



TISSUE DONATION, ETHICS AND REGULATION IN AUSTRALIA

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SUMMARY

Australia's population is approaching 25 million (www.abs.gov.au). Spread over 7.69 million square kilometers, it is one of the most sparsely populated countries in the world. Australia is serviced by 12 tissue and eye banks, 2 donation/retrieval agencies and 1 private processing facility. The sector is regulated by the Commonwealth Government through the Therapeutic Goods Administration (TGA) with human blood, tissue and cellular therapy manufacturers licensed in compliance with an Australian Code of Good Manufacturing Practice, 2013 (cGMP). The cGMP is complimented by mandatory standards for tissue (musculoskeletal, cardiovascular, ocular, skin), labelling, donor selection and minimisation of infectious disease transmission. Australia's 6 states and 2 territories each have their own legislation governing consent and supply of tissue for clinical and research use. Significant variation exists, requiring compliance with the laws of each jurisdiction where tissue is retrieved and supplied. Systems for deceased donor referral, consent and medical / social history interview also vary in each jurisdiction, yet individual banks remain responsible for donor acceptance. The Australian Government's Organ & Tissue Authority contributes to deceased donor referral and consent in varying roles. Femoral head donation from hip replacement surgery remains a major source of bone to meet an ever increasing demand for musculoskeletal tissue. 4,248 living and 364 deceased tissue donors were reported in Australia for 2017, plus an additional 1,027 eye only donors. 7,470 patients received tissue and 2,175 patients received corneal transplants from Australian donors (www.donatelife.gov.au). Unfortunately, no data is collated for transplant of imported tissue. The Commonwealth, in consultation with the sector, is undertaking a review of national policy, governance and funding in response to the Analysis of the Australian Eye & Tissue Sector, 2016. The National Health and Medical Research Council is currently reviewing the Organ and Tissue Donation After Death, For Transplantation, guidelines for ethical practice, 2007.

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