

Legal and Ethical Challenges in the Use of Human Biomaterials in Stem Cell Therapies and Regenerative Medicine: A Focus on Sri Lanka

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The field of biomedical engineering, especially in the areas of stem cell therapies and regenerative medicine, has experienced significant advancements, providing transformative potential for treating a wide range of diseases and injuries. These advanced medical techniques enhance the body's natural healing capabilities, thereby greatly improving patients' quality of life. However, the increasing reliance on human cells and tissues has led to the development of a growing market for human biomaterials, which presents substantial ethical and legal challenges. Sri Lanka, recognized as one of the largest donors of human cells and tissues, faces unique challenges due to its diverse religious background and economic conditions. Despite its significant contribution, the legal framework in Sri Lanka concerning the procurement and use of human biomaterials remains inadequate. The Transplantation of Human Tissues Act No. 48 of 1987, along with existing regulations, primarily addresses transplantation and fails to comprehensively cover the broader use of human biomaterials in fields like stem cell therapies and regenerative medicine. This regulatory gap raises serious ethical and legal issues, as it does not sufficiently protect donors' rights. This research aims to clearly articulate the ethical and legal challenges associated with using human biomaterials in biomedical engineering research, with a particular emphasis on stem cell therapies and regenerative medicine in Sri Lanka. The research will compare the legal regimes of Sri Lanka with those of India to identify ethical and legal issues in the commercialization of human biomaterials and the consequences of inadequate legal frameworks and enforcement mechanisms. Additionally, the research will address how these inadequacies affect the rights of donors and propose ways in which international cooperation can enhance regulatory standards to address these challenges effectively. A doctrinal approach will be adopted, utilizing qualitative methods for the analysis of both primary and secondary data.

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