

## 8. USE OF HUMAN TISSUE SAMPLES

### 8.1 National Health Act, 2003 (Act No. 61 of 2003) Section 68

Section 68 of the National Health Act, 2003 (Act No.61 of 2003) make provision for the minister to make regulations relating to tissue, cells, organs, blood, blood products and gametes:

- (1) The Minister may make regulations regarding-
  - (a) the post-mortem examination of bodies of deceased persons;
  - (b) the preservation, use and disposal of bodies, including unclaimed bodies;
  - (c) the removal of donated tissue or cells from persons, tissue or cells obtained from post-mortem examinations and the procurement, processing, storage, supply and allocation of tissue or human cells by institutions and persons;
  - (d) tissue transplants;
  - (e) the production, packaging, sealing, labelling, storage and supplying of therapeutic, diagnostic and prophylactic substances from tissue;
  - (f) the supply of tissue, organs, oocytes, human stem cells and other human cells, blood, blood products or gametes;
  - (g) the importation and exportation of tissue, human cells, blood, blood products or gametes
  - (h) the withdrawal of blood from living persons and the preservation, testing, processing, supply or disposal of withdrawn or imported blood;
  - (i) the administering of blood and any blood product to living persons;
  - (j) the production, packaging, sealing, labelling and supplying of blood and blood products;
  - (k) the bringing together outside the human body of male and female gametes, and research with regard to the product of the union of those gametes;
  - (l) the artificial fertilisation of persons;
  - (m) the appointment and functions of inspectors of anatomy and investigating officers;
  - (n) the records and registers to be kept by persons and institutions;
  - (o) the returns and reports, including extracts from registers, to be submitted to specified persons and institutions;
  - (p) the acquisition, storage, harvesting, utilisation or manipulation of tissue, blood, blood products, organs, gametes, oocytes or human stem cells for any purpose;
  - (q) the appointment and functions of inspectors of the national blood transfusion service and progenitor cell transplant institutions; and
  - (r) any other matter relating to regulating the control and the use of human bodies, tissue, organs, gametes, blood and blood products in humans.
- (2) The Minister, with the concurrence of the Cabinet member responsible for finance, may make regulations concerning the payment of persons or institutions in connection with procurement, storage, supply, import or export of human bodies, tissue, blood, blood products or gametes.
- (3) The Minister may, if it is consistent with the objects of this Act and upon such conditions as the Minister may deem fit, by notice in the *Gazette* exempt any person or category of persons from any or all of the regulations made under this section.

The principles of ethical conduct and review described in the above statement should govern all research using human tissues or bodies within the prescribed regulations of the National Health Act, 2003 (Act No. 61 of 2003) (also see Appendix E).

Where human tissue is to be used in research, researchers and research ethics committees must be satisfied that the research proposal conforms to the guidelines. The additional ethical issues that arise in genetic research using human tissue need to be addressed in conformity with human genetic research (Reproductive Biology and Genetic Research [MRC Book 2]).

Approval must be obtained from accredited research ethics committees for collecting samples of human material for research. New research ethics committee approval must be obtained for all research projects not specifically mentioned when consent was originally obtained.

## 8.2 Respect for persons

The fundamental ethical principle to be observed in the use of human tissue samples for research is respect for the person. This is reflected in:

- Provision to the donor of full information about the purposes of the sampling, or an outline of the research proposal;
- The donor's consent to the use of the sample in the experiment being planned;
- The donor's consent to storage and future use of the sample for other research;
- Giving donors the assurance that all secondary use of donated tissue samples will require approval of an accredited research ethics committee;
- Reassuring donors that no tests of known clinical value for diagnosing or predicting disease on samples can be linked to them without their consent;
- Provision for appropriate and secure storage of tissue samples;
- Provision and maintenance of appropriate and secure systems to ensure confidentiality and privacy in the recording, storage and release of data;
- Accountability in the care and usage of samples;
- A statement of the duration of sample storage.

If research using human tissue samples will require access to medical records of donors, consent for permission to use information in the donors' medical records should be obtained.

It is important for institutions or organisations, in conjunction with their ethics committees, to determine when consent should be sought for the use of tissue in research or when a waiver of the requirement for consent may be considered.

## 8.3 Institutional responsibility

Institutions or organisations at which research involving the use of human tissue samples is conducted, should develop policies regulating the conduct and ethical approval of such research. All research must conform to the National Health Act, 2003 (Act No 61 of 2003) and other relevant legislation and also be consistent with this statement. These policies must provide guidance to researchers and ethics committees in relation to soliciting or accepting voluntary donations of, and specifying conditions for, the use of human tissue samples in research. In their development, relevant considerations should include:

- The nature and cultural or religious sensitivity of the person who was the source of the sample;
- The original reason for its collection;
- The purpose of the research.

It is the responsibility of the institution or organisation at which research involving human tissues samples is conducted, to ensure that all uses of human tissue samples are in accordance with the consent given by the donors. It is also the responsibility of such institutions or organisations to maintain proper records of all uses of the human tissues samples in their custody. These records should include copies of ethics approval obtained for all uses. Research ethics committees and regulatory authorities should be given access to these records.

Samples that are no longer required should be disposed of safely and sensitively.

## 8.4 Where consent would be required

Where human tissue samples are collected for purposes including research, consent for their use in research is generally required. Consent should:

- Be voluntary;
- Be specific to the purpose for which the tissue is to be used;
- Be honoured by the provision of full information about the project, including advice as to whether tissue samples are to be stored after completion of the research for which consent is given.

Where it is proposed that stored human tissue samples are to be used for a research purposes different from that of the previously approved research, consent for the use of the tissue samples in the new research should be obtained.

The consent of donors should be obtained where it is proposed to use tissue samples that have been:

- Held in storage following, or in association with, clinical investigations;
- Held in archives or banks; or removed in the course of a clinical procedure and not required for any clinical purpose, in research that may lead to harm, benefit or injustice to a donor of such tissue.

### **8.5 Where the requirement for consent might be waived**

A research ethics committee may sometimes waive, with or without conditions, the requirement for consent. In determining whether consent may be waived, or waived subject to conditions, a research ethics committee may take into account:

- The nature of existing consent relating to the collection and storage of the sample;
- The justification presented for seeking waiver of consent, including the extent to which it is impossible or difficult or intrusive to obtain consent;
- The proposed arrangements to protect privacy, including the extent to which it is possible to de-identify the sample;
- The extent to which the proposed research poses a risk to the privacy or wellbeing of the donor;
- Whether the research proposal is an extension of, or closely related to, a previously approved research project;
- The possibility of commercial exploitation of derivatives of the sample, and relevant statutory provisions.

### **8.6 Confidentiality**

Where human tissue samples or related information are gathered in the course of a professional relationship, professional confidentiality must be observed. Identification of samples must be limited to the minimum necessary to achieve the stated objectives of the study. If the study may produce information relevant to the health and wellbeing of the person from whom the sample was derived, the ethics committee may request procedures to identify participants to facilitate appropriate follow-up.

### **8.7 Human tissue repositories**

Human tissue is collected, stored and distributed for research purposes by a human tissue repository. The three components of repository activities are:

- Collection of samples;
- Storage and data management in an appropriate repository;
- Investigation of recipients.

The research ethics committee (REC) should oversee the operation of the repository and its data management centre. Supervision would include:

- REC review and approval of a protocol specifying conditions under which data and specimens may be collected and shared;
- Ensuring adequate provisions are made for the protection of the privacy of the donors and the maintenance of the confidentiality of the data;
- REC review and approval of a sample collection protocol and the informed consent document for the distribution to tissue collectors and their local RECs;