

Human tissue donation in Sri Lanka: Legal, ethical and regulatory challenges

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Human tissue donation plays a vital role in modern medicine, enabling various lifesaving and life enhancing interventions. However, the existing legal and policy framework governing tissue donation in Sri Lanka remains underdeveloped and lacks coherence, leading to significant regulatory and ethical challenges. This research uses a doctrinal methodology to critically examine Sri Lanka's statutes, case law, and related legal instruments, with special reference to the Transplantation of Human Tissues Act and its subsidiary legislation. The research also incorporates secondary sources, such as scholarly commentary, policy papers, and the UN regulatory framework, to provide a wider comparative perspective. The findings highlight number of systemic shortcomings, including the absence of a centralized regulatory body, outdated statutory provisions, inadequate procedural safeguards concerning informed consent, and insufficient enforcement mechanisms to ensure ethical compliance. Infrastructural limitations, such as the lack of a national tissue bank system, insufficiently trained personnel, and weak inter-agency coordination, further hinder the effective implementation of the existing legal framework. Personal beliefs shaped by cultural and religious traditions, together with a general lack of awareness, contribute to public reluctance, posing a challenge to advancing voluntary and ethically sound tissue donations. To address these challenges, this study recommends substantial legal and institutional reforms, including the establishment of a centralized oversight authority, legislative reform to clarify consent procedures and donor protections, and the introduction of public education campaigns to foster greater societal engagement and trust in the donation process.

Keywords: *Human tissue donation, Regulatory framework, Transplantation of Human Tissues Act, Informed consent, Sri Lanka*