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World Health Organization

INDIGENOUS PEOPLES & PARTICIPATORY HEALTH RESEARCH

PLANNING & MANAGEMENT ■ PREPARING RESEARCH AGREEMENTS

DRAFT FOR COMMENTS

Centre for Indigenous Peoples'
Nutrition and Environment

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A large number of institutions and individuals, both indigenous and non-indigenous, have provided comments and feedback on this document. While these are too numerous to name individually, we sincerely thank all who contributed their time and effort in this way.

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A Spanish version of the document is being prepared for circulation and comments.

Further comments and suggestions on this document and its use in the field are welcome, and should be addressed to:

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FOREWORD

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 and the research operations may vary, requiring additional management layers, the fundamental principles remain unchanged for both developed and developing countries.

This document does not purport to address in depth questions over which national and international consensus is still lacking – for example intellectual property rights in the sphere of traditional knowledge or human genome research – or to advise specific courses of action in those areas. It is not intended to be prescriptive or definitive, but to alert researchers to some of the specificities of research with Indigenous Peoples, and conversely, to inform Indigenous Peoples about what they can legitimately expect and require in the context of a collaborative research project.

Many questions were raised during the drafting and review process that are outside the scope of this document. For instance, what exactly constitutes a community? How can the principles outlined here be accommodated where research encompasses both indigenous and non-indigenous participants? What should be done in the case of indigenous populations that are widely dispersed or that straddle national borders? What is the role of a research agreement in circumstances where national ethics guidelines are not yet in place? Discussion on these and other broad questions can usefully be continued at both national and international level.

PREFACE

This document aims to help fill a gap in the field of research management identified 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 scientific 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 fields of research involving Indigenous Peoples.

The need for research agreements stems from problems encountered in research that many Indigenous Peoples feel are specific to their cultural and political situation, and that are not sufficiently covered by scientific 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 benefits 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 signed agreements between the parties. As such, they provide an opportunity for full discussion, exploration, and clarification of all aspects of the proposed research, from both the researchers' and the population's perspective. This process facilitates mutual understanding, trust, and the acceptance by all parties of their duties and responsibilities. It also helps to develop a sense of joint ownership of the research process, leading to more mutually satisfactory outcomes.

Two main benefits can be envisaged from a wide adoption of these principles for participatory research management. First, promoting a more equitable

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 and improving health problems and outcomes through mutually identified and agreed approaches and interventions.

All health research involving humans requires ethics clearance in accordance with established national mechanisms. This involves peer-review of research proposals and clearance through an ethics review board or committee. **This document is not intended as a substitute or replacement for national and international medical research ethics procedures.**

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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 the development process (UNDP, 2000).

Participatory research:

a research process that endeavours to balance interests, benefits and responsibilities between the IP and the RI concerned, through a commitment to equitable research partnership. The term "participatory research" carries the implication that the entire process, from planning to reporting, will be transparent and accessible to all parties involved. This has also been referred to as "collaborative research."

Indigenous Community:

a group or groups of indigenous people which may share cultural, social, political, health, or economic interests, but not necessarily a particular geographic location.

Research Institution:

a nationally or internationally recognized institution or organization (academic, government, non-profit), a primary objective of which is to undertake research, for the purposes of advancing health knowledge, facilitating health policy-making, or creating strategies and solutions to health problems and conditions relevant to the study population.

Peer review:

review and critique of a research proposal or text for publication by persons with similar (peer) or relevant background.

1.3 AUDIENCE

The document has two primary target audiences:

◆ Research institutions: to increase their awareness of the particularities of health research with IP, which are not adequately reflected in existing guidelines on the research process;

◆ Indigenous Peoples: to enhance their awareness of their interests and potential role within a collaborative health research process.

1.4 IMPLICATIONS FOR DEVELOPING COUNTRIES

The information in this document is based on experiences with IP in developed countries, with clearly identifiable 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.

◆ In some parts of the developing world, there is less clarity over the concept of "indigenous". However, the provisions of this document can be applied to research involving any marginalized groups with sociocultural or political systems and practices distinct from those of the mainstream population in a country.

◆ Mechanisms for ethical review may be weak or non-existent in some developing countries. In addition, Indigenous Peoples and other marginalized populations in such countries are not likely to be familiar with research management procedures or the ethical requirements of the research process. The research institutions and national authorities have a particular responsibility to adhere strictly to high ethical standards, and to take special measures to inform their prospective indigenous partners about the provisions of national or international guidelines. Holding seminars on these issues at national, subnational, or local level has been suggested as a suitable way of beginning to address this information gap.

◆ Indigenous Peoples and other marginalized populations in developing countries frequently lack independent resources, infrastructure, and political representation. Many live in remote areas in conditions of poverty. They are unlikely to be in a position to contribute financially to a collaborative research process, as do some IP in industrialized countries. This should in no way affect their status as full collaborative partners.

◆ Every effort should be made to obtain information from the Indigenous Peoples or marginalized populations themselves on their health problems and priorities; only if direct access is problematic should third parties be approached in this respect.

◆ As noted by the WHO Advisory Committee on Health Research (ACHR) (WHO, 2002), there is a substantial international consensus that research should be done in developing countries only if it has potential benefits for the local population. Research in developing countries should be directed at health problems in those countries; the benefits of the research should be available to the research participants and to the broader community in which the research takes place. The means by which this will be ensured should be worked out between the investigators and representatives of the community prior to commencement of the research, and should be detailed in the initial informed consent process.

◆ WHO recognizes that special attention needs to be given to the ethical aspects of research in a developing country context and that ethical issues need to be addressed within the relevant national and social context. The context will differ between developed and developing countries, as well as among developing countries. The populations of very poor developing countries are especially vulnerable to economic exploitation by developed countries or outside organizations and corporations, whose primary mission is not related to the health of the people.

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 for the purpose.

This situation is further complicated by the lack, in many developing countries, of strong regulatory mechanisms, such as ethics review boards or committees.[2] An important priority for all developing countries is to develop the necessary regulatory structures to address both the scientific and the ethical dimensions of research. ANNEX A contains a summary of the essential provisions of international ethics guidelines, as well as a listing of some relevant national guidelines.

2. Recognizing this lack, Family Health International in the USA recently developed a Research Ethics Training Curriculum (Rivera et al., 2001). Its purpose is to increase the capacity in developing countries to address issues of research ethics. This work will be helpful for those wishing to expand their knowledge on human research ethics, or to operationalize these procedures.

GUIDING PRINCIPLES FOR PARTICIPATORY HEALTH RESEARCH

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 collectivity or to individuals. National ethical guidelines, such as those developed in Australia, Canada and New Zealand, provide information on a wide range of requirements for working with IP. Details of such guidelines are given in the Appendix to ANNEX A.

◆ Informed individual consent should be obtained in accordance with accepted ethical procedures. For complex issues, the process may need to be field-tested. Consent is truly informed when the person understands (a) the purpose and nature of the study, (b) what participation in the study requires him or her to do and to risk, and (c) what benefits are intended to result from the study (CIOMS, 1991). The boundaries of the consent obtained should not be exceeded, for example by using information provided in an informal context and not intended for research purposes.

◆ 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 consent, should be discussed and agreed jointly by the research partners. For some types of research, or in the event of oral consent, a witness may be required. In all situations, the consent form should be read to potential participants in an acceptable manner and language, and at a level and speed that permit comprehension. Clarification should be provided as needed, and the procedure should not be rushed. Participants should fully understand that they can continue or end the interview at any time, and that they may agree or refuse to participate without penalty (Tri-Council, 1998).

◆ The research will, in addition to the informed consent of individuals, require the consent of recognized representatives of the IP. This is commonly done at community leadership level, through the indigenous community's own internal procedures. In the model used in this document, community consent is obtained through the process of creating a research agreement. Whatever the process used, a description of it should be included in the documents submitted to the ethics review committee when seeking approval for the research.

◆ A third level of consent should be sought from a wider indigenous organization (umbrella organization), if this exists. As well as providing additional collective consent, this measure ensures that a larger collective is informed about and consents to the research; this larger group may be in a position to assist in a variety of ways. Obtaining consent from community leaders or an umbrella organization is *not*, however, a substitute for securing the consent of individual participants. Neither is consent from an umbrella organization a substitute for consent from the community leadership. Depending on the structure of the indigenous community concerned, it may be necessary to obtain three levels of consent: from individuals, from the community, and from an umbrella organization. With simpler structures, the consent of individuals and community leadership may suffice.

◆ Where the main contact is between an RI and an umbrella organization authorized to represent regional or local IP groups or communities, the umbrella organization must be able to demonstrate to the RI that they have the collective consent of the groups or communities concerned (see ANNEX D as an example). The RI should have evidence of how consent is obtained from the communities that will participate in the research. Problems or concerns related to the research raised by individuals must be addressed by the RI at that level, and not exclusively through the umbrella organization.

◆ Even when collective consent has been obtained, it can be withdrawn in cases where conflict between the parties cannot be resolved or there is clear violation of ethical principles. For

projects of long duration, collective consent should be reaffirmed periodically. It is the shared responsibility of the IP and the RI to ensure that research does not proceed without the collective consent of the communities involved, provided through their recognized representatives.

◆ Research activities should be conducted in a mutually understood and agreed language. Any data and final reports held by the IP should be in a language and format that can be utilized by them independently of the researchers.

◆ Confidentiality should be ensured through an appropriate data-coding system, and by limiting access to the data. Individuals who have access to confidential data should undertake to respect that confidentiality.

◆ The boundaries of use of any information given by the IP to the RI should be agreed by both parties. For example, a community may restrict discussion of specific topics, or limit the number of individuals authorized to speak on certain cultural issues. If an individual recognized by the community as having the right to speak provides information that is subject to such restrictions, the researchers should respect the wishes of the community (Piquemal, 2001).

◆ Considerable debate is ongoing at national, regional, and international levels on intellectual property rights, particularly in relation to access to genetic resources and benefit-sharing, and the protection of traditional knowledge. It is beyond the scope of this document to address these questions in detail. However, it is generally agreed that current arrangements are inadequate, and consensus is building that all research should be based on appropriate benefit-sharing agreements, preferably defined in advance between the research sponsors and local representatives (WHO, 2002). The work of the World Intellectual Property Organization (WIPO) on genetic resources and associated traditional knowledge is directly relevant to this issue (see box, opposite).

◆ Issues related to intellectual property rights and benefit-sharing should be discussed fully by the research partners in the light of the nature of the knowledge or information to be provided by the IP, its current and potential economic implications, and national and international legal provisions and recommendations in this domain.

◆ As a key principle, the RI must be open about potential economic benefits originating wholly or in part from information obtained from research with the IP. Research agreements should indicate whether the research is expected to produce short-term or long-term economic benefits. If so, the research agreement should provide for a fair profit-sharing agreement.

PROTECTING TRADITIONAL KNOWLEDGE

While specific recommendations on protection of intellectual property rights are beyond the scope of this document, it is important to point out current concerns about exclusive reliance on western models. The protection of traditional medical knowledge has been intensively discussed in the WTO TRIPS Council, in the context of the review of Article 27.3(b) of the TRIPS Agreement. Among the issues relevant to traditional medical knowledge are the following:

(a) protection of traditional knowledge, either through existing forms of intellectual property rights or other laws, or through a sui generis form of protection;

(b) prevention of improper patenting of public-domain traditional knowledge and plant genetic resources, including through the documentation and publication of such knowledge and resources (as part of searchable prior art);

(c) the relationship between the TRIPS Agreement and the Convention on Biological Diversity in general, and the operational implementation of the provisions of prior informed consent and fair and equitable benefit-sharing, as set out in Article 8(j) of the Convention on Biological Diversity (CBD) in particular;[a]

(d) the relationship between the work in the TRIPS Council and intergovernmental discussions on this issue, such as in the CBD, WIPO, FAO, and UNCTAD (WHO/WTO, 2002).

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore is a valuable source of information on this topic. (http://www.wipo.int/globalissues/index.html)

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 knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices, and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices"(http://www.biodiv.org).

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 modifications in accordance with their needs, insofar as changes do not bias the research.

◆ The goals, objectives, and methods of the research should be agreed between the partners. The research process (planning, design, methods, consent forms, data forms, data collection, analysis, interpretation, dissemination and reporting) should be open and collaborative. In-depth consultation with community representatives, leaders, and members should be undertaken to ensure "informed collaboration and to refine research questions, data collection instruments and frames for analysis" (O'Neil et al., 1993). The IP should define the degree of involvement they envisage (Scott & Receveur, 1995).

◆ Work should not start until the research has been authorized by the national, regional, or local research ethics committee, and any research agreement planned between the parties has been drawn up and signed.

2.4 BENEFITS

◆ The benefits of the research should include:

a) improved health status or services for the research population, or prospects of such improvement within a defined period of time through interventions discussed and agreed with the IP. The benefits, and the timeframes involved, will depend on the type and scale of the planned research;

b) resources and funding for the training, employment (where appropriate capacities exist), and general capacity-building of community members in all aspects of the research process. In the past, community members have generally been employed in a token way, or in areas such as translation and data collection. This does not allow them to obtain a full understanding of the research process.

◆ Benefits to both the RI and the IP include publication and dissemination of research findings and methodologies, the development of interventions and, for RIs, peer acknowledgement of contributions to the advancement of medical and public health knowledge.

◆ Prior to publication, both the IP and the RI should have the opportunity to review manuscripts and comment on the interpretation of the data.

◆ Depending on the type of research, economic benefits may be anticipated in some cases. The equitable distribution of these benefits should be agreed and reflected in the research agreement.

3 COMMUNICATING ABOUT RESEARCH

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. In some developed countries, centres or institutions for research involving IP have been established. In developing countries, if direct access to public or community health departments at a nearby university or health institute is not feasible, community health concerns may best be addressed first to the local authorities. If communities are making their concerns known at international level, an intergovernmental organization or international nongovernmental organization (NGO) may be instrumental in bringing these concerns to the attention of the appropriate national or sub-national authorities.

3.2 INITIATION BY A RESEARCH INSTITUTION

If researchers without previous experience of working with a particular indigenous group are interested in pursuing a research topic with that group, they should first ascertain if there is an appropriate indigenous institution to consult. In some developed countries, extensive indigenous-controlled structures are in place. A phone call or visit should be made to the research office, if one exists, or to the head of the health department or to the local leaders to discuss the possibility of collaboration.

In developing countries, an independent indigenous infrastructure is uncommon. If direct contact with the community is not feasible, an approach to local government departments may be the best channel. Local NGOs may in some cases be able to provide advice on how the RI could establish appropriate initial contacts with indigenous communities.

3.3 PRESENTATION OF A RESEARCH IDEA

Any agreed research topic should be of relevance to the health status and needs of the IP. This is likely to be the case if the initial approach is made by the IP. If the first approach is made by the RI, consultations with the IP concerned over the research ideas and goals should take place *before* a research proposal is drawn up (Maori Health Committee of the Health Research Council of New Zealand, 1998). These are important in allowing community members to question openly the value and benefit of the research to them. If a draft research proposal has already been formulated by the RI, the IP should have the opportunity to propose alterations to suit their needs.

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 may be useful for the parties to jointly prepare a research agreement. This helps to ensure that all steps of the research activity are understood, and agreed conditions and responsibilities on each side are clearly spelled out. This process is usually carried out between an indigenous committee formed for the purpose, or its designated representatives, and representatives of the RI.

ROLES AND RESPONSIBILITIES

Both the RI and the IP have the responsibility to enter into a fair, honest, and respectful relationship with each other, in a spirit of true collaboration.

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 viewpoints in every community, and that the opinions of community leaders or councils may not be shared by everyone. In situations where there is known to be dissent within the community, it remains with the IP to decide who will speak on their behalf. Difficulties of this kind are likely to require a lengthy consultation period to identify who will represent a community and to ensure that all voices are heard.

◆ The lines of authority within the RI must be clarified to the IP. Details of contact persons at a suitably senior level, and modes of access to them, should be made clear.

4.2 CONFLICT RESOLUTION

◆ ***Among IP:*** where different representatives or authorities of the IP cannot agree, the RI should proceed only if adequate assurance is obtained from community leaders that this will not harm the IP, will generate the anticipated benefits, will not disrespect "local ethics", and will not bias the results (for example through exclusion of a significant portion of the population), and that there is adequate support within the community to bring the research to a conclusion.

◆ ***Between the IP and the RI:*** one of the purposes of preparing a research agreement is to anticipate areas where conflict may arise. In the event of conflict, both parties have the right to expect that a fair and concerted effort will be made to resolve the issue through all available mechanisms, either separately or jointly. The involvement of ethics committees or other neutral parties may be required. The research should continue unless there has been a clearly demonstrated violation of ethical principles by the RI, or both parties agree that its continuation is no longer in the interests of the community. Concerns expressed by individuals must be directly addressed by the RI at community or individual level, and not exclusively through an umbrella IP organization.

4.3 LIAISON

A critical aspect of the research partnership is ensuring that communication between the parties does not break down. Frequently, the IP will select a committee to follow the research and maintain communication with the RI.

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;

◆ where the IP do not possess the resources or capacity to provide infrastructural support or to negotiate independently, to ensure, together with the national authorities, that the IP are adequately involved, supported and protected in the research, in line with national and international ethics guidelines as well as the principles of this document;

◆ to provide opportunities for the IP to review and comment on research findings prior to publication;

◆ to uphold the highest standards of research and act in strict accordance with national and international ethical guidelines, as well as with local indigenous ethics.

The IP have the following obligations:

◆ to inform the RI immediately if, following internal consultations, they decide to withdraw from the research, and to provide the reasons for this decision;

◆ to facilitate the research activity by all possible means, to ensure that its

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 cooperation, provided that there are no changes in the agreed approach, expected outcomes, or anticipated benefits;

◆ where prior agreement designates the IP as the final owner of research data, requests by the RI for further use of the information will be considered and authorized by the IP. Such requests should be discussed and agreed in advance, and confirmed by the relevant research ethics mechanisms in accordance with usual research procedures.

The IP can expect that:

◆ the stated health benefits of the proposed research will be made available to them, and that suitable economic benefit-sharing agreements will be put in place;

◆ capacity-building and skills enhancement will form part of the research process;

◆ where the IP do not have their own resources and capacity, the RI or donors will assume all costs related to the research, without placing any limitation on the status of the IP as a full collaborative partner;

◆ participants in a joint research activity who have contributed in a significant capacity (e.g. through conceptual work, interpretation of data, writing up of findings) will be associated with the published findings, and either acknowledged in the manuscript or named as co-authors, as appropriate to the contribution made.

◆ Ideally, agreements between the IP and the RI should be made with the expectation of a commitment to a long-term and mutually beneficial relationship focused on the protection and promotion of indigenous health. Both partners should do everything possible to ensure the physical safety of all who participate in the research process.

5

PREPARING A HEALTH RESEARCH AGREEMENT

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 identities of the parties making the agreement;
- that a community representative will be present during meetings of the ethics committee that reviews the proposed research, in accordance with ethics guidelines;
- the source and any conditions of the funding for the research, and reporting obligations by the RI;
- the relevance of the research to both parties;
- the broad purpose, goals, scope, and duration of the research;
- the types and extent of activities the research will involve;
- the expected outputs and products, which will depend on the nature and purpose of the research;
- potential risks or problems for the community;
- the research methods and procedures involved, including purpose and number of interventions or interviews;
- the profile of the required research participants and how these will be selected;
- a description of the individual informed consent form (language, style), its content (see example in ANNEX C), and the process by which informed consent will be obtained;
- a description of the levels of collective consent required, and how it will be obtained;

◆ 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 the research in various capacities, and amount of financial or other compensation (if any) to be paid to them; financial compensation should not be excessive in relation to local living standards;

◆ respective financial and logistic responsibilities of the partners (e.g. salaries, equipment, office space, accommodation, supplies, transport, health care costs), including payment modalities;

◆ conditions relating to dissemination of the research findings to the IP and third parties, including media;

◆ conditions relating to formal publication (including whether the IP will be identified and how any differences in interpretation of the data will be addressed);

◆ provisions for benefit-sharing in circumstances where intellectual property rights or other forms of economic gain may be expected to result from the research, in the short or long term;

◆ the course of action to be followed by both parties if the research is stopped due to an unforeseen inability to reach its objectives, or as a result of a collective decision by the IP that they no longer wish to participate.

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

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ANNEX

KEY ELEMENTS OF RESEARCH ETHICS PROCEDURES & GUIDELINES

All public health and biomedical research should conform to established national or international scientific and ethical standards, a brief overview of which is given below. These standards, together with specialized guidelines on research with indigenous peoples developed by countries such as Australia, Canada, New Zealand and the United States of America, form the foundation for this document.

National and international standards and guidelines are reviewed and updated periodically. This annex draws extensively on the Council of International Organizations of Medical Sciences' *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, and *International Guidelines for Ethical Review of Epidemiological Studies* (see References). These are commonly used in circumstances where adequate national ethics guidelines do not exist. They also frequently serve as the basis for preparation of national ethics guidelines. A number of national and other guidelines on ethics are listed in the appendix to this annex.

GENERAL ETHICAL PRINCIPLES[3]

All research involving human subjects should be conducted in accordance with four basic ethical principles, namely *respect for persons, beneficence, non-maleficence, and justice*. It is usually assumed that these principles guide the conscientious preparation of proposals for scientific studies. In varying circumstances, they may be expressed differently and given different weight, and their application, in all good faith, may have different effects and lead to different decisions or courses of action.

Respect for persons incorporates at least two other fundamental ethical principles, namely:

a) autonomy, which requires that those who are capable of deliberation about their personal goals should be treated with respect for their capacity for self-determination; and

b) protection of persons with impaired or diminished autonomy, which requires that those who are dependent or vulnerable be afforded security against harm or abuse.

Beneficence is the ethical obligation to maximize possible benefits and to minimize possible harms and wrongs. This principle gives rise to norms requiring that the risks of research be reasonable in the light of the expected benefits, that the research design be

3. Reproduced from CIOMS, 2002.

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 of ethical review committees

The basic responsibilities of ethical review committees are:

◆ to determine that all proposed interventions, particularly the administration of drugs and vaccines or the use of medical devices or procedures under development, are acceptably safe to be undertaken in humans or to verify that another competent expert body has done so;

◆ to determine that the proposed research is scientifically sound or to verify that another competent expert body has done so;

◆ to ensure that all other ethical concerns arising from a protocol are satisfactorily resolved both in principle and in practice;

◆ to consider the qualifications of the investigators, including education in the principles of research practice, and the conditions of the research site with a view to ensuring the safe conduct of the trial; and

◆ to keep records of decisions and take measures to follow up on the conduct of ongoing research projects.

Membership of ethical review committees

The CIOMS Guidelines stipulate that, as well as physicians, scientists and other professionals such as nurses, lawyers, ethicists and clergy, membership of ethical review committees should include lay persons qualified to represent the cultural and moral values of the community in which the research will take place and to ensure that the rights of the research subjects will be respected. They further state that a national or local ethical review committee responsible for reviewing and approving proposals for externally sponsored research should have among its members or consultants persons who are thoroughly familiar with the customs and traditions of the population or community concerned and sensitive to issues of human dignity. These provisions are of particular relevance to research involving indigenous populations.

CIOMS GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

The 21 guidelines and related commentaries were updated in 2002. Of special interest and relevance to health research involving Indigenous Peoples are Guidelines 3, 4, 5, 6, 8, 10, 12, 13, 18, and 20.

CIOMS GUIDELINES	
1	Ethical justification and scientific validity of biomedical research involving human subjects
2	Ethical review committees
3	Ethical review of externally sponsored research
4	Individual informed consent
5	Obtaining informed consent: essential information for prospective research subjects
6	Obtaining informed consent: obligations of sponsors and investigators
7	Inducement to participate in research
8	Benefits and risks of study participation
9	Special limitations on risk when research involves individuals who are not capable of giving informed consent
10	Research in populations and communities with limited resources
11	Choice of control in clinical trials
12	Equitable distribution of burdens and benefits in the selection of groups of subjects in research
13	Research involving vulnerable persons
14	Research involving children
15	Research involving individuals who by reason of mental or behavioural disorders are not capable of giving adequately informed consent
16	Women as research participants
17	Pregnant women as research participants
18	Safeguarding confidentiality
19	Right of injured subjects to treatment and compensation
20	Strengthening capacity for ethical and scientific review and biomedical research
21	Ethical obligation of external sponsors to provide health-care services.

Appendix 1 to the Guidelines details items to be included in a protocol (or associated documents) for biomedical research involving human subjects.

The CIOMS *International Guidelines for Ethical Review of Epidemiological Studies* (1991) are based on the same general ethical principles, but outline how these are applicable to epidemiological, rather than biomedical, research.

Core documentation required by ethics review committees

The following is a brief summary of the *minimum* items required for submission to an ethics review board or committee. Additional items that may be required will depend on the nature and scope of the proposed research.

The core documentation should include:

- the research proposal, showing the exact methods and procedures to be followed;
- evidence that the investigators' education and experience are appropriate for the proposed research;
- a statement on potential risks, demonstrating that they are within acceptable limits and are justifiable in relation to the anticipated benefits to participants, and to the role of the research in furthering global knowledge;
- a statement that no unethical deception of participants is involved, and no exaggeration of proposed benefits;
- a description of how confidentiality will be protected;
- a statement of how free and informed consent will be obtained. This will include
- the informed consent form to be used, describing the aims and objectives of the research, the procedures to be undertaken, and how this will be presented to participants;
- the informed consent form should contain the following elements:

  i) a statement indicating that participation is voluntary, obtained without institutional or social pressure, and that there are no penalties for non-participation;

  ii) a statement of any risks that may be incurred during or following participation;

  iii) a statement of any inducements or compensations for participation;

  iv) a statement confirming that participation can be withdrawn at any time, for any reason, without penalty;

  v) a statement on protection of privacy through strict confidentiality of the data;

  vi) an indication that only information or samples described in the informed consent form can be obtained without additional review and approval by the ethics review committee;

  vi) information on contacts within the RI for participants in case of questions or concerns.

For research involving IP, this essential documentation would also include proof of collective consent, and a copy of the research agreement, if one exists.

APPENDIX: LIST OF SELECTED ETHICS GUIDELINES

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

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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-named research project with the following understanding:

1. **The purpose of this research project, as discussed with and understood by ..... in the community, is:**
   - to improve the understanding of how food practices convey different benefits or risks from a nutrients/contaminants point of view and also culturally and economically; and
   - to establish a baseline dietary intake against which future dietary studies could be compared to assess changes in food intake; and
   - to identify food/nutrition related concerns and potential food/nutritional problems in the community.

2. **The scope of this research project (that is, what issues, events, or activities are to be involved, and the degree of participation by community residents), as discussed with and understood by ..... in this community, is:**
   - The issues in this project are nutritional and will be addressed through organizational meetings with community members and dietary interviews of a sample of adult men and women which will be conducted in Fall 1994 and possibly in Spring 1994 as well.
   - The communities participating in Spring 1994 are a subset of all communities which participate in the Fall 1994. The community can elect to participate in both series of interviews or in the Fall 1994 only.

- To participate in Spring 1994, the community must select one member who will be employed as interviewer by the project and will participate in a training workshop to be held in ….. in February 1994 (exact date to be announced).
- Community members who will participate as respondents will volunteer approximately one hour to participate in the interview.

3. Methods to be used, as agreed by the researchers and the community, are:

- A member of the community will be employed by the project to conduct dietary interviews of one adult man and one adult woman from each randomly selected participating household during at least one season (Fall 1994) and possibly two seasons if the community decides to participate also in Spring 1994.
- The dietary interview takes approximately one hour to administer, is confidential and voluntary. Questions are asked about the frequency of traditional food consumption, the dietary intake in the day preceding the interview, and a series of questions on the family and cultural attributes of traditional foods.

4. Community training and participation, as agreed, is to include:

- One community member will attend the ….. training workshop in February, 1994, a 2-day training session in dietary interview methodology.
- The interviewer will learn techniques common to any survey methodology as well as techniques specific to this particular project.
- It is also within the goals of this project to develop community capabilities to conduct and analyze their own data. Software to aid in this process will be made available to community members. Additional training on the use of this software (EpiInfo) will be offered.
- The development of this project is based on sincere communication between community members and researchers. All efforts will be made to incorporate and address local concerns and recommendations at each step of the project.
- At the end of the project, the researchers will participate in community meetings to discuss the results of the analysis with community members.

5. Information collected is to be shared, distributed, and stored in these agreed ways:

- The data collected are confidential and no name is attached to a record. Copies will be kept at CINE where the data will be converted to an electronic form. The data will be kept on diskettes at the band office and at CINE. The researchers and CINE will be available to answer questions and assist community members should community members decide to use these data for different purposes, beyond the objectives of this particular project.
- A final report will be distributed after approval from the community members.

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, in all participating communities, to report on the overall project results.
   - Each researcher will also be available during the course of the project to address particular questions that may arise.

9. **Communication with the media and other parties, (including funding agencies) outside the named researchers and the community, will be handled in these agreed ways:**
   - The funding agency ..... organizes two meetings a year during which the project progress is summarized. In these meetings, as well as during any public communication on project progress and findings, the researchers will be aware of their responsibilities and commitments to the welfare of the communities involved.

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, specific, and timely manner; and
- act as a resource to the community for nutrition-related questions.

The researchers agree to stop the research project under the following conditions:

- if community leaders, for example the Chief and Council, decide to withdraw participation; or
- if the researchers believe that the project will no longer benefit the community.

DATE	DATE
SIGNATURE(S) OF MAIN RESEARCHERS	SIGNATURE(S) OF COMMUNITY CONTACT PERSON(S)
SIGNATURE(S) OF WITNESSES	SIGNATURE(S) OF WITNESSES

ANNEX C

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 supervisors, whose contact details are shown below.

RESEARCH SUPERVISORS

(REPRESENTING THE RI)	(REPRESENTING THE IP)
1. _____	1. _____
2. _____	2. _____

DO WE HAVE YOUR PERMISSION TO BEGIN? YES ☐ NO ☐

_____
RESPONDENT'S SIGNATURE

_____
RESPONDENT'S NAME

_____
HOUSE NUMBER

_____
COMMUNITY

Interviewer, once you have given a copy of the consent form to the respondent, please initial this form: _____ (*your initials*). This acknowledges that you have read the consent form to the respondent in language that the respondent, to the best of your knowledge, understands, and that you have provided the respondent with a written copy in English.

INTERVIEWER, KEEP THIS FORM ATTACHED TO THE FIRST QUESTIONNAIRE AND USE IT TO CHECK THE RECORD FOR COMPLETENESS. THE FIELD SUPERVISOR WILL CHECK AGAIN.

_____
RESPONDENT'S ID

	CHECK WHEN COMPLETED	
Interviewer	Supervisor	
I. Frequency of Traditional Foods Use	☐	☐
II. Individual 24-hr recall	☐	☐
III. Sociocultural Questionnaire	☐	☐

ANNEX

D

EXAMPLE OF COLLECTIVE CONSENT OBTAINED FROM AN INDIGENOUS ORGANIZATION

(NAMES AND PLACES HAVE BEEN OMITTED)

[NAME OF IP]

TERRITORIAL BOARD MEETING

[DATE]

MOTION

WHEREAS ….. of the ….. rely on traditional country food in the way of caribou, moose and fish to supplement their diets and to remain in touch with the land;

AND WHEREAS recent studies, such as the [*name of study*] funded by ……, and other research, have indicated that industrial contaminants such as cadmium, mercury, organochlorines (DDT and toxaphene), and other man-made chemicals are present in virtually all parts of the food chain;

AND WHEREAS the missing gap to date in relating the scientific studies to the human health issue is the lack of dietary or consumption data for the various communities in the ……. In other words, how much contaminated country food is being consumed;

AND WHEREAS one of the objectives of the …… Program is to protect the health of Canada's northern people and northern ecosystem, as related to food chain contamination by taking action to implement a focused research program which includes a commitment to responsible northern research to quantify the effects of contaminants to the arctic ecosystems and the relative risks and benefits to humans from the consumption of harvested animals which may contain contaminants in order to develop human health and environmental protection measures;

AND WHEREAS another objective of the …….. Program is to provide timely advice to northern native people regarding benefits and potential risks of consumption of country foods in order to support their preferred way of life;

AND WHEREAS the Centre for Indigenous Peoples' Nutrition and the Environment (CINE) at McGill University is an independent research and training centre established with funding from … to conduct community-based research and provide training on the diets, nutrition and environmental health of native people, with special emphasis on the Arctic;

AND WHEREAS the ..... Nation is in an excellent position to propose a specific project relating to a dietary survey in the [*place*];

AND THEREFORE BE IT RESOLVED that the … Nation work with the Centre for Indigenous Peoples' Nutrition and the Environment (CINE) at McGill University to develop a research project to define the levels of consumption of fish and other traditional foods in … and … communities to therefore understand the extent of traditional food use in order to define contaminant and nutrient intake, so that timely advice regarding benefits and risks of food consumption can be made.

AND BE IT FURTHER RESOLVED that application for funding of the research be made to [*donor*] no later than January 29, 19....

MOVED BY: _____

SECONDED BY: _____

MOTION CARRIED UNANIMOUSLY :

_____

Date: _____