the research.

Another important element is that research on ethnicity is sometimes perceived as invasive by the subjects of the research. A long-term effect of the Norwegianisation of the Sámi and the Kven people is that questions about ethnicity may be perceived as offensive and as invading private space. It is far from certain that all who perceive themselves as Sámi or Kven, as the questionnaires invite respondents to do, answered the questions in keeping with their self-perception and/or their linguistic and ethnic backgrounds. Some do not have a sense of their Sámi or Kven roots since family networks have kept quiet about it for several genera-
tions. In that sense, one cannot necessarily view any of the questions in Figures 1 and 2 as sources of objective data on ethnicity. Information based solely on the questions in Figures 1 or 2 can therefore lead to a skewed selection with a view to ethnicity.

Figure 2: Questions about ethnicity in Young in the North and in the Youth Health Study in Northern Norway

<table>
<thead>
<tr>
<th>I consider myself to be:</th>
<th>Agree</th>
<th>Partly agree</th>
<th>Partly disagree</th>
<th>Disagree completely</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norwegian</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sámi</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kven</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finnish</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other (please specify)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

My ethnicity is (specify one or more of the figures below)
1 = Norwegian, 2 = Sámi, 3 = Kven, 4 = Finnish, 5 = Other

My father's ethnicity is (specify one or more of the figures above)

My mother's ethnicity is (specify one or more of the figures above)

The weakness of using the STN area and the language administrative area as surrogate measures of Sámi ethnicity is that there is also a substantial proportion of non-Sámi people in these areas. The use of geographical areas can lead to erroneous and/or inaccurate conclusions. The advantage of such surrogate measures is that one avoids the high costs of large data collection activities at the individual level and the problems associated with a low response rate in population surveys.

Ethnic affiliation is considered sensitive personal information and is subject to special rules for processing (cf. §§2 and 9 of the Personal Data Act). The processing of sensitive data is generally more demanding when dealing with smaller populations. For that reason, data on ethnicity can help ensure that otherwise satisfactorily anonymised material can be traced to groups and individuals (92).

5.6 New legislation and regulations on health research

Legislation in the field of research is in constant flux. Lately, there have been several proposals for new legislation and new regulations, including proposals for new regulations relating to population-based medical studies, and a recommendation has been submitted for a new system for simpler and safer health data.

Both the EU regulations on clinical trials on medicinal products for human use and the EU General Data Protection Regulation will also affect the regulation of health research. The purpose of the General Data Protection Regulation is to ensure good protection of personal data at the same time as personal data can be exchanged freely within the EEA. The regulatory form entails full harmonisation of the rules for the protection of privacy in the EU/EEA. This suggests that it is basically not allowed to derogate from the rules or to impose sup-
plementary rules. However, the regulation itself allows national rules to be issued in certain cases.

The regulation perpetuates many of the principles and rules in the current data protection directive, but it also introduces some new rules that call for amendments to Norwegian legislation. For example, the rule about licensing and mandatory reporting has been rescinded and superseded by rules about risk assessment and the obligation to provide documentation. In actual practice, this means that accountability is moved from the Norwegian Data Protection Authority and/or REC to the research institutions and project managers.

The methods for medical research are developing rapidly. New technology has developed new ways to use health data and other personal data, making it possible to link data from various sources on a global scale and in ways that were not previously possible.

Accordingly, it is important that the ethical standards for Sámi health research are framed in a manner that is both dynamic and possible to implement during every stage of the research process, regardless of who is responsible for their planning, approval and implementation.

5.7 Communication

Reporting on research is usually perceived as scientific communication in respected academic journals, books or lectures at scholarly conferences and seminars. However, reporting on research is more comprehensive and also includes popular science activities, which are presented in a wide variety of forms, e.g. interviews, articles or feature articles in newspapers and popular science publications, lectures, blog posts and posts on social media. The ease of communicating research depends on the research project and the approach, or on what the media and the general public are interested in.

Popular reporting on research has not enjoyed particularly high status among researchers and research institutions. In this context, it is important to emphasise that research belongs in the public sphere. Today, there is no legislation that requires researchers to communicate their research back to society. The Health Research Act (93) says nothing about communicating research results. §4 of the Research Ethics Act, the researchers’ duty to exercise due care (94), emphasises that researchers shall exercise due care to ensure that all research takes place in accordance with recognised ethical standards for research that apply to preparations for research, the reporting of research and other research-related activities. The latter can include communicating results through popular science, which is important and which makes researchers visible in the social debate.

Many national research institutions, including UiT - The Arctic University of Norway, have elevated popular science communications activities in their strategy programmes by introducing prizes for outstanding research communications (95). The motivation is to render visible and raise the status of communications activities. In today's media and information society, good professional and artistic communications are decisive for image-building and the legitimisation of a university's societal responsibilities.

More focus on communications activities and researchers' responsibility to give knowledge back to society is also relevant internationally. In particular, communications activities and coordination of guidelines are formulated by and for indigenous groups when research projects are planned in indigenous communities (96-98).
Good research-based knowledge about the health situation of the Sámi is wanted both by the Sámi and by the Norwegian authorities. Mutual understanding between researchers and users/participants is absolutely essential for developing research that is useful to society. Participatory research takes place in many stages, and everything from cooperation on research hypotheses to communicating the results is done together with the communities or the groups on which the research is being performed.

However, communications activities are not only about rendering research results visible after material has been collected and analysed. Equally, communications activities involve coordination with all players prior to data collection, during the collection itself and during the processing of the data afterwards. Thus, communication is part of the methodology work and must be considered absolutely decisive in order for research to have legitimacy in the communities in which it is performed. Most of the Sámi health studies have given priority to communicating results to the Sámi communities. A good example is the study entitled ‘Everyday life of reindeer herding’, cf. point 4.5 (99). Another example is the survey of health and living conditions in areas with Sámi and Norwegian co-habitation, SAMINOR. In that context, priority was given to publishing findings in the clinical part of SAMINOR, not only in the form of municipal reports on the health situation and meetings with health administrators/politicians, but also to the entire population in the form of town hall meetings (95). As part of their communications work, the Sámi youth studies have published their results in brochures and reports (Young in Sápmi), made in collaboration with the young people themselves. The results are also conveyed through the media and lectures (29).

Communications, both academic and popular, are important for improving understanding and acceptance of research in indigenous societies.

6 Relevant indigenous principles

6.1 ILO Convention No. 169 and the UN Conventions of 1966

ILO Convention No. 169 concerning Indigenous and Tribal Peoples in Independent Countries has a special provision about health in Article 25:

1. Governments shall ensure that adequate health services are made available to the peoples concerned or shall provide them with resources to allow them to design and deliver such services under their own responsibility and control, so that they may enjoy the highest attainable standard of physical and mental health.

2. Health services shall, to the extent possible, be community-based. These services shall be planned and administered in cooperation with the peoples concerned and take into account their economic, geographic, social and cultural conditions as well as their traditional preventive care, healing practices and medicines.

9The convention is from 1989, and Norway was the first country to ratify the convention (in 1990).
3. The health care system shall give preference to the training and employment of local community health workers and focus on primary health care while maintaining strong links with other levels of health care services.

4. The provision of such health services shall be coordinated with other social, economic and cultural measures in the country.

This provision specifies the criteria for ensuring the best possible health services for indigenous peoples. Here in Norway, that would be the Sámi. The Health Services must be supported by the local community and be planned and administrated in collaboration with the people in question. This provision says nothing in particular about health research, but the requirements for health services, as they appear in Article 25, also mean that it is necessary that health research on indigenous peoples be carried out in accordance with the same requirements.

The right to participate in research design also ensues from Article 7, which, in Norway, gives the Sámi the right to participate in decision-making processes that involve them. Indigenous peoples shall, insofar as possible, maintain control over their own financial, social and cultural development. Health is mentioned in particular in Article 7:

2. The improvement of the conditions of life and work and levels of health and education of the peoples concerned, with their participation and cooperation, shall be a matter of priority in plans for the overall economic development of areas they inhabit. Special projects for development of the areas in question shall also be so designed as to promote such improvement.

There is a general provision featuring a requirement for consultations with the country’s indigenous peoples in Article 6 of ILO Convention No. 169. In Norway, this obligation to consult is manifested in the Consultation Agreement between the Government and the Sámediggi/the Sámi Parliament from 2005. In it, it states by way of introduction that “[a]s an indigenous people, the Sámi have the right to be consulted on matters that may impact them directly”. ¹⁰

In this context, reference can also be made to the International Covenant on Civil and Political Rights and the UN Covenant on Economic, Social and Cultural Rights, both from 1966 and ratified by Norway in 1972. Through the Human Rights Act (100), both covenants have been incorporated into Norwegian law and given precedence before other legislation. Article 1 of both covenants states:

“All peoples have the right to self-determination. By virtue of this right, they freely determine their political position and freely promote their own economic, social and cultural development.”

Pursuant to these two covenants, in Norway it is recognised that the Sámi have the right to self-determination, but there is not always agreement about how far this self-determination extends, although this disagreement is primarily associated with land and natural resources, rather than with the questions we are dealing with here.

¹⁰ The convention is from 1989, and Norway was the first country to ratify the convention (in 1990).
6.2 The UN Declaration on the Rights of Indigenous Peoples

In 2007, the UN General Assembly adopted the United Nations Declaration on the Rights of Indigenous Peoples. The Declaration was drawn up by a group of experts on indigenous peoples at the UN, and it was the culmination of many years of work. One of the most difficult questions involved indigenous people’s right to self-determination and what is inherent in this concept. The provision on self-determination is found in Article 3:

“Indigenous peoples have the right to self-determination. By virtue of this right, they freely determine their political position and freely promote their own economic, social and cultural development.”

The Declaration on the Rights of Indigenous Peoples also contains provisions on health, and we would like to emphasise Article 23:

“Indigenous peoples have the right to determine and develop priorities and strategies for exercising their right to development. In particular, indigenous peoples have the right to be actively involved in developing and determining health, housing and other economic and social programmes affecting them and, as far as possible, to administer such programmes through their own institutions.”

Health research intended to improve health programmes will be covered by this provision.

7 Ethical guidelines for Sámi health research

Before we review the proposal for ethical guidelines, we would like to reiterate the Committee’s understanding of Sámi health research:

Sámi health research is research intended to obtain new knowledge about diseases or health in the broad sense. This also includes research on health services and research on human biological material. In this sense, Sámi health research may include:

1) questions/research issues that include the Sámi as a group, and/or
2) questions/research issues in municipalities/regions in which the Sámi are in the majority or account for a substantial percentage of the general public, and/or
3) questions/research issues which include Sámi language, culture, traditions and/or history.

The research can be performed by Sámi or non-Sámi researchers/research groups. It may feature different research designs and may be performed using different research methods.
7.1 Values

Ethical guidelines for Sámi health research shall strengthen the rights of the Sámi as a group in respect of research projects. This is also emphasised in the Ministry of Health and Care Services’ hearing on the regulations governing population-based medical studies, Chapter 11.2.6 (101): “If studies are to include information about ethnicity, such as in SAMINOR 1 and SAMINOR 2, this requires a special ethical review”.

Important values will facilitate coordination between health researchers, institutions, society and the population. Some of these values have already been implemented in today’s health research. They emphasise the value of human life and human rights, and attach importance to ensuring that participants’ safety and social welfare take precedence over the interests of science and society. Through informed, voluntary, express and documented consent, the individual’s interests are protected, and one thereby ensures that the individual is guaranteed ownership of his/her own tests and information about his/her own research results.

Against the background of Sámi rights and the important research ethics principles that form the platform for health research, the Committee proposes that Sámi health research be based on the core values in the summary in Figure 3:

![Figure 3: Important values for ethical guidelines for Sámi health research and research on Sámi human biological material](image)

Relations between the Sámi communities and the researchers must be characterised by respect, reciprocity, equality, accountability, cultural assurance and Sámi self-determination in every research project, regardless of the project’s objectives, design or method. These values are based on recognition and appreciation of the Sámi as a people and on respect for their integrity. A research project’s design determines whether the project will succeed in achieving its objectives, benefit the participants or the community, and be able to help effect positive changes in public health. A project that builds on equality and reciprocity between researchers and the Sámi population throughout every step of the research process affords
the greatest potential for reflecting the above-mentioned core values on which all research that directly or indirectly impacts the Sámi communities or the Sámi people should be based.

7.2 Sámi self-determination and health research

Sámi self-determination is a right pursuant to the international rights of indigenous peoples, as established by Article 1 and Article 27 of the International Covenant on Civil and Political Rights (OHCHR) and ILO Convention No. 169 on Indigenous and Tribal Peoples in Independent Countries, and the UN Declaration on the Rights of Indigenous Peoples. In a health research perspective, Sámi self-determination can be embodied in two basic principles: collective consent and acknowledgement and recognition of Sámi affiliation.

7.2.1 Collective consent

Sámi self-determination is guaranteed through the principle of collective consent in all Sámi health research. Collective consent is required before a project that involves the Sámi can be set in motion.

The Sámediggi/ the Sámi Parliament, or the body designated by the Sámediggi, shall ensure compliance with the principle of collective consent.

The requirement for collective consent does not involve individuals’ right to give or withhold consent for participation in research projects. The collective consent exists in addition to other required approvals, e.g. from the Norwegian Data Protection Authority or REC.

For research projects that require collective consent, it is the Sámediggi in Norway, or the body designated by the Sámediggi, that shall consider the research project in advance. Approval by the Sámediggi or the body so designated shall be considered a collective consent.

7.2.2 Acknowledgement and recognition of Sámi affiliation

As a people, the Sámi have a right to knowledge about their own health. The registration of ethnic affiliation is a prerequisite for knowledge of ethnic groups’ health situation and living conditions. Ethnic registration has been misused earlier, not least by researchers. Consequently, as a variable, in all contexts, ethnicity must be used in a balanced and responsible manner so that research contributes to knowledge and not to stigmatisation.

Sámi ethnicity shall be recognised and acknowledged in a culturally safe and responsible manner that preserves Sámi values and standards associated with Sámi affiliation.

7.3 Ethical guidelines for Sámi health research

7.3.1 Partnership between research institutions and the Sámi communities

Researchers shall respect the culture, values and traditions of Sámi society and Sámi informants when performing research that involves same. This means that the Sámi communities are to have joint consultation on the project. It is desirable that future research projects be based insofar as possible on the principle of equal partnership between the research community and the Sámi communities from the time an idea is conceived until the results from the study are to be reported.
The research shall also benefit the Sámi communities. Insofar as necessary, the researcher must explain how the partnership will be implemented and safeguarded.

7.3.2 Knowledge about Sámi conditions

The researcher shall show that he/she is knowledgeable about health, traditions, history, traditional knowledge and social conditions in the Sámi communities. The researcher shall recognise the dignity of the individual or the group, showing respect for cultural values and norms.

Participants are to experience that the research in which they are to participate is safe from the cultural perspective. This means that the research should shed light on and take into account cultural factors, values and practices that may be of significance for the purposes of the study.

The research should reflect the diversity and variation in the Sámi culture and the Sámi communities, and not help create or propagate stereotypes about the Sámi.

The researcher must render visible/document his/her expertise in the field of Sámi culture, Sámi health and Sámi living conditions, based on the requirements that exist.

7.3.3 Respectful and responsible treatment of human biological material and genetic research

Research on human biological material can be sensitive for the Sámi due to past racist and discriminatory research and the abuse of results for non-medical purposes. Genetic research is of special interest in the light of recent technology. Human genomic research, e.g. in large sets of data that map genetic variation and diversity, may be experienced by indigenous peoples as being especially threatening.

In examining human biological material, researchers shall

a) behave respectfully and explain the goal of collecting the material, the method of collection, storage, sharing, exporting, the types of analyses of the material and its destruction

7.3.4 Securing collective consent for population studies with previous broad consent

Many ongoing and already approved projects are subject to a broad consent for more detailed, broadly defined research purposes. In the event new projects will be using already collected data and material that fall under the definition of Sámi health research, collective consent must be obtained nonetheless. This may be the case in longitudinal studies and population surveys.

Also in cases with broad consent, researchers must obtain collective consent for new projects.
Referanser


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101. Hearing-- The regulations governing population-based medical studies: Hearing before the Ministry of Health and Care Services (2017)
Appendix 1: The Committee's working methods

The Committee has had eleven meetings, usually in Tromsø. The meetings have been held at the Division of Paediatric and Adolescent Psychiatry at the University Hospital in Northern Norway and at the Centre for Sámi Studies at UiT - The Arctic University of Norway. The Committee participated in the centennial celebrations of the first of gathering of the Sámi nation in Tráante (Trondheim).

To obtain the requisite expertise, we have invited experts to deliver lectures followed by discussions. This has been a very fruitful method for further stimulating discussions about ethical issues. Reindeer owner Inger Marit Eira-Åhren and researcher Svanhild Møllersen from the project entitled ‘Everyday life of reindeer herding’ talked about how they have built up a partnership in Sámi health research. Committee members Ann Ragnhild Broderstad and Bent Martin Eliassen talked about the SAMINOR study and the challenges involving ethnicity and how to engage and communicate findings to local populations. Researcher John Kyllingstad talked about how the concept of race still looms in the background of genetic research, and Heidi Bentzen reported on challenges in connection with big data. Ingeborg Larssen from the Sámediggi/ the Sámi Parliament provided information about Sámi skeletal material at the Department of Anatomy in Oslo, and the researchers Kvalvik and Ursin spoke about HUNT, Health Studies in Nord-Trøndelag County, and the challenges associated with registering South Sámi identity and storing biological and other data. PhD student Inger Dagsvold has written Chapter 4.4. Qualitative Sámi health research.

The Committee members have participated in several conferences: SAMINOR “Gozihit deravašvuodălii – Monitoring health” in autumn 2016 and the Nordic Model for Personalized Medicine in spring 2017 about dynamic consent, among other topics. The Committee chair and secretary have participated in a seminar and had a meeting with Janet Smylie, head of the Well Living House Action Research Centre and associate professor at the Dalla Lana School of Public Health, University of Toronto, about incorporating indigenous leadership into health research.
Vedlegg 2: Mandat og presisering av mandatet

058/16: CLARIFICATION OF THE MANDATE AND APPOINTMENT OF MEMBERS TO THE EXECUTIVE COMMITTEE FOR ETHICAL GUIDELINES IN SÁMI HEALTH RESEARCH.

5 April 2016 Sámediggi/ the Sámi Parliament Executive Council
SR–058/16:

Decision
The Sámediggi/ the Sámi Parliament has embarked on a project to draw up ethical guidelines for Sámi health research and the use and administration of Sámi human biological material. An Executive Committee has been appointed, consisting of representatives of Sámi health research communities and legal expertise. The Sámediggi is providing the secretariat functions for the Committee.

Indigenous rights embodied in ILO Convention No. 169, the United Nations Declaration on the Rights of Indigenous Peoples and other relevant international conventions form the basis for the work.

Mandate:
- Draft ethical guidelines for Sámi health research, including research that involves Sámi human biological material
- Identify and discuss challenges associated with the storage and right of disposition of Sámi human biological material
- Discuss ethical issues that must be covered by the ethical guidelines
- Discuss the legal status of the guidelines
- Consider further treatment of the guidelines at the national and international levels

Executive Committee members:
Committee chair: Prof. Siv Kvernmo, University of Tromsø,
Dr. Med. Ann Ragnhild Broderstad, University of Tromsø,
Prof. Kirsti Strøm Bull, University of Oslo,
Post. doc. Bent Martin Eiaassen, University of Tromsø,
Dr. Heidi Eriksen Utsjok, Sámi National Competence Center for Mental Health Services (SANKS)/SáNáG
Office Manager May Britt Rossvold, REC Tromsø,
Psychologist Jon Petter Stoor, Sámi National Competence Center for Mental Health Services (SANKS)/SáNáG

Mearrádus:
Sámediggi lea álgahan barggu ránkadit ehtalaš njuolggadusaid sámi dearvvašvuodadutkamii ja geavahit ja hálldašit sámi humána biologalaš materiála. Ásahuvvo bargolávdegoddí mas leat áirasat sámi dearvvašvuodadutkan birrasis ja juridihkalaš áššedovdit. Sámedikki veahkeha doallat čállindoaimma lávdegoddái

Álgoábmotrievttit mat leat ILO konvenšuvnnas nr 169. ON julggaštus álgoábmotrivttiid birra ja eará guoskevaš riikkaidgaskasaš konvenšuvnnaš leat vuoddi dán bargui.
Mandáhta:

Bargolávdegotti galgá hábmet áldohovtsa ehtalaš njuolggadusaide sámi deargvuvaodadutkama várás ja maid dutkami mii guoskkaha mas sámi humána biologalaš materiála.

• Identifiseret ja suokkardallat hástalusaid vurkema ja ráddnrievtti sámi humána biologalaš materiála badjel
• Digaštallat ehtalaš čuolmaid maid ehtalaš njuolggadusat galget fátmmastit
• Digaštallat njuolggadusaid juridihkalash stáhtusa
• Guorahallat njuolggadusaid viidáset meannudeami sisriikkalaččat ja gaskariikkalaččat

Bargolávdegotti miellahtut:

Lávdegotti jodiheaddji: Prof. Siv Kvernmo, UiT
Dr.med. Ann Ragnhild Broderstad, UiT
Prof. Kirsti Støren Bull, UiO
Post.doc Bent Martin Eliassen, UiT
Dr. Heidi Eriksen, Ohcejohka, SANKS/SáNáG
Kánturhoavda May Britt Rossvo, REK Tromsø
Psykologa Jon Petter Stoor, SANKS/SáNáG