The University of KwaZulu-Natal recently hosted a Symposium on Medico-Legal and Ethical Implications of Human Tissue Use, which coincided with recent discussions on proposed amendments to Chapter 8 of the National Health Act 61 of 2003. The Symposium made a number of recommendations regarding: (i) how to overcome the shortage of donations of human tissue; (ii) the need to update the current policy and regulations regarding the use of human tissue; (iii) whether a human tissue co-ordinating body should be established; (iv) the need for national guidelines for the use of human tissue in teaching and research; and (v) how legacy collections involving human tissue should be dealt with.

The timing of the Symposium was apposite, given the recent indictment of a number of prominent medical practitioners allegedly involved in contravening the Human Tissue Act 65 of 1983, and the concerns that have arisen regarding the use of human tissue from both the living and the dead for teaching and research – particularly concerning the medical, legal and ethical consequences of such use. The public display of human cadavers in Body Worlds and its spin-off plastinate exhibitions, the Saartje Baartman reparation, and the exhumation findings of the South African Truth and Reconciliation Commission have also caused controversy. It also coincided with important discussions to amend Chapter 8 of the National Health Act 61 of 2003 regarding the use of human tissue.

Shortages of donated tissue

The donation of human tissue is currently governed by the Human Tissue Act 65 of 1983, as amended, but will be replaced by Chapter 8 of the National Health Act 61 of 2003 when the chapter is brought into effect. There is general agreement that the provisions of the Human Tissue Act and those currently in the National Health Act are inadequate to meet the challenges of modern medicine in respect of the use of human tissue. As a result a number of proposed amendments to the National Health Act have been submitted to the Department of Health, and these together with other suggestions were discussed at the Symposium. Some of the factors that emerged during the Symposium were that there has been a significant reduction in the available cadaveric organs and tissue for clinical and research use from several of the state mortuaries since they were taken over from the police by the provincial departments of health in 2006. This seems to be in part due to perceptions (not necessarily correct) regarding the constitutional and ethical limitations on the use of human tissue from deceased persons, and in part because in some provinces it appears that the police no longer see it as their duty to assist in taking ‘reasonable steps’ to locate persons who may be able to consent to unclaimed bodies in state mortuaries being used for tissue donation. In terms of the Human Tissue Act the Director-General of Health or other authorised persons may only consent to the donation of an unclaimed body or tissue from such a body after they are ‘satisfied that all reasonable steps have been taken to locate’ the persons required to give consent.

The Symposium dealt generally with the medicolegal and ethical implications of human tissue use in South Africa and the lessons to be learnt from practices in the UK and New Zealand. In particular participants learnt about the operation of the UK Human Tissue Authority as a co-ordinating body, and the New Zealand approach when dealing with cultural reservations by the Maoris about legacy collections and the use of human tissue. The participants were divided into four commissions to consider the following issues: What general amendments should be made to policies and regulations regarding the use of human tissue? Should there be a human tissue co-ordinating body? Should there be national guidelines for the use of human tissue in teaching and research? How should human tissue legacy collections be dealt with?

General amendments to policy and regulations regarding the use of human tissue

The commissions on general amendments to policy and regulations regarding the use of human tissue recommended that policies should provide a framework that informs everything else in the relevant legislation and should be couched within the context of the four ethical principles of patient autonomy, beneficence, non-maleficence and justice or fairness. The legislation should not be obstructive to tissue use, and where sanctions are to be imposed these should be clearly spelt out. Simple language should be used in all legislation so that lawyers are not needed to interpret the statute’s meaning. Regulations are more flexible than Acts and detailed requirements emerging from policies should be enshrined
in regulations rather than Acts. South African policies and regulations regarding the use of human tissue should be informed by the Constitution and best international practices. Public education and community consultations should take place to encourage donations of human tissue, using indigenous languages and ensuring cultural sensitivity. The relevant statutory professional bodies should synthesise the contents of policies, Acts and regulations in guidelines and booklets for their members so that they are easily understood. Policies and regulations should include more rather than less information so that practitioners are given maximum guidance.

**A human tissue co-ordinating body**

The commission on the need to establish a human tissue co-ordinating body recommended that a body should be established similar to the UK Human Tissue Authority. Because of the short-age of funding in the Department of Health and the likelihood that establishment of a human tissue co-ordinating body would not be seen as a priority, it was suggested that the body should be seen as multi-sectoral and independent of the Department. The body should be an independent statutory body funded by government and the private sector, and like the UK Human Tissue Authority, should give guidance to Government, public officials and professionals on the retention and storage of human tissue, publish codes of practice, and issue and withdraw licences for certain procedures. It should also have a mixture of lay and professional members as well as government representatives, and should be supported by operational staff to carry out monitoring, licensing and inspections. The body should perform the duties and functions of the present inspectors of anatomy and human tissue inspectors. The body should have a small executive core membership and accredited committees in the different provinces, similar to how the research ethics committees operate in terms of the National Health Act. The body should also raise a licence fee to help cover its running costs.

**National guidelines for the use of human tissue in teaching and research**

The commission on national guidelines for the use of human tissue in teaching and research recommended that there should be an education programme on tissue donation for the general public, emphasising the importance of the dignity and respect shown to cadavers. The programme should be sensitive to cultural differences and present human tissue donation within the context of an ethical framework. There should be a standardised consent form for the whole country setting out how bodies will be used and disposed of, and indicating how long bodies and tissues will be held and when and where they can be reclaimed. Institutions that receive donations should be sensitive to the concerns of families and if the latter change their mind, and it is possible to return the remains to them, this should be done. In respect of natural deaths reasonable attempts should be made by the police to contact the families. Until contact has been made bodies should be refrigerated for 7 days, and then embalmed and kept up to 3 months while attempts are made to contact the relatives. Only after the expiry of 3 months should unclaimed bodies or tissue be available for teaching and research. All procedures should be documented. Inspectors of anatomy should have a standardised national job description and police officers should be deputised as human tissue inspectors. Heads of anatomy departments at universities should ensure that their facilities are visited by the relevant inspector of anatomy.

**Legacy collections involving human tissue**

The commission on legacy collections involving human tissue recommended that there should be a national audit of all legacy collections of human bodies and tissues in universities, museums and other institutions. Before being handed back to claimants, the collections should be properly documented and, where appropriate, relevant research should be completed. Legacy collections of South African people in foreign countries such as Belgium and the USA should also be audited and computerised. Repatriation of remains should be done on a case-by-case basis, but a close relationship between the deceased and the claimants should be established before such repatriation. No time limits should be placed on how old the remains are or when they were acquired, nor should there be a cut-off point at which no further claims will be entertained. Stricter controls are needed over human tissue leaving the country, and an explanation should be given when proper procedures are not followed. There needs to be more transparency regarding the export of tissue (e.g. foreskins from KwaZulu-Natal), and South Africans should be given access to information about how the tissue was used. There should also be benefit-sharing for South Africa from the fruits of the materials exported. In the spirit of the Truth and Reconciliation Commission, where appropriate, restitution should be provided on a case-by-case basis.

The deliberations of the participants and the recommendations of the commissions were fed into the on-going consultation process regarding the proposed amendments to the National Health Act and its regulations.