

Roche Principles for use of Human Stem Cells

Background

Stem cells and their applications offer enormous potential for new treatments, and for extending and enhancing the quality of a patient's life. Roche is keenly aware of the promise of stem cells both as a tool for discovery and as a possible future treatment.

In the discovery phase, stem cells help us better understand how the human body works, and they might help uncover the underlying causes of serious diseases. In a laboratory setting, differentiated cell lines derived from human stem cells might also enable researchers to predict drug metabolism and thus the safety of medicines more accurately than existing techniques, including animal research¹.

The future benefits that stem cells might bring to patients account for the high level of interest Roche has in exploring and developing the technology. Roche currently applies stem cells as research tools as well as tools to investigate potential future treatments.

Stem cells are particular cells that have the unique capacity to renew themselves and to give rise to specialized cell types such as heart cells or blood cells. Stem cells are classified as follows:

- **Adult stem cells** are derived from tissues like bone marrow or cord blood. These cells are already successfully used for the treatment of patients with leukemia. The treatment of further diseases with adult stem cells is currently under evaluation. However, those cells give rise only to limited number of cell types. Hence the need for concomitant research on embryonic stem cells for certain applications is still remaining.
- **Embryonic stem cells**, as their name suggests, are isolated from embryos. These cells are pluripotent, which means that they can develop into any fetal or adult cell type (blood, heart, brain cells, etc.), but they can't develop into a complete organism.
- **Induced pluripotent stem cells (iPS)** are derived from cells, such as skin cells, and are being re-programmed to a pluripotent stage, once re-programmed they exhibit similar properties as embryonic stem cells. If iPS cell technology develops as expected, it may eventually replace the need to derive stem cells from embryos.

Research on stem cells raises certain ethical questions. Roche is aware of these ethical concerns. However, we believe that the vast potential and hope that stem cells might bring to patients to treat, prevent or diagnose a disease justifies stem cell research, provided this research is done in a responsible manner, in compliance with laws and regulations, and in dialogue with stakeholders.

¹ See also Roche's Position on Animal Research: http://www.roche.com/animal_research.pdf

Roche is committed to a responsible and transparent approach to stem cell research. For this reason, clear principles for conducting such research have been developed in consultation with Roche's independent Science and Ethics Advisory Group (SEAG)².

SEAG consists of external experts in the fields of ethics, law and social science, as well as lay members of the community such as patient advocates. SEAG advises Roche, on a regular basis, regarding issues associated with innovative developments in biomedicine, including human stem cell research with particular emphasis on their ethical impact.

Scope

The following principles apply to all research projects involving human stem cells that Roche undertakes. These include:

- projects using stem cell research as a discovery tool
- projects looking into potential therapeutic modalities.

All Roche employees involved in human stem cell research are subject to these principles. These principles are designed to be applicable worldwide, subject to national laws and regulations.

General Principles for Human Stem Cells for Research

Principles 1-7 apply to research on all human stem cells.

- 1) The ultimate aim of Roche's research using stem cells is to increase the understanding of serious diseases and to develop effective treatments.
- 2) Each research project must have clear scientific objectives and design, in particular in accordance with good clinical practice.
- 3) Prior written, informed consent of the donor³ of the genetic material⁴ must be obtained before human stem cell research is carried out. Such consent is voluntary and can be withdrawn by the donor at any time if and as long as the material is not anonymised⁵.
- 4) Roche will not offer any inducements, financial or otherwise, to donors.
- 5) Roche will comply with all applicable national laws and regulations on stem cell research, which may differ from country to country.
- 6) Roche is committed to open dialogue with stakeholders in this area of research.

² http://www.roche.com/en/ethics_advisory_group.pdf

³ The term donor is generally understood as an individual who donates biological material, and, in the case of human embryo donation (in jurisdictions where applicable), the individual or couple for whose reproductive use embryos were created.

⁴ Examples of genetic material: tissue, gametes (=eggs or sperm), embryos.

⁵ As anonymised samples and associated data are not traceable back to the human subject, it is not possible to undertake actions such as sample withdrawal, or the return of individual results, even at the human subject's request.

- 7) Roche will require that all its external contractors, who perform stem cell research for Roche, follow the same principles and conduct their research with the same high standards as Roche.

Principles for Human Embryonic Stem Cells for Research

In addition to principles 1-7, principles 8-10 apply to research on human embryonic stem cells.

- 8) Roche intends to move toward using technologies such as Induced Pluripotent Stem Cells that could one day replace the need to derive stem cells from embryos. Until such technologies are fully developed, parallel research using both embryonic stem cells and iPS is necessary.
- 9) In the case of stem cell lines derived from embryos, Roche uses only embryos that have been created through *in vitro* fertilisation for reproductive purposes, that are no longer needed for those purposes, and that have been donated for research (with voluntary and informed consent).
- 10) Roche will not engage in human reproductive cloning⁶.

⁶ See also Roche's Position on Human Stem Cells and Cloning:
http://www.roche.com/sus_pos_stem_clon.pdf