**Unit 22**

**Hand-out 1: Free, Prior and Informed Consent**

#### Introduction

The concept and practice of informed consent has been developed in various contexts, including biomedical and behavioural research, medical practice, international trade and human rights. Each field has its own particular codes of conduct, which arose from different historical precedents of coercion, manipulation, withholding of information and so on. This hand-out briefly reviews the background of some important codes and conventions to identify what essential features they have in common.[[1]](#footnote-1) It also offers operational definitions of ‘free, prior and informed consent’. Finally, this hand-out highlights some of the challenges in implementing free, prior and informed consent.

#### Background

The Nuremburg Code (1949)[[2]](#footnote-2) and the Belmont Report (1979)[[3]](#footnote-3) were developed to protect the rights of the individual as a participant in biomedical and behavioural research. The Nuremburg Code emphasizes the following elements of informed consent: the individual’s legal capacity to give consent, the free power of choice, and sufficient knowledge and comprehension to have understanding and make an enlightened decision. The Belmont Report (1979) acknowledges individual autonomy and seeks to protect those with diminished autonomy. Autonomy is the capacity of a rational individual to make an informed, un-coerced decision.

Similarly, in medical practice, informed consent is the idea that a person must be fully informed about and understand the potential benefits and risks of his or her choice of treatment. An uninformed person is at risk of mistakenly making a choice not reflective of his or her values or wishes.

There are international conventions that address informed consent beyond the level of the individual (i.e. for nations, communities, ethnic minorities, etc.). The Rotterdam Convention (1988)[[4]](#footnote-4) is an inter-governmental agreement that promotes sharing responsibility and information regarding the trade of toxic materials between nations. One of its key provisions is a procedure for prior informed consent such that parties may make informed decisions about whether to allow the import of hazardous chemicals. The convention calls for an open exchange of information, including proper labelling of hazardous chemicals, instructions for their safe handling and details about any restrictions or bans on certain chemicals.

Prior informed consent has also been used in the protection of the rights of indigenous peoples and traditional/local knowledge. The Indigenous and Tribal Peoples Convention (1989)[[5]](#footnote-5) includes the basic ethical principles of respect and participation. Respect for indigenous peoples includes recognition of their right to exercise control over their cultural, social and economic development. The Convention requires governments to consult with indigenous peoples and ensure their informed participation in planned development activities on their lands and resources. Relocation may not occur without their free and informed consent.

The Convention on Biological Diversity also emphasizes the principles of respect and participation in the context of intellectual property rights and access to traditional knowledge.[[6]](#footnote-6) It attempts to ensure ‘fair and equitable sharing’ of benefits from genetic resources between local communities and outsiders. Prior informed consent allows community involvement in decision-making about the use of traditional knowledge.

Despite the widespread recognition of the importance of this practice, there are currently no protocols for informed consent in community-based inventorying. In other fields, this practice has been called ‘informed consent’ (e.g. in medical practice and social research), ‘prior informed consent’ (e.g. in the Convention on Biological Diversity) and ‘free, prior and informed consent’ (e.g. in the UN Permanent Forum on Indigenous Issues).

The use of informed consent is motivated by ethics. As mentioned in Units 7 and 8, ethics are norms of conduct and professional practice. community-based inventorying practitioners, like other professionals, have specialized training which involves certain moral responsibilities. One of these responsibilities is ensuring that participation is achieved through open, honest and voluntary processes. Thus, a code of ethics for community-based inventorying must include the development of standard protocols for free, prior and informed consent.

#### Definitions and operational issues

Although there are many common ethical principles shared in these different contexts, an operational definition of ‘free, prior and informed consent’ is not as straightforward as it may seem. Practitioners of community-based inventorying should be aware of certain questions that arise in the analysis of this concept.

‘Free’ means that people have a choice to participate. How can this be ensured in practice? What can be done to verify that consent was freely obtained? Who obtains consent? Who gives consent? Could the community designate a third party as responsible for obtaining consent?

‘Prior’ means advanced notice, which is necessary to allow time for deliberation and negotiations. How much time in advance is needed? Clearly understood yet flexible schedules are essential for the participatory process.

‘Written’ means that the process is formally documented. The documentation of consent raises both legal and operational issues, which may vary depending on the project context. Is a written, legally binding document necessary? How can consent be negotiated and documented in an oral society? What if people are reluctant to be pinned down in writing?

‘Informed’ means open, understandable, two-way communication. What information must be provided? In what form should information disclosure take place? Information and concepts must be communicated in a language understandable to the community. Participants must understand the proposed activities and their relevant rights. Participants must also know and understand both positive and negative outcomes.

‘Consent’ means general agreement among all members of the community. How is consent given and who gives the consent? How can negotiations maintain trust and legitimacy? How detailed should any statement or agreement be? Consensus should be achieved according to customary laws and practices. This follows the basic rule of ‘handing over the stick’, or giving ownership and control of the process to the participants. However, issues of empowerment and potential exploitation should not be overlooked.

#### Other challenges

There are many other challenges in the implementation of informed consent. Several issues have been outlined by Firestone (2003)[[7]](#footnote-7) in the context of the Convention on Biological Diversity, but these issues are also relevant for community-based inventorying:

It is difficult to design rules that will work for every community and every issue.

There may not be a single representative for an entire community, thus it is important to be as inclusive as possible in community consultations. It is also essential to follow customary decision-making processes.

Uneven power relationships may influence the effectiveness of informed consent. Building trust with outsiders may be difficult among marginalized groups.

Informed decisions may require a certain level of expertise, information and education about technical and legal matters. It may be necessary to build capacity within the community before community members can evaluate a proposed project and its potential outcomes. Without a complete understanding of the project or its possible implications, some community members may not be fully aware of the risks of sharing certain information (e.g. traditional knowledge).

Cultural values about general hospitality may conflict with protection of knowledge. Community control over information dissemination may be weakened.

#### Risks and unintended consequences

Community-based inventorying may be conducted for a wide range of beneficial purposes, such as:

* identifying and safeguarding ICH
* providing community cohesion and leverage for collective action
* forming a basis for territorial planning and socioeconomic integration.

Despite good intentions, participatory community-based inventorying also includes certain risks and unintended consequences.

* The use of advanced technology could be exclusive to the few who possess the knowledge to use it.
* Inventorying could increase tensions among different stakeholders, especially where there are uneven power relations.
* Inventorying may also reveal potentially sensitive information, which may breach the trust of participants and even expose them to danger if such information is misappropriated.

Although it may be impossible to foresee all the potential negative outcomes of a community-based inventorying project, it is essential to incorporate this awareness among participants in the process of obtaining informed consent.

#### Checklist for informed consent in Community-based inventorying

While there currently are no standard protocols for free, prior and informed consent in community-based inventorying, a suggested checklist of elements to be included in the design of free, prior and informed consent documentation is presented below. This is not an exhaustive list and free, prior and informed consent documentation should be tailored to meet the needs of each project and community. The suggested elements include:

* a statement on the purpose of the proposed community-based inventorying project
* an explanation of the type of inventory to be produced
* a description of the methods to be used to collect data and produce the inventory
* a statement on the expected timeframe for the community-based inventorying project
* an explanation of the rights of participants, including voluntary participation, confidentiality, etc.
* an explanation about custodianship of the outputs of the community-based inventoying project
* a description of any reasonably foreseeable risks of the community-based inventorying project
* an explanation of whom to contact for answers to pertinent questions about the community-based inventorying project
* a statement of agreement to participate in the community-based inventorying project.
1. . More detailed information about domestic and international laws and practices of informed consent can be found in the following documents: ‘An Overview of the Principle of Free, Prior and Informed Consent and Indigenous Peoples in International and Domestic Law and Practices’ [www.austlii.edu.au/au/journals/AILR/2005/36.html](http://www.austlii.edu.au/au/journals/AILR/2005/36.html) and [http://undesadspd.org/IndigenousPeoples.aspx](http://tinyurl.com/ly6nwm) and ‘Legal commentary on the concept of free, prior and informed consent’ <http://tinyurl.com/n6t366>. [↑](#footnote-ref-1)
2. . The Nuremburg Code: [www.hhs.gov/ohrp/archive/nurcode.html](http://www.hhs.gov/ohrp/archive/nurcode.html). [↑](#footnote-ref-2)
3. . The Belmont Report: [www.hhs.gov/ohrp/humansubjects/guidance/belmont.html](http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html). [↑](#footnote-ref-3)
4. . The prior informed consent (PIC) procedure: [www.pic.int/](http://www.pic.int/home.php?type=t&id=27&sid=29). [↑](#footnote-ref-4)
5. . Indigenous and Tribal Peoples Convention: [www.ilo.org/ilolex/cgi-lex/convde.pl?C169](http://www.ilo.org/ilolex/cgi-lex/convde.pl?C169). [↑](#footnote-ref-5)
6. . Convention on Biological Diversity, Article 8(j) and related provisions: [www.cbd.int/decision/cop/?id=7158](http://www.cbd.int/decision/cop/?id=7158). [↑](#footnote-ref-6)
7. . Firestone, L.A. 2003. You say yes, I say no: defining community prior informed consent under the Convention on Biological Diversity. Georgetown International Environmental Law Review, 16: 171. [↑](#footnote-ref-7)