Ethical Guidelines for Indigenous Health Research

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MAIN FINDINGS

In this report, the Centre for Sami Health Research (SSHF) presents an overview of selected documents of ethical guidelines for health research on indigenous peoples in Canada, Greenland, Australia and New Zealand. The aim has been to create a knowledge base to use for preparing a draft of guidelines for health research on the Sami people in Norway. This report focuses specifically on provisions related to collective consent, guidelines for storing human biological material and other data, and indigenous peoples' rights to this data. The included documents are applicable on various levels, i.e. international, national, regional, local or project-specific levels.

We found 5 documents in Canada (A–E), 4 in New Zealand (J–M) and 3 in Australia (G–I). World Health Organization and Greenland had 1 document each (N and F, respectively), while we found 0 documents in Alaska (Table 1). Documents A, I, K and L are not in their entirety guidelines for indigenous health research, but rather include separate chapters or provisions on indigenous peoples. A total of 13 documents had guidelines related to collective consent, 11 had general provisions relating to storage and right of use of indigenous data, and 6 included specific descriptions of storage and right of use of human biological material from indigenous peoples (Table 1). Only documents B and H may be considered "best practice"; they set an absolute requirement for collective consent and give indigenous peoples full control and influence on research that affects them directly or indirectly. Several documents require a formal research agreement to be established between researchers and indigenous peoples to define the latter's involvement in health research (documents A, C, D, G, H, M and N).

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PREFACE

The Norwegian act relating to medical and health research (the Health Research Act) came into force in 1 July 2009. The law establishes some general minimum requirements for research organisation and content. It sets a requirement that researchers must be conscious of ethics. International regulations that Norway is bound by are also incorporated into the legal framework. The Regional Committees for Medical and Health Research Ethics (REK) administers the legislation. REK gives preliminary approval for research projects and assesses general research ethics. In addition to the legislation, its assessments are based on guidelines and rules such as the Declaration of Helsinki, the professional associations' codes of ethics, and/or court decisions.

Human dignity and rights are central in the Health Research Act, and participants’ safety and welfare shall take precedence over science and the public interest. The individual’s interests are safeguarded by ensuring that they give informed, voluntary, explicit and verifiable consent, and that they are given ownership of test samples and information about their research results. The legislation is designed to protect individuals; group rights in health research are not specifically mentioned.

The Sami population in Norway is a minority both in terms of numbers, and political power and influence. This is also the situation for most of the world's indigenous peoples. The injustices that the Sami and other indigenous peoples have been subjected to – both as citizens and as research subjects – are well documented; historically, health researchers have not treated indigenous peoples with the respect that, today, is a matter of course. In indigenous areas, many thus remain sceptical of research and researchers. As a health researcher, it is important to be conscious of previous ethical transgressions.

Because of this history, international indigenous health research is regulated by specific guidelines. Indigenous peoples are also more often involved as equal parties to the research carried out in their communities. In Norway, Sweden and Finland, there are no guidelines for Sami health research, and there has also been less tradition of involving participants in the research work.

With the backdrop of history and legislation, the Centre for Sami Health Research has worked on the project "Ethical Guidelines for Health Research in Sami Societies". The research director at the Centre for Sami Health Research is a member of the Arctic Human Health Expert Groups (AHHEG), one of the working groups of the Arctic Council. The AHHEG decided approximately five years ago to produce a review of ethical guidelines and to draft ethical guidelines for Arctic indigenous health research. The Centre for Sami Health Research by its leader undertook the task of leading this work. The indigenous representatives in the working group recognised the need for such guidelines and put the issue on the agenda. Simultaneously, the centre acknowledged a clear need for ethical guidelines for Sami health research; due to a growing interest and a greater focus the last few years on indigenous health both nationally and internationally, there has been increasing interest in access to the centre’s data sources. In the same period, the Sami Parliament of Norway called for similar guidelines. As these projects shared the same theme and project leadership, the preliminary phases of the projects were consolidated. A review of relevant guidelines was to form a basis for ethical guidelines for health research on Arctic indigenous peoples in general and on Sami in particular.

The project "Ethical Guidelines for Health Research in Sami Societies" consists of three parts. Part one was the report "Use of Sami ethnicity in research databases and health records".[1] Part two of the project – which also is part of the AHHEG project – is this report providing a general overview of key documents including guidelines for health research on indigenous peoples in comparable countries. A committee appointed by the Sami Parliament of Norway consisting of health scientists, lawyers and REK North completes by December 2017 draft guidelines for Sami health research in Norway. The committee's work is the third and final part of the project.

We want to thank the Sami Parliament for good cooperation in this process, and hope the work gives new insights and knowledge for all who work in health research in Sami communities.

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ABBREVIATIONS

REK	Regional Committees for Medical and Health Research
AHHEG	Arctic Human Health Expert Group
UiO	University of Oslo
SSH	Centre for Sami Health Research (Senter for samisk helseforskning)
AIAN	American Indian/Alaska Native
AN	Alaska Native
UN	The United Nations
TSI	Torres Strait Islander Peoples
FNGC	First Nations Information Governance Committee
OCAP®	Ownership, control, access, possession
RHS	First Nations Regional Longitudinal Health Survey
AH	Aboriginal health
MRC	Medical Research Council
NKG	National Kaitiaki Group
HRC	Health Research Council
WHO	World Health Organization
Ibid.	Ibidem (same place).

1. INTRODUCTION

In this report, the Centre for Sami Health Research (SSHF) presents a general overview of selected documents of ethical guidelines for health research on indigenous peoples in Canada, Greenland, Australia and New Zealand. The aim has been to create an overall knowledge base to use for preparing a draft of guidelines for health research on the Sami people in Norway. No such guidelines exist today, either in Norway, Sweden or Finland. The exception, in Norway, are the policies for Sami material included in the temporary guidelines for use and management of skeletal material at the University of Oslo (The Schreiner Collections).[2]

This report is a working document and the second part of the project "Ethical Guidelines for Health Research in Sami Societies". In the first part of this project, SSHF published in 2015 a report on health surveys and studies published in Norway in the last 30 years where Sami ethnicity was included as a variable.[1] This work was funded by the Sami Parliament in Norway. A committee appointed by the Sami Parliament of Norway consisting of health scientists, lawyers and REK North completes by December 2017 draft guidelines for Sami health research in Norway. The committee’s work is the third and final part of the project.

The main purpose of the documents in this report is to guide researchers in the planning, implementation and follow-up stages of health research projects that include or affect indigenous peoples. The guidelines are also used as a tool by ethics committees when research projects are evaluated. The guidelines may also be used by indigenous peoples themselves in their meetings with scientists.

The documents explain to varying degrees how indigenous peoples can or should be included in the research process. This report focuses specifically on provisions related to collective consent, guidelines for storing human biological material and other data, and indigenous peoples' rights to this data. Storage and return (repatriation) of, and research into, human remains are not discussed beyond what is covered in section 2.2. This report reflects the mandate given by the Sami Parliament to the aforementioned committee.

Documents from Alaska, Canada, Greenland, Australia and New Zealand were given priority. The first three were included as these are countries and regions within the geographical area of the AHHEG, i.e. the Arctic region (see Forward). Prioritised were also countries from other continents that are somewhat comparable with Norway, Alaska, Canada and Greenland. Australia and New Zealand were therefore included. Apart from Alaska, the US was not included in order to limit the scope of this publication. The countries and regions reviewed in this report are functioning constitutional states or regions within such, with considerable wealth measured in gross domestic product. This makes them comparable with Norway. However, they differ from each other and in relation to Norway when it comes to judicial rules, systems for funding, and ethical evaluation of research. The principles underlying the above documents' guidelines may still be relevant and can be used as inspiration for drafting ethical guidelines for health research on the Sami people in Norway.

In the following overview, we will not describe the country or region's respective ethical review processes or systems for research funding. The practical application of the guidelines will not be discussed, as that would go beyond the framework for this report. The report therefore only briefly summarises some fundamental principles and priorities presented in the included documents' guidelines. This summary and the subsequent discussion are not intended to be exhaustive; the reader is, hence, advised to consult the respective documents for detailed descriptions of key guidelines.

The Centre for Sami Health Research hopes that this report will lay the foundations for preparing ethical guidelines for health research on the Sami people in Norway. We also hope that the report may be used as a framework for drawing up ethical guidelines for health research on Arctic indigenous peoples in general.

2. BACKGROUND

In this chapter, I will take the opportunity to present some conceptual clarifications and clarify some prerequisites for assessing ethical guidelines for indigenous health research.

2.1. The Declaration of Helsinki

Today, no one working with research ethics can avoid dealing with it. The Declaration of Helsinki builds on the Nuremberg Code and emphasises among other things the necessity of having the participants' informed consent, respect for the individual, and fairness and balance between the individual's risk, burden and benefits of participation in the research. The need for codes and guidelines became evident after the last World War's monstrous ethical violations against disadvantaged groups. The Declaration of Helsinki has been revised several times, most recently in 2013. All health research, also that which includes indigenous peoples, must uphold the principles of the Declaration of Helsinki.[3] [4]

2.2. Temporary guidelines for use and management of skeletal materials at the University of Oslo, Institutional group for medical sciences (The Schreiner Collections)

As mentioned in the previous chapter, there are currently no general ethical guidelines for health research on the Sami people in Norway. The exception is the rules for Sami skeletal material in the specific guidelines for use and management of skeletal material at the University of Oslo (UiO).[2]

Norwegian museums and collections contain the remains of between 12,000 and 15,000 individuals found in graves and cremation burial sites from prehistoric and historic times.[5] Most of the cremated remains and about half of the non-cremated remains are kept in the storage facilities of the administering archaeological museums. The other half of the non-cremated remains are stored in the Schreiner Collections, i.e. the skeleton collection at the Institute of Medical Sciences, Section of Anatomy, University of Oslo; the remains of approximately 900 Sami individuals are stored here.[5]

From the 1850s and well into the 1900s, large amounts of Sami skeletal material[*] were collected from pre-Christian and Christian burial sites primarily in Finnmark. The University of Oslo has not conducted its own excavations since 1939. Gathering of skeleton parts from Sami graves has since then consisted of archaeological museums submitting material from pre-Christian graves.[6]

Paragraphs 6 of the mentioned document states: "Sami skeletal material shall to the extent possible be separated from other material in the collection. Such material shall as far as possible be kept securely and should not be visible to visitors." Further: "The Sami Parliament or a designated body must approve use of Sami skeletal material for research purposes. Similarly, the Sami Parliament or a designated body must authorise any lending of Sami material."

Paragraph 9 reads: "The Sami Parliament has the right to repatriate all or parts of the Sami skeletal material for other storage/placement than at the University of Oslo. The formal

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[*] See the Temporary guidelines for use and management of skeletal material at the University of Oslo (The Schreiner Collections)[2] for definition of «Sami skeletal material».

decision for repatriation is taken by the Board of the Medical Faculty. The costs of such repatriation will be covered by the University of Oslo."

Particular ethical dilemmas are raised surrounding the storage and return (repatriation) of, and research into, human remains in general[5] and remains of Sami individuals in particular.[6] As mentioned above, this will not be referred to or discussed in this report. It should nevertheless be noted that research into human remains in Norway generally has its own ethical guidelines[7] and its own research ethics committee – the Skeletal committee.[8] All research projects on human remains should be evaluated by the committee, the guidelines states. The committee is part of the Norwegian National Research Ethics Committees (NESH).

2.3. Types of guidelines

Some of the included documents (see section 4.2) are not necessarily guidelines in the true sense, but rather "policies" or "codes of conduct".

Guidelines[9] are: […] *a formal statement about a defined task or function. Examples include clinical practice guidelines, guidelines for application of preventive screening procedures, and ethical guidelines for ethical conduct of epidemiological practice and research. [Guidelines….] contrast with code of conduct, in which the rules are intended to be strictly adhered to and may include penalties for violation. In the terminology developed by the European Community, directives are stronger than recommendations, which are stronger than guidelines. In North America, guidelines is normal usage also for recommendations (p. 126).*

A "code of conduct"[9] is: […] *a formal statement of desirable conduct that research workers and/or practitioners are expected to honour; there may be penalties for violation. Examples include the Hippocratic Oath, the Nürnberg (Nuremberg) Code, and the Helsinki Declaration, which govern requirements for research on human subjects* (p. 48).

A "policy" [9] is: […] *a guide to action to change what would otherwise occur; a decision about amounts and allocations of resources; a statement of commitment to certain areas of concern; the distribution of the amount shows the priorities of decision makers. Public policy is policy at any level of government* (s. 216).

For convenience, we will generally refer to all the included documents' provisions as guidelines, but we will in the presentation of each document (section 4.2) refer to their respective provisions as either guidelines, codes or policies.

2.4. Minimum standard, good practice or best practice

When preparing guidelines, they may represent a minimum standard, a good practice or a best practice for ethical indigenous health research, per Appendix A of document J, chapter 7. In regards to the inclusion of indigenous peoples in the research process, this may refer to the differences between consulting indigenous peoples, engaging indigenous peoples, or giving indigenous peoples a guiding role and a high degree of control. These are not official definitions, and in several of the documents these concepts (for example *consult* and *engage*) are used interchangeably; however, the inclusion of indigenous peoples in the research process is in the documents recommended to a varying degree.

The term *consultation* suggests that there has been a constructive criticism of the proposed research project and its potential impact on indigenous peoples. The process has also given affected communities the opportunity to discuss and comment on the research focus and timeliness. The consultation may also help to contextualise information leaflets and arrange the best possible distribution of research findings. This is a "minimum standard".

Engagement of indigenous peoples involves systematic incorporation of their needs, so that the research is of direct and practical benefit to indigenous peoples and their societies. Such an approach aims to answer questions that are particularly relevant and important to indigenous peoples. The researchers include specific issues referring to the explicit needs of indigenous communities in their protocols, and outline clear measures to respect local cultures and values in the research process. This is a "good practice".

Giving indigenous peoples a guiding role and a high degree of control of the research involves incorporating them from the planning phase through to development and implementation of the research. This also means allowing indigenous people to monitor the project at every stage, including the analysis and distribution of results. The main goal and purpose of the research is to benefit the affected indigenous peoples and communities, and the protocol should explicitly describe specific measures to ensure this (document J, p. 30–31). This is a “best practice”.

2.5. Collective consent, storage and indigenous rights to data

As mentioned in the introduction, this report focuses specifically on the different documents’ guidelines relating to free and informed collective consent, and to provisions on storage and indigenous rights to human biological material and other data.

"Free and informed collective consent" (hereinafter called collective consent) refers to a consent given—without coercion and pressure—collectively by a local community or an indigenous group that is directly or indirectly affected by the proposed research. Such consent is in addition to the required free and informed individual consent described for example in the Declaration of Helsinki. This definition is based on a summary of the documents presented in section 4.2 that include such descriptions and regulations.

Research that *directly* affects indigenous peoples is for example research that explicitly includes indigenous peoples in the hypothesis or research question, and where the intention is to generalise findings to one or more indigenous groups. Indigenous peoples are *indirectly* affected in projects that for example include geographic areas easily associated with indigenous groups, such as epidemiological population surveys that include districts or municipalities with a significant Sami population. An example of research that neither directly nor indirectly affects indigenous peoples would be studies based on interviews with a limited number of individuals of indigenous descent—who either identify as indigenous or not—which does not intend to generalise its findings to indigenous peoples in general or to specific indigenous areas (see document A, p. 116–117). Small and non-representative studies may of course affect indigenous peoples; the project's research questions and/or hypotheses must be considered when its impact on indigenous peoples is considered.

"Provisions for storage of human biological material and other data" refers to descriptions of how information about research participants is stored, managed and secured. This report also focuses on rights to human biological material and other data, which implies a focus on how guidelines give affected indigenous people rights to determine the use and storage of data.

2.6. Included indigenous peoples

There is no general, internationally accepted definition of indigenous peoples. The ILO Convention 169 on indigenous and tribal peoples in independent states[10] defines indigenous peoples as follows in Article 1. (b):

“peoples in independent countries who are regarded as indigenous on account of their descent from the populations which inhabited the country, or a geographical region to which the country belongs, at the time of conquest or colonisation or the establishment of present state boundaries and who, irrespective of their legal status, retain some or all of their own social, economic, cultural and political institutions.” In addition, indigenous peoples often represent a non-dominant group in society.[11]

Many are familiar with the skull measurements of the Sami people in Norway from the early 1900s until the Second World War.[12] Virtually all indigenous peoples have historically been subjected to unethical and useless research.[13] All the included documents (Table 1) were produced—wholly or partially—as a consequence of previous unethical research practices.

Indigenous peoples’ legal statuses vary,[14] and Banks[15] and Banks og Koivurova[16] have previously described the situation of Arctic indigenous peoples. The status of indigenous peoples in their respective nation states is of great importance, given that this will affect relevant health legislation and related guidelines. These matters will not be dealt with here, but they are important for the reader to keep in mind.

Alaska

Indigenous peoples in the United States are often in official statistics referred to as American Indian/Alaska Native (AIAN). In 2010 there were 138,312 AIAN in Alaska, constituting 19.5% of Alaska's total population.[17] These are figures from the US Census Bureau and represent the people in the census who identified as AIAN in combination with any other ethnicity. Not everyone who identified as AIAN in Alaska specified what tribe or ethnic group they belonged to. Among those who did, 91% reported as belonging to an Alaska Native (AN) group. Roughly, we can divide AN into three main groups[18] (internal distribution in parantheses[19]): Aleutian (11%), Inuit (57%) and Indian (32%). Approximately 20% of these (estimate) speak at least one of the more than 20 different AN languages in Alaska.[20] In the period 2009–2013, the difference in life expectancy between AN (70.7 years) and Whites in Alaska (79.1 years) was 8.4 years.[21]

Canada

Indigenous peoples in Canada are Indians (First Nations), Inuit or Métis. The latter are descendants of First Nations and European settlers. In 2011, 1.4 million people in Canada had indigenous ancestry. This represents 4% of the total population.[22] Among those with an indigenous background, 61% were First Nations, 32% were Métis and 4% were Inuit. Other indigenous identities amounted to 2%, while 0.8% reported more than one indigenous identity.[22] More than 60 indigenous languages are spoken in Canada.[23] Just over 17% of Canada’s indigenous peoples speak an indigenous language fluently; significantly more Inuit (64%) speak an indigenous language fluently compared to First Nations (22%) and Métis (3%).[23] Predicated life expectancy for 2017 is as follows: First Nations: 75.5 years; Inuit: 68.5; Métis: 77.0; and Canada’s general population: 81.0.[14]

Greenland

In 2015, Greenland had just under 56,000 inhabitants, of which 90% were Inuit.[14] Most Inuit in Greenland speak Kalaallisut, a language closely related to the Inupiaq-Inuit spoken in northern Alaska and Canada. Together with Danish, it is the official language on the island.[18] Greenland is part of Denmark, but is self-governed and enjoys a large degree of autonomy. The difference in life expectancy in the period 2009–2013 between Greenlanders (those born in Greenland, 70.3 years) and Denmark's total population (79.5 years) was 9.2 years.[14]

Australia

The estimated number of indigenous people in Australia (Aboriginals and Torres Strait Islanders [TSI]) was 686,800 in 2014–2015; this corresponds to 3% of the total population.[24] Among these, 90% identified as Aboriginal, 6% as TSI and 4% identified as both.[24] More than 145 indigenous languages are spoken in Australia.[25] In 2014–2015, 11% of indigenous peoples above 14 years had an indigenous language as their main language at home. There are significantly more speakers of indigenous languages in rural areas than in urban areas.[24] In the period 2010–2012, average life expectancy for indigenous peoples was 71.4 years. This is 10 years less than for the rest of the population.[14]

New Zealand

Maori people accounted for 14.9% (n=598,605) of the total population in 2013. 20% of Maori people spoke the language fluently in 2013.[26] Pacific peoples are people who live in New Zealand but originated from Pacific island nations which were once part of the nation state New Zealand, and people from the Cook Islands, Niue and Tokelau (see document N, p. 2).

They represent a large variation in languages and cultural expression. In the period 2010–2014, life expectancy for Maori was 75.1 years, compared to 82.1 years in the general population.[14]

3. METHOD

Three main methods were used in the search for documents: systematic literature searches, searches on relevant websites, and the use of research networks. The latter has been a supplement to gain access to any unpublished/unknown guidelines. The literature review was in large parts conducted during July 2016.

3.1. Systematic literature searches

A research librarian at NTNU's Library of Medicine and Health assisted with the systematic literature search and recommended using both Google Scholar and Google. Google Scholar (scholar.google.no) is Google's scientific/academic search engine and should cover many areas: books, book chapters and "grey literature" (e.g. guidelines, reports, dissertations and conference papers). The search engine is interdisciplinary and is therefore well suited for an "unusual topic." Documents that are considered as professional—based on structure and citations—are made available here. Traditional databases such as PubMed are not suitable for a search for ethical guidelines, as these exclusively prioritise research articles.[27]

In Google Scholar, only the first 1,000 hits are displayed for each search. The following search string was used:

Ethical | ethics | guidelines | policy | code | conduct indigenous | aboriginal | indian | native | "first nations" | metis | inuit | maori | pacific health research

We also conducted a traditional Google search (www.google.no) with the same search string. "Regular" Google only shows the 200–400 first and most relevant hits, but does provide a choice to repeat the search with the omitted results included. Only the 200–400 first hits were assessed in the literature search.

3.2. Review of relevant websites

Websites of relevant institutions in the respective countries and regions were searched through using the key words “guidelines”, “ethical guidelines”, “code” and “policy” in combination with relevant indigenous groups.

- Alaska: http://dhss.alaska.gov/Pages/default.aspx, http://www.alaska.edu/alaska/
- Canada: http://www.hc-sc.gc.ca/index-eng.php, http://www.cihr-irsc.gc.ca/e/193.html
- Australia: http://www.health.gov.au/, http://www.lowitja.org.au/ethics
- New Zealand: http://www.health.govt.nz/, http://www.hrc.govt.nz/

3.3. Use of research network

The following health researchers were contacted:

- Professor Peter Bjerregaard at the National Institute of Public Health, University of Southern Denmark, Copenhagen, Denmark.
- MD James Berner at the Center for Alaska Native Health Research, University of Alaska Fairbanks, Alaska.
- Dr. Thomas Hennessey at the Arctic Investigations Program, US Centers for Disease Control and Prevention, Anchorage, Alaska.

3.4. Inclusion and exclusion criteria

Applicable guidelines specifically developed for health research on indigenous peoples in Alaska, Canada, Greenland, Australia or New Zealand were included. General guidelines for health research in the same countries and regions where indigenous peoples were explicitly mentioned or discussed were also included. General guidelines for research on indigenous peoples were excluded.

4. RESULTS

4.1. SEARCH RESULTS

The Google Scholar search gave 2.75 million hits, of which the first one hundred hits contained no documents of guidelines, but rather various scientific publications—both articles and books—about ethics and research on indigenous peoples (results not shown). Google Scholar thus prioritised research papers and academic literature above guidelines and other "grey literature".

Therefore, we also conducted a traditional Google search with the same search term, and got 237 million hits (Figure 1). A total of 11 documents were included through the systematic literature search, after a total of 315 titles were excluded. The excluded titles included outdated guidelines for health research on indigenous peoples, general guidelines for research on indigenous peoples, research literature, general descriptions on websites of government departments, ministries, directorates and research councils, and news stories.

Documents K and L were found by searching on the mentioned relevant websites.

Peter Bjerregaard relayed the attached guidelines for health research in Greenland, while Berner and Hennessey could confirm that there are no official guidelines for indigenous health research in Alaska.

Figure 1. Systematic literature search

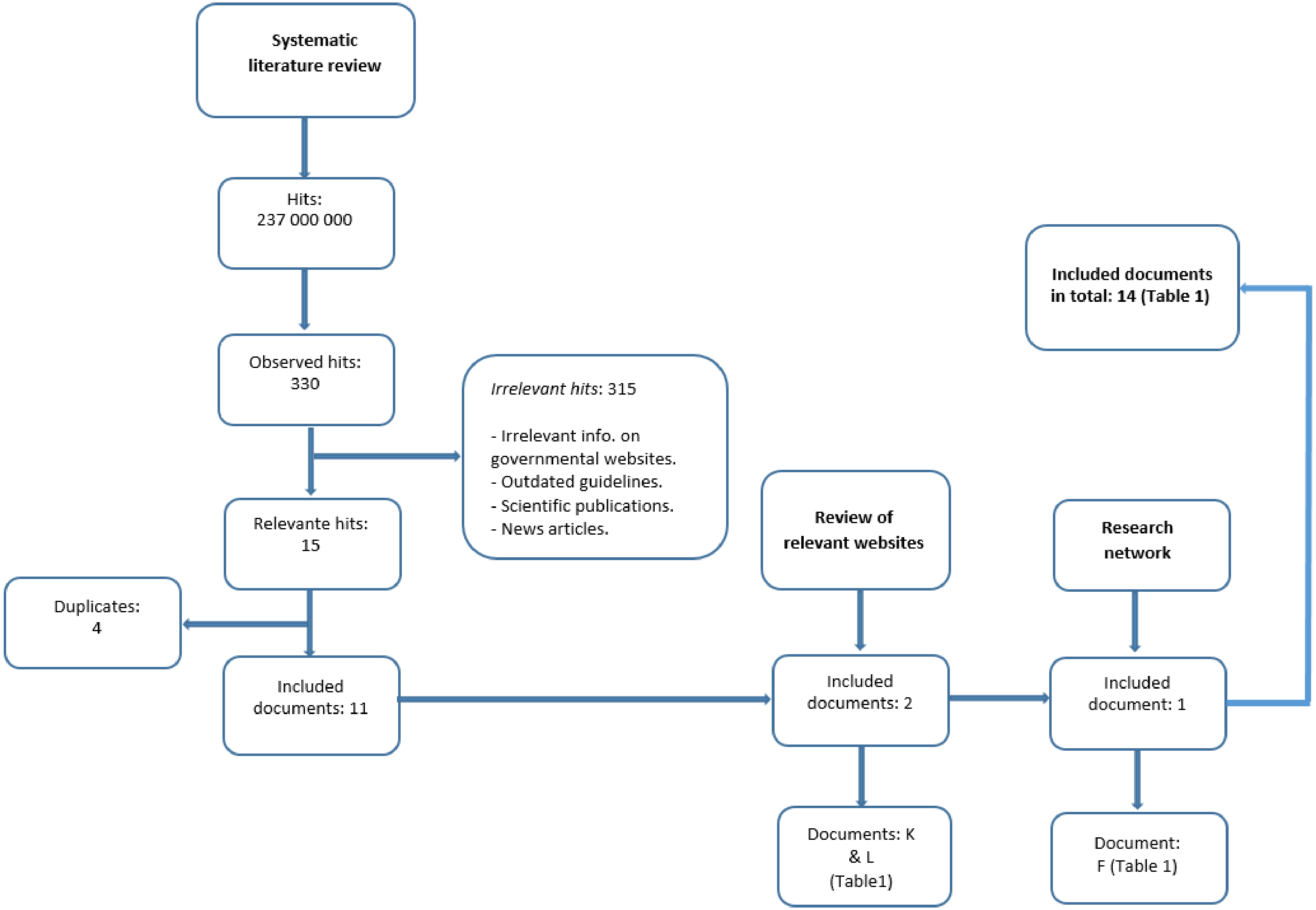

Table 1: Ethical guidelines for indigenous health research

						Descriptions of:	Descriptions of rights to and/or storage of:	
D	**Unit**	**Year**	**Title**	**Region, country**	**Indigenous group(s)**	**collective consent**	**general indigenous data**	**HBM especially**
A	Canadian Institute of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada	2014	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Ch. 9: *Research Involving the First Nations, Inuit and Métis Peoples of Canada.*	Canada	First nations, Inuit, Metis	Yes	Yes	Yes
B	First Nations Regional Longitudinal Health Survey	2007	Code of Research Ethics	Canada	First Nations	Yes	Yes	No
C	The Aboriginal Health Research Review Committee	2003	Guidelines for Ethical Aboriginal Research.	Canada	First Nations, Manitoulin Area	Yes	Yes	No
D	Prairie Women's Health Centre of Excellence	2004	Ethical Guidelines for Aboriginal Women's Health Research	Canada	First Nations, Inuit, Metis	Yes	No	No
E	Métis Centre, National Aboriginal Health Organization	2011	Principles of Ethical Métis Research	Canada	Métis	Yes	No	No
F	Danish/Greenlandic Society for Circumpolar Health	2015	Good research practice in Greenland – A guideline	Greenland	Inhabitants of Greenland	Yes	Yes	Yes
G	National Health & Medical Research Council	2003	Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and	Australia	Aboriginals and Torres Strait Islander peoples	Yes	Yes	No

			Torres Strait Islander Health Research.					
H	Aboriginal Health (AH) & Medical Research Council (MRC) of New South Wales's Ethics Committee	2013	AH&MRC Guidelines for Research into Aboriginal Health. Key principles.	Australia	Aboriginals and Torres Strait Islander peoples	Yes	Yes	Yes
I	The National Health and Medical Research Council, the Australia Research Council, and the Australia Vice-Chancellors' Committee	2007 (2015)	National Statement on Ethical Conduct in Human Research	Australia	Aboriginals and Torres Strait Islander peoples	No	No	No
J	Health Research Council of New Zealand, The Maori Health Committee.	2010	Guidelines for Researchers on Health Research Involving Maori. Version 2	New Zealand	Maori	Yes	Yes	Yes
K	National Ethics Advisory Committee, Ministry of Health	2012	Ethical Guidelines for Observational Studies: Observational research, audits and related activities. Revised edition.	New Zealand	Maori	Yes	Yes	No
L	National Ethics Advisory Committee, Ministry of Health	2012	Ethical Guidelines for Intervention Studies: Revised edition	New Zealand	Maori	Yes	Yes	Yes
M	Health Research Council of New Zealand	2014	Pacific Health Research Guidelines	New Zealand	Pacific peoples, New Zealand	Yes	Yes	Yes
N	World Health Organization	2003	Indigenous peoples & participatory health research. Planning and management – Preparing research agreements	The World	Indigenous peoples	Yes	Yes	No

D = documents, HBM = Human Biological Material

4.2. DOCUMENTS

The included documents' guidelines are applicable on various levels, i.e. international, national, regional, local or project-specific levels. In the summary that follows, we will as mentioned not describe the country/region's respective ethical review processes. It should nonetheless be mentioned that the review processes vary considerably and take place on national, regional and local levels. For a detailed description of these processes, the reader is referred to the respective documents and to the responsible institution's website.

4.2.1. Canada

Five documents were included from Canada. The guidelines in document A applies at national level and for research funded by the various units responsible (see Table 1). Document E also applies at national level, while B and D are project-specific documents. Guideline C is local/regional and specific to research in the Manitoulin area.

A) *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, Chapter 9: Research Involving the First Nations, Inuit and Métis Peoples of Canada.*

This policy is developed by the Canadian Institute of Health Research, Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada. It applies to all research in Canada involving humans. Its basic principles are respect for the individual, the individual's welfare and justice. Chapter 9 of the document is exclusively reserved for research on indigenous peoples. Until 2010, the Canadian Institute of Health Research had its own guidelines,[28] which are no longer applicable and hence not included in this report.

Both national and regional ethics committees assess health research in Canada. As a prerequisite for funding, the above institutions require that researchers and their respective employers implement the policy's ethical principles and articles, and that they are guided by the policy’s suggested initiatives. The document emphasises that scientists are responsible for familiarising themselves with and complying with relevant laws and regulations related to consent and the privacy of research participants. These laws and regulations can vary between Canada's various areas of jurisdiction. Scientists could end up in a situation where the ethical guidelines contradict legal provisions; in such situations, legal provisions take precedence (see page 10 of the document).

Collective consent

The document does not address collective consent directly, but rather on “community engagement”. This is a process that establishes interaction between researchers and relevant indigenous communities. The partnership will vary depending on the community context and the nature of the research.

Engagement of indigenous peoples must happen before data collection commences and hence before individual participants sign an informed consent. Researchers will present a plan to the relevant ethics committees for how indigenous engagement will happen. In cases where it is likely that research will affect indigenous communities, researchers shall seek to involve the relevant local community. Conditions that require such involvement include, but are not limited to:

- Research conducted in indigenous areas;

- Studies that use indigenous identity as criteria for inclusion;
- Research that seeks input from participants with respect to a local community's cultural heritage objects, traditional knowledge or unique characteristics;
- Research where indigenous identity or affiliation with an indigenous community is used as a variable in the analysis of research data;
- Interpretation of research results that will refer to indigenous communities, language, history and culture.

Engagement can involve anything from a "good practice" to a "best practice" approach (see chapter 2). The policy states that indigenous peoples and scientists—in those cases where this is possible (see section 9.2 of the document)—should enter a formal research agreement with the purpose of clarifying and reaffirming mutual expectations and obligations (see section 9.11 of the document). As a minimum, the research agreement should include ethical standards to secure individual consent and should specify measures linked to community participation and decision-making, sharing of benefits and how the agreement is updated. Furthermore, the purpose of the research and mutual responsibility with respect to project design, data collection, data management, analysis and interpretation should be specified. Any sharing of royalties related to intellectual property should be discussed. Rules regarding co-authorship are also a topic that should be touched upon. In cases where a community has already established or lives by a set of rules—informal or formal—related to research and research activities (for example document C), these may be included in the agreement. In cases where local guidelines are contrary to this policy, this must be identified and managed either in advance or consecutively in cases where conflicts arise during the project period. See section 9.11 of the document for a detailed description of the research agreement.

Right of use and storage of data

In the policy’s section 9.8, it says: *Many First Nations communities across Canada have adopted an ethics code originally developed to govern practices in the First Nations Regional Longitudinal Health Survey. The code asserts ownership of, control of, access to, and possession (OCAP) of research processes affecting participant communities, and the resulting data. OCAP addresses issues of privacy, intellectual property, data custody and secondary use of data […]*. See the description of document B below.

Right of use and storage of human biological material

Section 9.19 says: *As part of community engagement, researchers shall address and specify in the research agreement the rights and proprietary interests of individuals and communities, to the extent such exist, in human biological materials and associated data to be collected, stored and used in the course of the research.*

Canadian law does not recognise direct property rights to human biological material. Researchers should nevertheless be aware that indigenous and local communities may wish to have control over and access to data and human biological material for research purposes. This is in line with traditional indigenous beliefs related to “full embodiment”, where each part and product of the human body is sacred and cannot be separated. Scientists and involved communities should address the following in a research agreement:

- The purpose of the collection, use and storage of human biological materials;
- Roles and responsibilities for ownership of data and human biological material; and

- Future use of human biological material and associated data, including handover to third parties and conditions for the involvement of local communities in this context.

B) *First Nations Regional Longitudinal Health Survey (RHS): Code of Research Ethics*

This is a “best practice” guideline that was created first and foremost to regulate research in the RHS. In 1996, the Assembly of First Nations Chiefs Committee decided that a First Nations health survey would be conducted every four years in Canada. This led to the establishment of RHS. A national committee (First Nations Information Governance Committee [FNGC]) was established, which included members from all involved regions. Health surveys were conducted in 1997, 2002–2003, and 2008–2010.[29]

RHS’s ethical code is based on the principles of *ownership*, *control*, *access* and *possession* (OCAP®).[2] The code explicitly recognises and respects that the First Nations people’s right to self-determination includes the right to make decisions about research in their communities. OCAP applies indigenous peoples’ right to self-determination to research.

Collective consent

OCAP® requires collective consent through the principle of control. First Nations peoples’ right to control over all aspects of their own lives and institutions includes research and information. The principle of “control” states that First Nations, their communities and representative bodies have a right to exercise control over research processes that affect them,

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[2] OCAP® is the registered trademark of the First Nations Information Governance Center (FNIGC): http://fnigc.ca/www.fnigc.ca/OCAP

and thus have the right to give or deny consent for such research. This includes all phases of research projects.

Right of use and storage of data

OCAP® establishes indigenous rights to their own data through the principles of "ownership", "access" and "possession". The principle of ownership refers to the relationships First Nations communities have to their cultural knowledge/data/information. The principle states that a community or group collectively owns the knowledge of themselves, in the same way that an individual owns their personal information. This is not the same as possession (see below).

First Nations must have access to information and data about themselves and their communities, regardless of where it is stored. This principle also refers to the right of First Nations' communities and organisations to manage and make decisions regarding access to their collective information.

While the ownership principle in OCAP® identifies the relationship between a people and their data, the idea of possession is more literal. Possession is a mechanism where ownership can be claimed and protected. When data is owned by one party, but is in the possession of another party, violations and abuse may take place. This is particularly important in situations where trust between the owner and proprietor is weakened. In the RHS, the solution was to give ownership and control of data on behalf of all involved parties to the First Nations Data Center[30], which is subject to the FNIGC. All raw data is password protected and stored on a server at the centre. Confidentiality in relation to the storage of data is ensured in accordance with the "Data Protection and Stewardship Protocol and Survival of Confidentiality Requirement of the regional contribution agreement." Data on the national level can be accessed by an application to FNGC’s Data Access subcommittee, which assesses the application for ethical approval in accordance with the attached code. Data on a regional level can be accessed after approval by a relevant regional governing committee or similar. Similarly, on the local level, data access can only be given following permission from the relevant authority (ibid).

C) *The Aboriginal Health Research Review Committee: Guidelines for Ethical Aboriginal Research.*

These guidelines are a manual for the development of ethical and culturally appropriate local community-based research in the Manitoulin area. All health research in Canada has undergone an ethical review at the national or regional levels. These guidelines form the basis for subsequent local reviews by the Aboriginal Health Research Review Committee. These guidelines can be considered as an addition to document A, and are based on “the seven grandfather teachings of respect, wisdom, love, honesty, humility, bravery and truth.” The guidelines interpret these principles and explain how they should be incorporated into research projects. The local ethical review will assess the projects’ ethical standards in relation to how the principles are prioritised.

Collective consent

The policy says nothing directly about collective consent. However, as mentioned previously, these are guidelines that apply on a local level in the Manitoulin area; the policy states that the guidelines can be used as a screening tool to help communities determine whether projects are ethically justifiable and desirable. Further, it states that ethics is closely related to culture and that it is important to recognise indigenous peoples’ values in research.

Right of use and storage of data

The guidelines do not mention human biological material in particular, but point out that the data from the project shall be owned by the affected local community through a formal agreement and appropriate arrangements in accordance with relevant laws and regulations.

D) *Prairie Women's Health Centre of Excellence: Ethical guidelines for Aboriginal Women's Health Research*

These guidelines are designed to ensure that all research funded by the Aboriginal Women's Health Research Program respects the relevant cultures, languages, knowledge and values. The guidelines are meant to be read as an addition to guideline A.

Collective consent

Informed consent should be obtained from all individuals and groups participating in the research. Collective consent may be obtained from groups organised in representative bodies or from authorised representatives for communities or organisations. For studies that are likely to affect certain indigenous communities, consultations focusing on planning, implementation and evaluation of results should be implemented with relevant and representative bodies. The document has no provisions relating to the storage of and rights to indigenous data, and constitutes per definition a "good practice".

E) *Métis Centre, National Aboriginal Health Organization: Principles of Ethical Métis Research*

This is a list of minimum principles established by the centre for research on Métis communities. These are not rules to be enforced but are, rather, a hypothetical basis for the involvement of Métis in research.

Collective consent

Here it is stated that some Métis societies may wish to give both individual and collective consent. It is the researcher's responsibility to establish which practices are applicable in the relevant communities. This involves consulting Métis "experts" (e.g. scientists, elders or historians) concerning which research is desirable and relevant. Storage of and rights to indigenous data are not specified.

4.2.2. Greenland

F) *Danish/Greenlandic Society for Circumpolar Health: Good research practice in Greenland – A guideline*

Greenlandic health research includes any form of health-related research where people living in Greenland supply or have supplied personal data, whether through questionnaires, interviews, data records, clinical examinations or collection of biological material.

Collective consent

Greenland is in many ways an independent country, and differs in that respect from the locales of other indigenous peoples. For other indigenous peoples where one often refer to "communities", the corresponding "community" in Greenland includes all of Greenlandic society, which is represented by the local Greenlandic government and its administrative bodies. All health research in Greenland must be reported to the Science Ethics Committee of Greenland and can only be initiated after the committee has given approval. Committee approval represents a collective consent, since its members are appointed by the Greenlandic government. At least one of the committee's four members shall speak both Danish and Greenlandic.

Right of use and storage of data

Use, handling and storage of data should live up to the Danish Data Protection Agency's regulations. Guidance on the use, handling and storage of data is given on their website.

4.2.3. Australia

Documents G and I apply at national level and are equivalent documents for health research into indigenous peoples in Australia, while document H functions at regional level.

G) *National Health & Medical Research Council: Values and Ethics – Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (Values and Ethics)*

The guidelines are based on the following values: "spirit and integrity", "reciprocity", "respect", "equality", "survival and protection" and "responsibility" (see document for further description). In cases where both the law and the above guidelines apply, the law takes precedence. In cases where the guidelines require a higher standard than what is prescribed by the law, researchers should apply this higher standard. These guidelines can be considered "good practice".

Collective consent

The document allows for consent on more levels than the individual. It states that in some cases and in some communities, consent is not only restricted to the individual, but may involve other parties, such as formally constituted bodies and collectives, or elders of the local community (document section 2.2.2).

It further states that respectful cooperation requires that formal agreements with indigenous communities are made prior to the research project, and that these clearly indicate how the research process will be conducted and who will participate. The agreement should describe how the above values will be followed up on. In the indigenous communities where a formal institutional structure exists, these should be used for the local communities' involvement.

Right of use and storage of data

Section 2.2.4 deals with storage of data. When personal information about research participants or a collective is gathered, stored, provided, applied or removed, researchers must strive to protect privacy and confidentiality as well as recognise the cultural vulnerability of the participants and collectives. It is vital that all aspects of the research process are based on respect; this is especially relevant for negotiations relating to for example publication of sensitive research findings. In addition, the publication of research findings should not take priority over the distribution and return of research to the indigenous peoples themselves. Specific provisions for possession and storage of human biological material are not discussed.

H) *Aboriginal Health (AH) & Medical Research Council (MRC) of New South Wales's Ethics Committee: AH&MRC Guidelines for Research into Aboriginal Health. Key principles.*

These guidelines are applicable at a regional level, and is used by said committee when assessing and processing applications for ethical approval of research projects. It is used in parallel with documents G and I, and is on a "best practice" level.

Collective consent

Indigenous peoples must have control over all aspects of the proposed research, including its design and implementation, ownership of data, interpretation of data, and reporting and publication of findings from research that involves indigenous health. This control should be established through a formal agreement between the parties involved. Control means that indigenous peoples and indigenous communities who participate in or are affected by the research should—in all phases—be fully informed of and agree to the research purpose and implementation. The concept of control exceeds "engagement" or "consultation", and requires a recognition that indigenous peoples have a right to make decisions about research that will affect them. How such control is implemented will vary from project to project.

Aboriginal community consent on the local level is necessary for the collection and use of health-related information if any of these factors are present:

- Indigenous peoples' experiences are the explicit focus in all or part of the project; or
- Data collection is explicitly focused on indigenous peoples; or
- Indigenous peoples as a group will be examined in the results; or
- The information will affect one or more indigenous communities; or

- Health funds reserved for indigenous peoples are a source of funding.

Formal consent and agreement to a research project must be obtained from the participating individuals and relevant indigenous organisations responsible for exercising indigenous control over the project. The latter consent must include the research purpose, relevance and use; how any future consent should be obtained following a change in the project; identification of who will have or is likely to have access to the information; provisions linked to the withdrawal of consent; and a requirement that future use of information and biological material that is not included in the current agreement must be subject to a new consent.

Right of use and storage of data

Affected indigenous peoples should own their respective data through participation in the research. An agreement between researchers and indigenous communities should include provisions on indigenous peoples' ownership of data, rights related to publishing results, and indigenous peoples' role in the implementation of findings. The agreement shall also describe data access and security, how data is stored, changes in the proposed use of the data, and the conditions under which a community can veto or edit the publication of sensitive information. It should also mention conditions such as local communities' ownership of blood and tissue samples.

I) *The National Health and Medical Research Council, the Australia Research Council, and the Australia Vice-Chancellors' Committee: National Statement*

These guidelines are intended for use by researchers, members of ethics committees, research managers and potential research participants. They refer to values such as research integrity, respect, benefit and justice. The document states that document G should also be consulted for research involving indigenous peoples. This document is at a minimum level.

Collective consent

There must be documented support for the research project in the relevant indigenous communities and groups, and research methods should engage with their social and cultural practices. To address this, researchers must seek advice from someone familiar with the indigenous culture and practice, or someone with indigenous people in their network who is familiar with the research practice. The document says nothing about storage of and rights to indigenous data generally, or human biological material from indigenous peoples specifically.

4.2.4. New Zealand

Documents J–M all have a national scope.

J) *Health Research Council of New Zealand, The Maori Health Committee: Guidelines for Researchers on Health Research Involving Maori. Version 2*

These guidelines are designed to assist researchers who intend to initiate health research involving Maori participants as a cohort or as part of a larger population. They are intended to inform researchers about the process of initiating consultation with the Maori. The purpose of the consultations is to ensure that research contributes positively to the Maori people's health development. The consultations will also be a foundation for establishing a working partnership between scientists and indigenous peoples.

These guidelines—on a “good practice” level—should be read in conjunction with other relevant ethical guidelines for health research in New Zealand. They stipulate that scientists should be familiar with the Waitangi Treaty’s provisions, especially those that refer to cooperation and its implications for indigenous health. The treaty was signed in 1840 between the United Kingdom and a number of Maori leaders. The treaty committed the Maori people to recognising the British rule and to only selling land to Britain. In return, Britain would respect and protect Maori property and give the indigenous population British citizenship.[31]

Collective consent

Informed consent should be required from both individuals and representative organisations. Consultation is emphasised as a vital step in the development of research involving Maori participants, or for topics that are of particular relevance to Maori people. The guidelines were produced on the basis that research should be a continuing cooperation between researchers and Maori communities or Maori groups. They further emphasise the Waitangi Treaty’s principles of “partnership”, “participation” and “protection”. This in turn means that researchers collaborate with Maori communities to ensure that their individual and collective rights are respected and protected. The engagement of Maori people should be ensured in all research phases, i.e. design, management, administration, implementation and analysis. This especially applies to research directly concerning the Maori people.

Right of use and storage of data

The point of the consultations is to identify and respond to issues before the research begins. Questions concerning intellectual property rights, access to data, the publishing process, authorship and storage of information/data can all be solved this way. Consideration should be given to creating an advisory group composed of local Maori people, health experts, and indigenous researchers. The group's task should be to ensure that the research is conducted in a culturally and ethically appropriate manner.

Right of use and storage of human biological material

It is stated that explicit consent, both individually and collectively, should be sought for storage of human biological material and in relation to genetic research.

K) *National Ethics Advisory Committee, Ministry of Health: Ethical Guidelines for Observational Studies: Observational research, audits and related activities. Revised edition.*

The guidelines include a reference to several legal regulations and international guidelines. These guidelines should also be read in conjunction with document J.

Research involving the Maori shall be done in partnership with the Maori. This should ensure that their individual and collective rights are respected and protected in order to realise any potential health gains. The Maori should therefore be involved in the design, management, administration, implementation and analysis of research. The guideline is a “good practice”.

Collective consent

In communities where collective decision-making is common, community leaders can express collective will. But individuals’ consent or refusal to participate in research must be respected; a leader may express agreement on behalf of a community, but an individual’s consent or refusal is binding. When individuals wish to participate in studies that community leaders do not agree to, the individuals must be informed of the consequences of this and be told why collective consent has not been given. Only after the individual has been given the opportunity to consider this information will they have the right to decide on participation.

Right of use and storage of data

The Maori should have control of records to ensure that data is used with the intention to improve Maori health, and that aggregated data is not used in a way that negatively affects the Maori people. This control is exercised by consulting official and relevant indigenous bodies such as "Kaitiaki" groups; in this context, a reference in the document is made to New Zealand's screening program for cervical cancer and the role of "National Kaitiaki Group (NKG)."[32] The screening program records and stores information about ethnicity. NKG is a group of six people appointed to ensure Maori control over the use of Maori women's screening data in research projects. The group will protect Maori women's screening data by ensuring that data are not used or published in inappropriate ways or in ways that reflect negatively on the Maori people. NKG shall also ensure that the data are used in a way that is of benefit to Maori women.[32] An application to NKG is required when the Maori are identified as a group in the analysis and presentation of research results. Detailed information is to be found on the NKG website.[32] [33]

L) *National Ethics Advisory Committee, Ministry of Health: Ethical Guidelines for Intervention Studies: Revised edition*

These guidelines share the same basis as those related to observational research (document K), but they also refer to specific legislation relevant for intervention studies.

One of the main goals of developing national guidelines is to reflect the principles of the Waitangi Treaty, protect Maori cultural interests, and ensure the Maori's welfare and participation in research and ethics reviews. The Maori should be involved in the design, administration, management, implementation and analysis of research, especially research involving Maori people. As New Zealand's indigenous people, the Maori must be recognised in research. Researchers should enter partnerships with indigenous peoples through their family groups, tribes and/or local communities to ensure that the Maori's individual and collective rights are respected.

Collective consent

If the research includes Maori communities, the relevant community bodies should be consulted. Consent should be obtained at the community level in a way that protects local traditions. The guidelines have no descriptions of indigenous rights over data or storage of indigenous data.

M) *Health Research Council (HRC) of New Zealand: Pacific Health Research Guidelines*

The purpose of the guidelines are to help guide HRC-funded health research involving Pacific peoples. These are "good practice" guidelines.

Collective consent

Meaningful engagement of Pacific peoples involves forming maintained and lasting relationships. A strategy of consultations is proposed, starting at the research idea stage and lasting until project completion. The point of the consultation is to provide the local community with all relevant information about the project’s purpose, implementation and the role of the local community. A representative group (informal or formal) should be consulted, and the talks should lead to a formal research agreement and collective consent. The consent may be non-written if this is in accordance with local tradition. The consent must still be documented in an appropriate manner.

Right of use and storage of data

Local communities must have full insight into the purpose of the research, who is involved, the research approach, how data is stored, and how the results will be used and shared with the local community. This process will give participants and communities the necessary information so that they can give free and informed consent.

Right of use and storage of human biological material

It is stated that the withdrawal of tissue and genetic material shall comply with ethical rules and procedures, following free and informed consent given by individuals and communities. It is important that scientists are aware of and respect that the human body is subject to cultural interpretation and part of a larger cosmological context. The consent and the research protocol must reflect these conditions. Participants must have full insight into how samples are used, how and for how long they are stored, and how they are disposed of. A contract should be signed specifying details of ownership. If samples are to be used for commercial purposes, for example for patents, lawyers should be engaged and the owner of the samples should be compensated per the agreement. The agreement must be based on reciprocity, be balanced, and be of benefit to individual participants and participating local communities.

4.2.5. World Health Organization

N) *World Health Organization (WHO): Indigenous peoples & participatory health research. Planning & management – Preparing research agreements*

The document—on a "good practice" level—does not replace mandatory national or institutional procedures for the review and authorisation of health research, nor is it intended as an independent ethical guideline. The purpose of this document is to provide information on how research institutions and indigenous peoples can cooperate in research based on a research agreement. Existing guidelines safeguard the need for research agreements to varying degrees.

Many indigenous peoples have found that systems for production, collection, ownership and sharing of knowledge and information are often unsatisfactory, and that the benefits of the research rarely come to them. Indigenous peoples have therefore often been reluctant to participate in research that does not include a meaningful consultation process and that does not recognise their own ideas about health. The need for research agreements is based on this evidence base.

Collective consent

The agreement may include a description related to the levels of collective consent that are required and how this should be obtained. Consent should, if appropriate, both be given on the local level and through an indigenous organisation (umbrella organisation). This should not replace individual consent. Consent given by an umbrella organisation is not a substitute for consent at the local level. Depending on societal structure, informed consent on three levels may be necessary (individual, local and organisational level).

Right of use and storage of data

The agreement must clarify how data should be stored, both in the short and long term, and how confidentiality is ensured. This includes provisions relating to access to, ownership of and restrictions on the use of data during and after the project. This also includes future use of the data. The document has no reference to jurisdiction over and storage of human biological materials.

5. BRIEF DISCUSSION OF RESULTS

5.1. Collective consent

Good research practice requires indigenous peoples' collective consent when the research directly or indirectly affects them. A collective agreement does not replace individual consent, but a process that leads to collective consent can better assess a project's implications for the affected indigenous peoples and communities.[34] Establishing a process of collective consent will help ensure that the affected peoples are involved in discussions about the relevance of the research. It will also increase the ability of researchers and communities to establish respectful relationships and negotiate culturally meaningful ethical parameters for the project (ibid.).

Ethical reviews of health research projects are based on principles and values given for instance in the Declaration of Helsinki. These are values that are considered as fundamental and universal ethical reference points. It can be argued, however, that ethics and beliefs about what is ethically acceptable are also culturally determined; ethics—understood as a discourse about morality—can be linked to the values and concepts arising from local practices,[34] as it is then conceivable that the ethical standards of research projects must also be interpreted in relation to indigenous peoples' own and local ethical standards. Implementing a requirement for collective consent can stimulate a discussion about local ethical beliefs. This should not be interpreted as indigenous peoples not upholding the Declaration of Helsinki, for example, but rather that indigenous traditions may demonstrate ethical convictions that are in addition to those set forth in the Declaration of Helsinki.

All the included documents stipulate that research must benefit affected indigenous peoples. Acquiring collective consent may make it easier to facilitate research that is deemed to be both culturally appropriate and helpful. A project's benefit to society should not only be up to an individual to consider, but should also be assessed by the affected indigenous peoples as a collective. This can be more readily facilitated through dialogue with indigenous peoples.

By giving collective consent, indigenous peoples can also define the research agenda; documents B from Canada and H from Australia require that the research address the needs of indigenous communities as defined by indigenous peoples themselves. This bottom-up perspective is partly in contrast to the other documents that largely promote a top-down approach, one which does not require that indigenous and local communities determine the agenda, but rather that research should benefit indigenous peoples, be appropriate for the community, not be harmful to society, or should promote indigenous interests.

Document B links collective consent to indigenous peoples' right to self-determination. None of the other documents have direct references to this. Indigenous peoples' right to self-determination is given by the United Nations (UN) International Covenant on Civil and Political Rights,[35] the UN Covenant on Economic, Social and Cultural Rights,[36] and the UN Declaration on the Rights of Indigenous Peoples.[37] It may be noted that guidelines for research on indigenous peoples in Australia – irrespective of discipline – have been drawn up only based on the latter declaration.[38] How said guideline (ibid.) relates to guidelines for indigenous health research in the same country is described in detail by the Lowitja Institute and the Australian Institute of Aboriginal and Torres Strait Islander Studies.[39] Indigenous peoples' right to self-determination is the principle that indigenous peoples, to the extent possible, should be given the decision-making powers in matters that affect them. Self-determination is a well-known principle in Norway; individual self-determination is about individuals being free—to the extent possible—to be able to make their own decisions about their lives without interference from the government or others. Indigenous self-determination therefore means that indigenous peoples are free to promote their political status and to pursue their own economic, social and cultural development.[40] Indigenous peoples' opportunity to collectively consent to research will contribute to realising these rights, according to document B; indeed, research provides a basis for economical, social and cultural development. Only documents B and H have an absolute and mandatory requirement for indigenous collective consent; the guidelines also stipulate that indigenous peoples own research that affects them directly or indirectly. It should be mentioned that document A makes clear references to OCAP®, without these principles being regarded as mandatory. In documents D and E from Canada, it is emphasised that they should be read and used in accordance with the guidelines in A; all these thus refer indirectly to the principles of OCAP® and indigenous peoples' right to self-determination.

5.2. Right of use and storage of human biological material and other indigenous data

Several documents stipulate that a formal research agreement is made between researchers and indigenous peoples to define the latter's involvement in health research (documents A, C, D, G, H, M and N). Documents A, C, H, M and N also require that the research agreement specifies rules for storage of and indigenous peoples' rights of use to human biological material and/or other indigenous data. B, F, G, J, K and L have guidelines related to storage of data without an explicit requirement for a research agreement. Documents A and B mention or base themselves on the principles of OCAP® for storage of and rights to indigenous data; OCAP thus requires that indigenous peoples have full control over this. The RHS's (document B) establishment of a separate research centre that includes data storage is an example of how this can be done in practice. In document K, a reference to the use of “Kaitiaki” groups is made, which may be a less costly option (see report p. 46). The other policies have only vague formulations related to the importance of indigenous influence on storage and use.

For human biological material, document A requires that the research agreement specify how data is stored, and establishes indigenous peoples’ rights to it. It also emphasises that the human body is sacred for many indigenous peoples and that the storage of human biological material may have to consider this. Document J states that storage of human biological material shall depend on explicit collective consent and consultations. How this consent should be obtained is not addressed. Document M, from New Zealand, also emphasises that this is subject to collective consent and that the storage of human biological material can be culturally sensitive. The same document specifies that the parties should sign a contract that clarifies ownership of the biological materials.

It is obvious that the storage of human biological material and other data, as well as indigenous peoples’ rights to it, is an important part of the research process. Several documents express the importance of indigenous peoples’ views on biological data being considered in the storage of such data, and state that questions of ownership should be addressed. Ethics and beliefs about what is ethically acceptable are, as mentioned, also culturally determined. It is thus conceivable that the research projects’ ethical standards for storage of data, and indigenous peoples’ rights to it, must also be interpreted based on local ethical standards, not only on ethical principles defined by scientists and general disciplines.

5.3. The report’s weaknesses and strengths

The countries’ and regions’ respective processes for ethical reviews and systems for research funding are, as mentioned earlier, not described in this report. This is due to the report's framework and scope. Such a broadening of the work would have been an advantage and would have given a more practical report, but would also have led to a significant delay in the completion of the work.

Using Google Scholar and “regular” Google in systematic searches has some disadvantages. The search algorithms are unknown; one does not quite know how key words are processed or how they are ordered. The search engines are also unstable, since the algorithms frequently change.[27] Consequently, it can be somewhat challenging to reproduce the literature searches of this report. The Google Scholar search (see section 3.1.) giving zero results is an indication of this instability.

The report’s strength is that several methods have been used to find relevant documents: systematic literature search, searches on selected websites, and the use of research networks.

6. CLOSING REMARKS

Despite Norway having considerable sources of knowledge in its health records, current legislation does not allow ethnicity to be recorded in central health records, medical records systems or other health databases. This makes it difficult to conduct research on health in different ethnic groups. The main task of the Centre for Sami Health Research is to generate research-based knowledge about Sami health conditions specifically. The centre's largest research project is the Population-based Study on Health and Living Conditions in Regions with Sami and Norwegian Populations – The SAMINOR Study. In the SAMINOR Study, participants' ethnicities can be defined using 11 questions about ethnicity and language. Combined with information from questionnaires, and clinical and biological measurements, this contributes to SAMINOR having a unique database. In addition, the survey covers a wide geographical area, which makes it a prime source of knowledge both in a national and international context.

Because of growing interest and a greater focus on indigenous health both nationally and internationally, there is increasing interest in access to the centre's data sources. The Centre for Sami Health Research therefore recognises a clear need for ethical guidelines for Sami health research (including Sami health services research), and research on Sami human biological material. This report provides an overview of international documents that could form a basis for developing such guidelines. We also hope that this report may be used as a framework for drawing up ethical guidelines for health research on Arctic indigenous peoples in general.

7. LINKS TO THE INCLUDED GUIDELINES

A: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

B: http://fnigc.ca/sites/default/files/ENpdf/RHS_General/rhs-code-of-research-ethics-2007.pdf

C: http://www.noojmowin-teg.ca/Shared%20Documents/GEAR%20-%20FINAL.pdf

D: http://www.pwhce.ca/pdf/ethicalGuidelines.pdf

E: http://chrr.info/images/stories/PrinciplesofEthicalMetisResearch-descriptive_001.pdf

F: http://gmsnet.dk/test/wp-content/uploads/2015/10/CodeOfConduct_final.pdf

G: https://www.nhmrc.gov.au/guidelines-publications/e52

H:http://www.ahmrc.org.au/index.php?option=com_docman&task=cat_view&gid=22&Itemid=45

I: https://www.nhmrc.gov.au/guidelines-publications/e72

J: http://www.hrc.govt.nz/sites/default/files/Guidelines%20for%20HR%20on%20Maori-%20Jul10%20revised%20for%20Te%20Ara%20Tika%20v2%20FINAL[1].pdf

K: http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research

L: http://neac.health.govt.nz/streamlined-ethical-guidelines-health-and-disability-research

M:http://www.hrc.govt.nz/sites/default/files/Pacific%20Health%20Research%20Guidelines%202014.pdf

N: http://www.who.int/ethics/indigenous_peoples/en/index6.html

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