

# Preface

Stem cell research and therapy herald a new era of medicine, called regenerative medicine. Stem cell transplantation brings some benefits for age-related degenerative diseases as well as genetic diseases. Although stem cell transplantation has a long history which is more than 50 years old, it still faces some safety, ethical, and regulatory issues. This volume, *Stem Cells in Clinical Applications: Safety, Ethics, and Regulations*, provides safety evaluations of stem cell treatments for some diseases and the ethical and regulatory dimensions of stem cell-based clinical applications in different countries.

The four chapters in Part I provide an introduction to the safety of stem cell transplantation. In chapter one, Gero Hütter discusses the safety of allogenic stem cell transplantation. Chapter two, by Erden Eren and colleagues introduces safety issues when using induced pluripotent stem cells in the treatment of neurodegenerative disease. Chapter three, written by Carlo S. Jackson, Marco Alessandrini and Michael S. Pepper provides an introduction to safety concerns of stem cell gene therapy. Finally, in chapter four Dimitrios Kouroupis and colleagues record the safety of non-expanded stem cells in clinical applications.

The 12 chapters in Part II address the ethical and regulatory dimensions of stem cell-based clinical applications. In chapter five, Fikile M. Mnisi explores the ethical controversies on the patenting of human embryonic stem cells in South Africa. Chapter six, by John D. Banja provides an overview of the ethical considerations in clinical stem cell research for neurological and orthopedic conditions. Chapter seven, by Barbara von Tigerstrom assesses current and emerging regulatory models for clinical stem cell research in the USA, the EU, Japan, and Australia. In chapter eight, Christine Hauskeller and Nicole Baur study the regulatory conditions for clinical stem cell research in the European Union and comment on the practical challenges for multi-country stem cell trials in this global region. In chapter nine, Tamra Lysaght examines differences in the framing of ethical concerns in professional guidelines by the International Society for Stem Cell Research (ISSCR) and the International Cellular Medicine Society (ICMS). Chapter ten, by Li Jiang focuses on the regulatory and legal situation for stem cell research in China. Jiang shows how a booming stem cell industry in China is, through an ongoing process of

regulatory reform, slowly brought under the control of the state. In chapter eleven, Shashank S. Tiwari, Paul Martin, and Sujatha Raman provide insights into regulatory developments in the governance of stem cell therapies in India, which are discussed in the light of the country's social and health-care context. In chapter twelve, Iñigo de Miguel Beriain offers a detailed analysis of the ethical and legal conflicts and positions surrounding the patenting of hESC in the context of the European Union. In chapter thirteen Achim Rosemann and colleagues provide an overview of the regulatory conditions for basic, preclinical, and clinical research in China that have emerged since the early 2000s. Chapter fourteen, by Achim Rosemann addresses the ethical aspects of the donation of human embryos and oocytes for hESC research by focusing on the critical role of clinicians and researchers. Chapter fifteen, also by Achim Rosemann, illustrates some of the key challenges for international stem cell trials in the light of the ongoing process of global regulatory diversification in the stem cell field.

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Ho Chi Minh City, Vietnam  
Coventry, UK

Phuc Van Pham  
Achim Rosemann

Safety, Ethics and Regulations

Pham, P.V.; Rosemann, A. (Eds.)

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