

# A Framework for Assessment and Management of Ethical Risks Related to Stem Cell Use in Tissue Engineering

Mircea Leabu

Address all correspondence to: Carol Davila, University of Medicine and Pharmacy, Department of Cellular and Molecular Medicine, 8, Eroilor Sanitari Blvd., 050474, Bucharest, Romania & Victor Babeş, National Institute of Pathology, 99-101, Splaiul Independentei, 050096, Bucharest, Romania; mircea.leabu@ivb.ro

**ABSTRACT:** No progress can ever be made without risk-taking. The discovery of stem cells and their improved handling brought new perspectives in tissue engineering. Nonetheless, whatever the method used to obtain stem cells (embryonic, from embryos got naturally, or by *in vitro* fertilization, produced by somatic cell nuclear transfer, by inducing pluripotent stem cells, or supplied by harvesting adult stem cells), their use in therapy, even through tissue engineered products, remains questionable due to the anticipated or unexpected risks. Both professionals in medicine and ethicists agree that the current biomedical technologies present indeed an element of risk, although it cannot be exactly described, nor anticipated. The major source of risk resides in the huge pressure made by the civil society representing the patients, as well as by the research policy makers, due to promising initial results in stem cell research and their application in tissue engineering. Throughout the debates on the implicit risks, several categories have been considered: health, socio-political, and moral risks. If approached from a bioethical perspective, all these categories intertwine. This paper aims to suggest a framework for assessment and management of ethical risks related to stem cell use in tissue engineering.

**KEY WORDS:** bioethics, risk assessment, risk management, precautionary principle, cell therapy, translational medicine ethics

## I. INTRODUCTION

Any progress, no matter in what field, originally meant taking a risk. Taking risks is a normal fact for humans and it is perceived, at least under some limits, as morally right. The morality of risk-taking also requires some degree of responsibility in both professional and moral terms.<sup>1</sup> Ethics has to play an important role in risk assessment and management, in order to help us rationally determine what is acceptable and what is not in terms of risk-taking. In case moral risks do exist, ethics becomes a leading actor in risk assessment and management, due to its impact on any ethical decision-making process. Medicine has developed through technological progress, and the new fields in biomedical research with supposedly swift and promising clinical application, such as gene therapy, cell therapy, or stem cell study, all bring good perspectives to the regenerative medicine, with the help of molecular diagnosis and immunomodulation. These new areas of contemporary medicine belong to the translational medicine, having as a motto “from bench to bedside.” The corollary of these new approaches is the personalized medicine. Tissue engineering and stem cell use in regenerative medicine are two areas of translational medicine which generate enormous expectations among both the