SDE/Draft/03.1

World Health Organization

INDIGENOUS PEOPLES & PARTICIPATORY HEALTH RESEARCH

PLANNING & MANAGEMENT
■
PREPARING RESEARCH AGREEMENTS

DRAFT FOR COMMENTS

Centre for Indigenous Peoples'
Nutrition and Environment

Design and layout by Inís: www.inis.ie

CONTENTS

REFERENCES

This document draws largely on experiences with research on indigenous health in developed countries, carried out in discrete communities with independent infrastructure and voice, and clearly defined leadership structures. These experiences are helpful in clarifying how and why research with Indigenous Peoples requires additional considerations. They also signal to Indigenous Peoples in both developed and developing countries that they can play an active role in the research process of which they may not currently be aware.

Essentially, the document can only serve as a template of basic principles to be observed in planning, organizing, and carrying out health research. Indigenous Peoples and communities worldwide are structured in different ways, and the template will have to be adapted to local needs and conditions in different contexts and settings. Nevertheless, while the size and complexity of both the communities

This document aims to help fll a gap in the feld of research management identifed by Indigenous Peoples. It provides information on the joint management of research by research institutions and Indigenous Peoples, particularly in relation to the drawing up of a research agreement specifying the terms and conditions under which health research for mutual benefit will be carried out. The document does not seek to replace obligatory national or institutional procedures for reviewing and authorizing health research, nor is it intended as an ethics guideline. Rather, the establishment of research agreements constitutes a prior and additional measure to be taken where all parties concerned feel it is in their interests.

Increasingly, in countries where indigenous issues are prominent, it is becoming standard practice to make a detailed and explicit research agreement before a research proposal is submitted for scientifc and ethical review. Going through this process can enhance mutual understanding and help reduce problems during the research. This document summarizes the most significant provisions of such an agreement, drawing on experiences in various countries and providing references to key literature. It will need to be adapted to different settings and circumstances, and to take into account legal and other national regulatory mechanisms governing research procedures. The main focus is on process rather than content, and the general principles should be applicable everywhere and to all felds of research involving Indigenous Peoples.

The need for research agreements stems from problems encountered in research that many Indigenous Peoples feel are specifc to their cultural and political situation, and that are not sufficiently covered by scientifc or ethics guidelines. The experience of Indigenous Peoples is that arrangements for the production, collection, ownership, and sharing of knowledge and information are often not satisfactory, and that the benefts of research rarely accrue to them. Consequently, Indigenous Peoples often have reservations about participating in research that does not involve a meaningful consultation process and fails to recognize their own approaches to health.

While research agreements of the kind proposed in this document are not legally binding, they do represent formal

approach to information acquisition and sharing, and to research benefits, together with greater involvement of those affected by the outcomes, will encourage the research needed to strengthen the evidence base on the health status of Indigenous Peoples worldwide. Secondly, it will facilitate stronger partnerships between academia and indigenous organizations and networks – an essential step towards advancing work on indigenous health at national and subnational levels. A growing body of indigenous health expertise at academic level can be called upon to help ensure that health research with Indigenous Peoples is carried out with appropriate managerial and ethical perspectives.

Promotion of this approach is consistent with WHO's role and function of providing support, advice and guidance to countries on health matters. It is also consistent with increasing international consensus on the need to reach agreement on critical matters before research work is started.

ACRONYMS

USED IN THIS DOCUMENT

ACHR	Advisory Committee on Health Research (of WHO)
CBD	Convention on Biological Diversity
CINE	Centre for Indigenous Peoples' Nutrition and Environment
CIOMS	Council for International Organizations of Medical Sciences
FAO	Food and Agriculture Organization of the United Nations
IP	Indigenous Peoples
NGO	Nongovernmental organization
RI	Research institution
TRIPS	Trade-Related Aspects of Intellectual Property Rights (WTO Agreement)
UNCTAD	United Nations Commission on Trade and Development
UNDP	United Nations Development Programme
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

This document provides information on how research projects can be set up between Indigenous Peoples and research institutions, in a collaborative and ethically appropriate manner, on the basis of good management practices. It outlines key principles for participatory research management, and steps in the communications process between Indigenous Peoples and research institutions from the development of a research idea to negotiation of a mutually acceptable research agreement. Beyond the basic principles outlined in this document, all culture-specific local rules, requirements, and ethics should be taken into account.

This information is likely to prove most useful in the context of community-based research carried out with the active involvement of participants identifying themselves as indigenous, for the purpose of addressing

1

INTRODUCTION

Health research involving Indigenous Peoples (IP) has generally been initiated and controlled by research institutions (RI); IP have often had little or no representation or rights with respect to the research process, or to the interpretation and use of the resulting data. Fundamental differences in perception between non-indigenous and indigenous peoples can affect the research process, and need to be clearly understood and taken into account before any research is started. These may include differing perspectives on what constitutes public and private life, notions of property, and the rights and interests of the group or collectivity as opposed to those of the individual (Tri-Council, 1998).

Health research involving Indigenous Peoples, whether initiated by the community itself or by a research institute, needs to be organized, designed and carried out in a manner that takes account of cultural differences, is based on mutual respect, and is beneficial and acceptable to both parties. The relationship should be one of collaboration, involving an express effort to balance the interests and responsibilities of the RI and the IP.

1.1 Aim and scope of the document

This document provides information on some guiding principles for management of collaborative health research, covering:

- the processes required at various stages of the research;
- the main issues to be negotiated between the RI and the IP;
- drawing up a research agreement;
- key ethical considerations that should govern all health research.

The lists of references and selected further reading, as well as the annexes, provide information on valuable resources on these and related subjects.

1.2 Definitions[1]

For the purposes of this document, the following definitions are used:

Indigenous Peoples:

Although there is no internationally accepted definition of Indigenous Peoples, the following four criteria are often applied under international law, and by United Nations bodies and agencies, to distinguish Indigenous Peoples:

- residence within or attachment to geographically distinct traditional habi-

1. These definitions apply to terms as used in this document, and are not necessarily applicable in other contexts.

tats, ancestral territories, and natural resources in these habitats and territories;

◆ maintenance of cultural and social identities, and social, economic, cultural and political institutions separate from mainstream or dominant societies and cultures;

◆ descent from population groups present in a given area, most frequently before modern states or territories were created and current borders defined;

◆ self-identification as being part of a distinct indigenous cultural group, and the display of desire to preserve that cultural identity.

The United Nations Development Programme (UNDP) notes that "despite common characteristics, no single accepted definition of Indigenous peoples that captures their diversity exists. Therefore, self-identification as indigenous or tribal is usually regarded as a fundamental criterion for determining indigenous or tribal groups, sometimes in combination with other variables such as language spoken and geographic location or concentration." UNDP further extends their coverage to a much wider array of groups which are susceptible to being disadvantaged in

ext " (D w̄ ext " r (ƙ` ˬ ʒ̄ ƙ ɜ ˬ ext "

1.4 Implications for developing countries

The information in this document is based on experiences with IP in developed countries, with clearly identifable community and leadership structures, access to independent infrastructure and resources, and a significant political voice. These conditions often do not apply in the developing world, where the following points should be taken into account.

This is a particular concern in relation to genetic research. A meaningful informed consent process is one way of protecting against such exploitation (WHO, 2002). However, low educational levels, or cultural or language barriers, may mean that special care has to be taken to ensure that consent is truly informed and that individuals and groups thoroughly understand what is being proposed and why. Field-testing of the informed consent process may in some situations be indicated, and funding allocated foray in ̣ ̀ ɔ ʤ ƙ ɜ̀ ψ я ﺥ

2.1 Funding

◆ Where Indigenous Peoples enjoy reasonable levels of autonomy, there should be a joint commitment to fund-seeking. The level of commitment of the IP will depend on the situation and their capacity. Even in developed countries, unequal access to funding may frequently mean that the primary responsibility is taken by the RI. In developing countries, this responsibility will generally fall to the RI, in collaboration with national authorities and, if appropriate, members of the international community. Where external funding is involved, agreement should be reached by both parties in advance on sources that do not conflict with indigenous interests.

2.2 Ethics and consent

◆ Health research undertaken between IP and RI should respect national and international ethical guidelines on research involving human subjects (see ANNEX A). Approval for such health research should be obtained from a university ethics committee, national medical research council or other national mechanism, as appropriate to the issues involved. In some developed countries, ethics committees have been established by indigenous-controlled organizations to represent the indigenous participants in proposed research. Where they exist, such committees have a say on any ethical issues and approval procedures pertaining to proposed research. Some universities have set up ethics subcommittees comprising indigenous persons. Beyond this, ethics guidelines recommend that community representatives from the research population should participate in ethics review committees.

◆ Health research should conform to the customary laws and ethics (values, needs, customs) of the IP involved. This may require that additional protocols are followed to minimize harm to the

◆ Informed individual consent is usually obtained in writing, but in cultures where people may be reluctant, for a variety of reasons, to sign a written document, oral consent can substitute for written consent (WHO, 2002). Such situations are likely to be encountered only infrequently but, in such cases, agreement should be reached in accordance with acceptable local practice. The process followed should be the same as that for written consent. It is the duty of the ethics review committee to ensure that informed consent has been adequately demonstrated in a culturally appropriate way.

◆ The content and format of the informed individual consent form, and the process to be followed in obtaining cons[illegible] For some pe[illegible] event of [illegible] required [illegible] form sho[illegible]

X G R>íß"P A%tF&%'b\Qg e E? 5 S0 3O 06Qg i @P0 ...t`YN"...ÁYJ

a. Article 8(j) of the Convention on Biodiversity establishes that each Contracting Party "shall, as far as possible and … subject to its national legislation, respect, preserve and maintain knowl

2.3 Partnership principles

◆ Both parties enter into a research relationship as equal partners.

◆ Health research is undertaken only if the proposed research topic and process are compatible with the health priorities and needs of the IP.

◆ Health research proposals should be prepared jointly, on the basis of prior consultations between the parties. If an RI presents a research idea or proposal before such consultations, the IP should have the opportunity to request modif-

3.1 Initiation by Indigenous Peoples

Where IP wish to approach an RI regarding a health need, and there have been no previous contacts or research relationship, community leaders may choose to make a preliminary contact.

Relevant documentation should be forwarded to all parties well in advance of any meeting. This should include a cover letter summarizing the proposed research topic or idea, the broad research questions to be asked, the methods to be used, and the estimated benefits. If a draft research proposal is to be presented by the RI, a more formal document should be prepared for discussion covering the purpose, goals, and objectives of the research, risks and benefits, potential methods, and timeframe. Questions should be answered fully, and interpretation provided where required.

Where there is no common language, all documents should be translated into appropriate local languages. If the language of the IP is exclusively oral, the most widely used national language may be used for written material, with documented records kept of when oral translation to the community was made.

During the initial meeting, the parties should decide whether the research idea or topic meets their respective needs and priorities, and whether the proposed collaboration should be pursued. If it is agreed that the interests of both parties can be served by preparing or seeking approval for a joint research proposal, a timeframe and the division of responsibilities can be prepared.

3.4 Obtaining approval for the research

All health research must meet the requirements of the ethics review board or committee of the RI (which is usually subject to national ethics regulations) and, depending on the nature and scope of the research, those of national medical research ethics councils or committees. Before this stage is reached, approval to proceed with the research needs to have been formally obtained by the RI from community leaders, IP representatives, and local community members, as appropriate to IP structure and practices (see section 2.2, "Ethics and consent"). For example, in Canada, approval is often given through an indigenous community resolution, signed by a quorum of council members (see ANNEX D).

Following initial approval by the IP, it

4 ROLES AND RESPONSIBILITIES

4.1 Authority

◆ The internal structures and governance processes of the IP must be recognized and respected. It should be understood that there are differing

Ideally, the committee should represent all relevant community-controlled organizations, in order to avoid undue influence, control or coercion by any one group. This committee also facilitates and promotes the research activity, and keeps itself well informed on relevant issues. Where the IP lack independent funding, the RI may need to provide resources for this purpose, but with the clear understanding that this does not compromise the committee's independence (Foster et al., 1998).

The specific responsibilities of this committee need to be defined according to the local context and type of research. They may include identification of appropriate researchers from the IP to work on the project, covering their training costs if funding permits, facilitating work in the community, playing a role in conflict resolution, and assuming administrative responsibilities in relation to IP involvement. A frequently used mechanism is for members of this committee, plus representatives of the RI, to form a joint steering committee for all purposes related to the management of the research.

4.4 Obligations

The RI has the following obligations:

- to enter into a fair and honest relationship with the IP concerned, and to accept the IP as full partners in the research;
- not to accept funding from any source that could be considered to be detrimental to the interests of indigenous peoples;
- to ensure that the lines of authority within the RI, and channels of communication with the IP, are clearly explained during initial discussions, and that those involved in the research or other designated personnel are available to IP representatives or community members to address any concerns or questions related to the research;
- to ensure that any research jointly undertaken should have clearly identified short-term and long-term health benefits for the IP. This may include arranging for the provision of health care where this is lacking, particularly in a developing country context;
- to inform the IP immediately if it considers that the research cannot, for reasons unforeseen at the outset, meet its original goals and objectives, and cannot provide the expected benefits to the IP. This contingency should be discussed between the parties as part of the research agreement, and a course of action decided on;

anticipated benefits to the community will materialize.

4.5 Expectations

The RI can expect that:

- the research will be satisfactorily concluded with the agreed level of community participation and coopera ê D u 8 n " r”

5

Drawing up a research agreement helps to ensure that the research process is transparent, interests are appropriately balanced, and that all parties reach understanding and agreement on a range of issues. Making a research agreement can also help anticipate and avoid potential conflicts, which might otherwise arise at a later stage. While a research agreement is not a legally binding document, it represents a formal summary of rights, responsibilities, and good faith between the parties. It should be produced in all languages relevant to the IP and the RI.

5.1 Issues to be covered

Below is a list of issues that might be covered by a research agreement; this list is not exhaustive, and may be expanded or contracted according to need. The issues to be included will depend on local conditions and context, and the nature and scope of the proposed health research. Much of the information contained in a research agreement will also be contained in the research protocol and other essential documents presented to the institutional or other ethics review committee. For an example of a research agreement created at the community leadership level, see ANNEX B.

The health research agreement may specify:

◆ the anticipated short-term and long-term benefits to the community, such as information gains, health status gains, interventions to be implemented and systematically evaluated, capacity-building and skills enhancement; a statement on the sustainability of health benefits should be included;

◆ the anticipated short-term and long-term benefits to the RI;

◆ coding, maintenance, and storage of data, in the short and long term, and measures to ensure confidentiality;

◆ access to, ownership of, and restrictions on use of the data during and after the project, including terms and conditions for future use of the data;

◆ identity of the individuals or organizations from the IP to be involved in data analysis and interpretation, and in liaison with the RI;

◆ the extent of involvement and participation of each party (roles and responsibilities), identifying specific obligations and commitments;

◆ type, level, and frequency of interaction between the IP and the RI, for purposes such as discussing concerns and receiving progress reports;

◆ mechanisms to be put in place to ensure regular and effective liaison and communication between the IP and the RI, including conflict resolution mechanisms, and how these will be implemented;

◆ precise time commitments required from community members involved in ae implemented;

5.2 General statement

A concluding statement such as the following can be added:

"The development of this health research activity is based on sincere communication between the two parties. Every effort will be made to address concerns expressed by either party, through the mechanisms outlined above, at each step of the project. Communication on all aspects of the work, including progress reports, will be regularly maintained through the means indicated above. At the end of the study, RI representatives will participate in IP community meetings to discuss the results and their implications."

SIGNATURE (on behalf of the RI)	SIGNATURE (on behalf of the community)
Principal Investigator	
POSITION	POSITION
DATE	DATE

SIGNATURE (on behalf of IP umbrella organization, if appropriate)

POSITION

DATE

Council for International Organizations of Medical Sciences. *International ethical guidelines for biomedical research involving human subjects.* CIOMS, Geneva, 2002 (http://www.cioms.ch/menu_texts_of_guidelines.htm).

Council for International Organizations of Medical Sciences. *[illegible]*

American Indian Law Center. *Model tribal research code with materials for tribal regulation for research and checklist for Indian health boards.* Albuquerque, USA, 1994.

Association of Canadian Universities for Northern Studies. *Ethical principles for the conduct of research in the North.* Ottawa, Canada, 1998.

Battiste M, Youngblood Henderson J. *Protecting indigenous knowledge and heritage. A global challenge.* Saskatoon, Canada, Purich Publishing, 2000 (Purich's Aboriginal Issues Series).

Burgess M, Brunger F with Asch and Macdonald. Section D-1. Negotiating collective acceptability of health research. Ottawa, Canada, Law Commission of Canada, 2001 (http://www.lcc.gc.ca/en/themes/gr/hrish/macdonald/sectionD.asp).

Centre for Indigenous Peoples' Nutrition and Environment (CINE). *CINE response strategy.* Montreal, Canada, McGill University (http://cine.mcgill.ca).

de Sweemer-Ba C. Informed consent:

sound, and that the investigators be competent both to conduct the research and to assure the well-being of the research subjects.

Non-maleficence ("Do no harm") holds a central position in the tradition of medical ethics, and guards against avoidable harm to research subjects.

Justice requires that cases considered to be alike be treated alike, and that cases considered to be different be treated in ways that acknowledge the difference. When the principle of justice is applied to dependent or vulnerable subjects, its main concern is with the rules of *distributive justice*. Studies should be designed to obtain knowledge that benefits the class of persons of which the subjects are representative: the class of persons bearing the burden should receive an appropriate benefit, and the class primarily intended to benefit should bear a fair proportion of the risks and burdens of the study.

The rules of distributive justice are applicable within and among communities. Weaker members of communities should not bear disproportionate burdens of studies from which all members of the community are intended to benefit, and more dependent communities and countries should not bear disproportionate burdens of studies from which all communities or countries are intended to benefit.

Basic responsibilities o

appendix: list of selected ethics guidelines

Health Research Council of New Zealand. *HRC guidelines on ethics in health research.* Specifc issues of concern. 1997. (http://www.hrc.govt.nz/ethguid4.htm).

Maori Health Committee of the Health Research Council of New Zealand. *Guidelines for researchers on health research Involving Maori.* Health Research Council of New Zealand, 1998 (http://www.hrc.govt.nz/maoguide.htm).

National Committee for Ethics in Social Science Research in Health. *Ethical guidelines for social science research in health.* Mumbai, India, Centre for Enquiry into Health and Allied Themes (CEHAT), 2000.

National Health and Medical Research Council. *Guidelines on ethical matters in Aboriginal and Torres Strait Islander health research.* Brisbane, Australia, 1991 (http://www.health.gov.au/nhmrc/publications/synopses/e11syn.htm)

National Health and Medical Research Council. *National statement on ethical conduct in research involving humans*. Brisbane, Australia, 1999 (http://www.health.gov.au/nhmrc/publications/humans/contents.htm; http://www.health.gov.au/nhmrc/publications/synopses/e35syn.htm).

Tri-Council. *Tri-Council policy statement. Ethical conduct for research involving humans.* Ottawa, Canada, Medical Research Council of Canada, Natural Sciences and Engineering Council of Canada, Social Sciences and Humans Research Council of Canada, 1998 (http://www.nserc.ca/programs/ethics/english/policy.htm).
In particular: Section 6: Research involving Aboriginal Peoples (http://www.nserc.ca/programs/ethics/english/sec06.htm).

UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development, and Research Training in Human Reproduction. *Guidelines for the establishment of scientifc and ethical review bodies*. WHO, Geneva, 2000 (http://www.who.int/reproductive health/hrp/SERG_guidelines.en.html).

University of Queensland. *University of Queensland guidelines for ethical review of research involving humans. Research involving Aboriginal and Torres Strait Islander Peoples.* Queensland, 1991 (http://www.uq.edu.au/research/services/human/aboriginal.html).

ANNEX

B

EXAMPLE OF A RESEARCH AGREEMENT CONCLUDED BETWEEN CINE AND AN INDIGENOUS COMMUNITY IN CANADA

(NAMES AND PLACES HAVE BEEN OMITTED)

RESEARCH AGREEMENT

"VARIANCE IN FOOD USE IN …….. COMMUNITIES"

The researchers, as named, and the ….. community agree to conduct the above-

•

6. **Informed consent of individual participants is to be obtained in these agreed ways.**
   - The consent form (copy attached) will be read by the interviewer to the respondent. A copy of the consent form will be left with the respondent so that the addresses of each researcher can be used at any time, should the respondent wish to contact the researchers for additional information.

7. **The names of participants and the community are to be protected in these agreed ways:**
   - As mentioned on the consent form, the interviews are confidential. In no instance will the name of a respondent be attached to a record. Since this project is being conducted in multiple communities in ....., and since one of the objectives is to study the variation in traditional food intake between communities, the communities will be identified by name unless decided otherwise by community members. For example, number codes might be considered.
   - Before distribution of the final report, each community will be consulted once again as to whether the community will be identified with its name, or whether a coding system should be used.

8. **Project progress will be communicated to the community in these agreed ways:**
   - In Summer 1994, the results of the project conducted during the preceding Spring will be presented to participating communities. The researchers will travel to the communities and hold public community meetings to this effect. Similarly, public community meetings will be held in the Summer 1995, d ! sways:

FUNDING, BENEFITS, AND COMMITMENTS

Funding

The main researchers have acquired funding and other forms of support for this research project from:

NAME OF DONOR

CONTACT NAME & ADDRESS

The funding agency has imposed the following criteria, disclosures, limitations, and reporting responsibilities on the main researchers:

- No limitations have been imposed on this project. The researchers must report the project progress to the funding agency twice a year.

Benefits

The main researchers wish to use this research project for benefit in these ways (for instance, by publishing the report and articles about it):

- The researchers will publish a final report to the funding agency in 1995. Scientific presentations in peer-reviewed conferences and publications will be made. The final report will be reviewed by community members prior to publication. Scientific presentations and articles engage only the responsibility of the researchers.

Benefits likely to be gained by the community through this research project are:

- *Educational*
  The community researcher, who will work as interviewer, will be trained in conducting surveys. The community researcher, as well as other community members, will also be trained in the use of a specialized software which can be used to collect and analyze dietary information as well as information from other fields, as needed, within and for the community.

- *Informational*
  The community at large, by focusing on its dietary practices, will learn about the health and cultural attributes of food practices. The information generated by this project will assist individuals in making informed decisions as to

their diets and food practices. The data generated by this project will be kept in the community, and may be used in the future to address new questions or compare changes in dietary practices.

- *Financial*
  The community member(s) employed as interviewer(s) will be compensated at the rate of …… per completed interview.

Commitments

The community's commitment to the researchers is to:

- recommend capable and reliable community members to collaborate/be employed in this project; and
- keep informed on the project progress, and help in leading the project toward meaningful results.

The researchers' main commitment to the community is to:

- inform the community on project progress in a clear, specifc, and timely manner; and
- act as a resource to the community] ų. . e act as esourcl

ANNEX

EXAMPLE OF A FORM FOR OBTAINING INDIVIDUAL INFORMED CONSENT

(NAMES AND PLACES HAVE BEEN OMITTED)

CONSENT FORM

"VARIANCE IN FOOD USE IN …….. COMMUNITIES"

The purpose of our work is to find out the kinds and the amounts of food eaten by the people in ….. communities, and in particular the use by adults and especially those who make maximum use of traditional ….. food. This work will help to define the benefits (nutrition and other values) and risks (contaminants) from the use of wildlife food to the ….. People in the different areas.

At the end of the study the leaders of the project will give a full report to the communities. The researchers will return to the communities for this, and will be available to discuss results from individuals, if they wish.

If you would like to participate in this interview, it will take about one hour of your time to answer questions about the food you eat. All information will be confidential and never publicly attached to your name. Number codes will be used on all forms.

This study will be done by the Centre for Indigenous Peoples' Nutrition and the Environment (CINE) in cooperation with the ….. Nation and the ….. Nation in ….. Funding is provided through ….. [name of donor].

At any time you can refuse to answer any or all of the questions and ask us to leave. The local community interviewer or the community administrator will answer any questions you may have about this study or will refer them to the research supervi-

ANNEX

EXAMPLE OF COLLECTIVE CONSENT OBTAINED FROM AN INDIGENOUS ORGANIZATION

(NAMES AND PLACES HAVE BEEN OMITTED)

[NAME OF IP]

TERRITORIAL BOARD MEETING

[DATE]