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**BEYOND THE EMBRYO: TRANSNATIONAL,
TRANSDISCIPLINARY AND TRANSLATIONAL PERSPECTIVES ON
STEM CELL RESEARCH**

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Over several decades, clinical trials of stem cell-based interventions (e.g. transplantation) have been carried out using umbilical cord blood stem cells and autologous adult stem cells to treat diseases such as leukemia, lymphoma and several inherited blood disorders. The safety and efficacy of these interventions has been well established.

Conversely, interventions using human embryonic stem cells and fetal tissue are still at the experimental stage. The conduct of clinical trials on tissues from these sources has given rise to controversy in several countries, given that some trials are proceeding with little scientific and governance oversight and no evaluation of clinical outcomes and safety.

A decade ago, when researchers learned to isolate and culture human embryonic stem cells, regenerative medicine entered a new era. Indeed, as a result of its potential to prevent and cure disease, stem cell research has become a crucial part of regenerative medicine. It has, for instance, offered a potentially unlimited source of cells for organ transplantation and therapy. It has also provided a successful model system for drug discovery, including new testing methods for drug efficacy, toxicity and safety. Stem cell research also promises to provide a better understanding of the processes of human cell differentiation and development, which may consequently lead to the discovery of new treatments for diseases such as cancer. Finally, recent findings using induced pluripotent stem (iPSCs) cells and somatic cell nuclear transfer (SCNT) affirm the potential for research on patient-specific and disease-specific stem cell lines that might eventually result in safe and effective therapies.

The heterogeneity of national and international policies on stem cell research (from basic research ethics to translational research, governance, patenting and commercialisation) is a reflection of the diversity of global socio-cultural, religious, economic, and historical contexts. The peculiarities of national institutional frameworks and the role of stakeholders are further factors that influence policy development. Across the board, the scientific, socio-ethical and legal issues associated with stem cell research remain controversial.

The articles section of this issue of SCRIPT-ed features seven papers presented at the workshop "*Beyond the Embryo: Transnational, Transdisciplinary and Translational Perspectives on Stem Cell Research*" held at the Brocher Foundation (Hermance, Geneva, 14-15 November 2009) and sponsored by the Brocher Foundation, the Centre of Genomics and Policy at McGill University, the Stem Cell Network of Canada and the Université de Genève.

This two-day international workshop sought to bring together the knowledge and expertise of both senior and talented young scholars, in order to describe and analyse the stem cell research environment, including its challenges and its impact. The workshop was broad in scope, as it explored both the scientific and ELSI challenges resulting from advances in stem cell research and related therapies.

As the title of the workshop suggests, the presentations and manuscripts included in this edition show how, in both national and international fora, we are witnessing a departure from an "embryo-centric" approach to one that is focused on the globalisation and governance of research and its clinical translation, along with the commercialisation of future stem cell-based diagnostics and therapeutics. Moreover, the workshop aimed, from a multidisciplinary and international perspective, to look

prospectively at new developments and to provide a unique picture of the international stem cell research environment.

Renowned investigators and young scholars from four continents contributed to an overview of transdisciplinary and transnational perspectives on stem cell research. As summarised in the report by Geoffrey Lomax entitled *Governance of Stem Cell Science: Multiple Models & Similar Outcomes* (see the reports section of this issue), the broad range of issues to be addressed included: recent scientific advances and policy developments, the patent and commercialisation landscape, ethical safeguards for research participants and the experience and perspectives of stakeholders (i.e. patients and advocacy groups). Issues raised by translational stem cell research involved scientific advances directed to moving stem cell-based therapies from the bench to the bedside (including banking and register initiatives) and to concomitant emerging governance and ELSI challenges.

The manuscript of Christen Rachul *et al*, “*Stem Cell Research in the News: More than Moral Status Debate?*” is an interesting analysis of the press coverage of the stem cell debate. It illustrates how, unlike scientific and political attitudes, the perspective of the press has (in countries such as the United Kingdom, Canada and United States) moved “beyond the embryo” debate.

Three other papers focus on national policy frameworks and their international implications. The article by Dominique McMahon and Halla Thorsteinsdóttir “*Lost in Translation: China’s Struggle to Develop Appropriate Stem Cell Regulations*”, examines the process of development towards the Chinese regulatory framework for stem cell research and therapies. The article highlights the challenges as well as the role played by society and culture in the prospect of such development. Their analysis provides important lessons that can be applied by any national or international actor attempting to develop a governance framework.

Similarly, the article by Mansooreh Saniei, “*Human Embryonic Stem Cell Research in Iran: The Role of the Islamic Context*”, also analyses the impact of society, culture and religion in the development of national stem cell research policies. It addresses the scientific and moral-religious position of human ESC research in Iran. Iran leads other Muslim countries with respect to stem cell research.

The global dimension is once again introduced in Aaron D Levine’s article “*Stem Cell Tourism: Assessing the State of Knowledge*”, which tackles the timely and controversial phenomenon of “stem cell tourism.” His review analyses existing information about unproven stem cell-based interventions, the patients who pursue them, and their outcomes.

Prasanna K Patra and Margaret Sleeboom-Faulkner continue with the analysis of national regulatory approaches and examine the provision of stem cell-based therapies, using India as a case study. Their manuscript analyses “*bionetworking*,” the different forms, characters and linkages adopted by particular individuals, practitioners, and private and public sector tertiary-level hospitals and health care centres in promoting and propagating mostly unproven stem cell-based therapies.

The last three articles propose novel approaches to commercialisation and patenting in the context of stem cell research. Carol George examines “*Open Access and the Regulation of Commercialisation of Human Stem Cell Lines in the UKSCB*”. She looks at issues of governance and commercialisation of the use of stem cell lines in

the context of the United Kingdom Stem Cell Bank. She examines the interaction of access policies and commercialisation strategies.

Finally, Yann Joly's manuscript, "*Clinical Translation of Stem Cell Therapies-Intellectual Property and Anticipatory Governance*", studies the impact of patents on the clinical translation of stem cell research. He proposes an innovative approach to the promotion of technology transfer: the creation of an anticipatory governance/real-time monitoring platform.

The Brocher Workshop, "*Beyond the Embryo: Transnational, Transdisciplinary and Translational Perspectives on Stem Cell Research*," was held in connection with the following international activities, organisations and networks: Canadian Stem Cell Network, International Stem Cell Forum, International Regulome Consortium, CIRM, International Society for Stem Cell Research and the Hinxton Group. We would like to thank them for their support. Special gratitude goes to the Brocher Foundation and to Professor Alexandre Mauron, whose invaluable support made the workshop such a success. We are also thankful to *SCRIPT-ed* for offering to publish the proceedings of the workshop.

Stem cell science and the public policy concerns that it generates are evolving simultaneously at a very rapid pace. This necessitates a conjoined approach to the monitoring and analysis of scientific advances and policy debates. It also calls for an international and multidisciplinary analysis of emerging scientific and socio-ethical and legal issues. We hope the above-mentioned articles provide a thought-provoking contribution to the achievement of these goals.