[Section 10]

HUMAN TISSUE

The use of human tissue for the purpose of research has proven to be of immense importance to the advancement of knowledge. The ethical considerations raised by research involving human tissue centre on the moral status of human tissue, on access to and the use of data from the tissue, and, consequently, on the standards that define precisely how those involved in research relate to one another. In this regard, it is a fundamental ethical principle that researchers, in the collection and use of human tissue, respect individual and community notions of human dignity and physical, spiritual and cultural integrity.

The status accorded the human body and its parts varies among individuals and cultures. It varies in part due to how people perceive, identify with or relate to their bodies. Some people or cultures take little interest in tissue removed from their bodies. Other cultures regard certain parts of the body (e.g., the placenta) as sacred. Other parts of the body may be regarded as appropriate for gift-giving, provided that the use for research does not compromise medical diagnosis or care. What some regard as an invasive method to acquire tissue samples, other individuals or cultures will not. These examples illustrate the continuing importance of assessing the ethics of research involving human subjects through a subject-centred perspective.

In Canadian society, it is generally held that human tissue itself deserves some degree of respect, for reasons of the dignity of the person from whom tissue is obtained. These principles are reflected in Canadian law and public policy, which generally allow competent individuals to donate, but not sell, human tissues for research. In this context, it is reasonable to draw the ethical conclusion that the use of tissue for research depends on an individual's altruism in donating the tissue with the expectation that social good will be advanced and human knowledge increased. In the case of genetic research, this altruistic gift has an added dimension: tissue obtained from the individual may reveal information about one's current or future health as well as that of biological relatives (see Section 8).

A. Privacy and Confidentiality

It is essential to protect the privacy of the individual and ensure confidentiality. Four categories of tissue can be distinguished:

- Identifiable tissue can be immediately linked to a specific individual (e.g., by way of an identifying tag or patient number).
- Traceable tissue is potentially traceable to a specific donor, provided there is access to further information, such as a patient record or a database.
- Anonymous tissue is anonymous due either to the absence of tags and records or the passage of time (e.g., tissue recovered from archaeological sites).
- Anonymized tissue was originally identified but has been permanently stripped of identifiers.

Genetic testing has greatly narrowed the concept of anonymous tissue (see Section 8), but the concept of traceable tissue is now wider, since it is now possible to identify biological relatives by using genetic markers.

A researcher may request REB approval for use of non-traceable tissue in research when such tissue was left over from different research or, for instance, from a pathological examination. In giving approval, the REB should address such issues as privacy, confidentiality, and, where appropriate, continuing consent or free and informed consent concerning the new research project.

The researcher and the REB should also address how likely it is that traceable tissue will be traced back to an individual. Although rendering tissue anonymous has the advantage of increasing confidentiality, it has the disadvantage of making it impossible to offer the benefits of research to donors and their families. This is particularly significant when research may disclose previously undiagnosed conditions, such as HIV infection or an inherited predisposition to breast cancer.

In the case of incompetent individuals, the principles developed in Section 2 regarding harm and third-party authorization should be observed. For example, the post-mortem acquisition of brain tissue from a person suffering from dementia would require the free and informed consent of an authorized third party if there were no prior directive of the deceased. Special care should also be taken to avoid apparent or real coercion when the subjects are drawn from groups in the care, or under the authority, power or control, of others.

B. Free and Informed Consent

It is essential to pay attention to the issues related to free and informed consent developed in Section 2; all relevant information should be provided to enable the potential subject to decide whether to give free and informed consent. Thus, reasonably anticipated harms, such as the possibility of future identification, must be disclosed. Advance directives, for example, may include donations of tissue. Since the law in some provinces requires that the free and informed consent be based on an understanding of the specific uses of tissue for research, researchers and REBs must be aware of, and conform to, the specific requirements of applicable law.

Article 10.1 **Research proposing the collection and use of human tissues requires ethics review by an REB. Among other things, the researcher shall demonstrate the following to the REB:**

(a) **That the collection and use of human tissues for research purposes shall be undertaken with the free and informed consent of competent donors;**

(b) **In the case of incompetent donors, free and informed consent shall be by an authorized third party;**

(c) **In the case of deceased donors, free and informed consent shall be expressed in a prior directive or through the exercise of free and informed consent by an authorized third party.**

Article 10.1 generally applies prospectively—that is, prior to the recovery of tissue intended for research purposes. It applies the general elements of free and informed consent in Section 2 to the specific case of tissue for particular types of potential donors. It should be read in conjunction with the requirements outlined below in Article 10.3 for the use of previously collected tissue. Article 10.1 also applies when the tissue to be used in research is acquired incidentally to therapeutic interventions. Individuals who do not wish to contribute tissue to particular research projects should be free to withhold consent without fear of penalty.

Article 10.2 **For the purpose of obtaining free and informed consent, researchers who seek to collect human tissue for research shall, as a minimum, provide potential donors or authorized third parties information about:**

(a) The purpose of the research;

(b) The type and amount of tissue to be taken, as well as the location where the tissue is to be taken;

(c) The manner in which tissue will be taken, the safety and invasiveness of acquisition, and the duration and conditions of preservation;

(d) The potential uses for the tissue including any commercial uses;

(e) The safeguards to protect the individual's privacy and confidentiality;

(f) Identifying information attached to specific tissue, and its potential traceability; and

(g) How the use of the tissue could affect privacy.

By providing individuals with information set out in Article 10.2 about the uses of their tissue, potential subjects will be empowered to decide if their concerns about privacy and confidentiality are met. Measures to protect privacy, confidentiality and anonymity should be proposed by the researcher and be considered adequate by the REB.

Disclosing such information also ensures that researchers and subjects understand that tissue gathered for one purpose (e.g., medical) may have serious implications from other perspectives (e.g., legal). Data linkage issues should also be addressed (see Section 3). It is also important to pay special attention to cultural or religious concerns regarding certain tissue or human products, such as zygotes, embryos and foetuses (see Section 9), as well as concerns that some individuals may have about certain types or applications of research.

C. Previously Collected Tissue

Article 10.3 **(a) When identification is possible, researchers shall seek to obtain free and informed consent from individuals, or from their authorized third parties, for the use of their previously collected tissue. The provisions of Article 10.2 also apply here.**

(b) When collected tissue has been provided by persons who are not individually identifiable (anonymous and anonymized tissue), and when there are no potential harms to them, there is no need to seek donors' permission to use their tissue for research purposes, unless applicable law so requires.

Article 10.3 applies the general principles of research involving identifying data of Section 2 to the specific case of tissue. The article—which should be read in conjunction with Articles 10.1 and 10.2—applies broadly to research in areas such as health sciences, anthropology and genetics. Identification is a matter of sensitivity for individuals, families and members of groups. As such, Article 10.3(a) requires consent for the use of previously collected tissue from which persons may be identified; Article 10.3(b) provides an exception to the consent requirement when the tissue does not permit identification and poses no potential harms.

Though it may not be possible to identify the individuals who provided the tissue, other ethical issues may warrant scrutiny. Some individuals may not want their tissue used for any research purposes regardless of anonymity. The interests of biological relatives or members of distinct cultural groups or other communities may be adversely affected through research uses of their anonymous tissue. Issues may also arise concerning any duties, in extraordinary circumstances, to make traceable tissue identifiable for purposes of providing significant or beneficial information to those who have provided the tissue (see Section 2). Researchers should address such issues to the satisfaction of the REB.