

Position on Human Pluripotent Stem Cell Research

Background

Human pluripotent stem cells are immature unspecialized cells with the potential to give rise in the laboratory to virtually any cell type of the human body, and as such offer many opportunities for advances in medicine. As a research tool, human pluripotent stem cells promise to expand our understanding of normal physiologic processes such as cell growth and differentiation, and to enable new insights into disease, which may lead to new ways to prevent, diagnose and treat a wide variety of disorders. Human pluripotent stem cells offer the potential of restoring health to patients with diseases characterized by a functional loss of normal cells. Among these are diabetes, Parkinson's, Alzheimer's, Huntington's, amyotrophic lateral sclerosis, muscular dystrophy, heart disease and many other disorders.

Significant scientific progress has been made in the area of human somatic (adult) stem cells and induced pluripotent stem cells. An international consensus has evolved around the ethical principles that govern stem cell research as embodied in the International Society for Stem Cell Research (ISSCR) Guidelines (2016), the National Academies' Guidelines (2010), and the U.S. National Institutes of Health (NIH) Guidelines (2009). These precedents establish an ethical framework to guide companies in their research.

Relevance

As the world's largest and most broadly based healthcare company, Johnson & Johnson is dedicated to bringing innovative, life-changing products and services to patients, doctors and customers. This work requires thoughtful consideration of new science and research programs that are grounded in the core values our Company has represented for decades. Our approach to human pluripotent stem cell research is deeply founded on our commitment to these core values and on our [Ethical Code for the Conduct of Research and Development](#).

Guiding Principles

As stated in [Our Credo](#): "We believe our first responsibility is to the patients, doctors and nurses, to mothers and fathers and all others who use our products and services. In meeting their needs everything we do must be of high quality." This is a constant guide to our decision-making and reinforces that the needs and wellbeing of the people we serve—patients and customers—must come first as we seek to break new ground with advances in science and technology.

Our Position

In recognition of the potential importance of human pluripotent stem cells in fundamental research and in the development of innovative therapies for patients, Johnson & Johnson established a committee to assure that the highest scientific and ethical standards are maintained in all research programs involving such cells. Where suitable for the purposes of the research, and where such research offers the prospect of highly significant scientific or clinical benefit, studies involving human embryonic stem cells will be considered. Such decisions will be reviewed by the committee, whose membership includes individuals from across the Johnson & Johnson Enterprise who are seasoned scientists aware of relevant technologies, as well as senior affiliate R&D leaders, our Law Department, Corporate Communications, and external experts in bioethics and healthcare.

The committee has established guidelines to govern the use of human pluripotent stem cells in research funded by Johnson & Johnson or its affiliated companies, and conducted either internally or as part of our research collaborations.

Purpose of the Johnson & Johnson guidelines: Stem cell research promises improvements in human health and relief from disease, infirmity and human suffering, and endeavors to create new clinical tools and treatments that can be made available and affordable throughout the world. The purpose of these guidelines is to ensure that human pluripotent stem cell research conducted by Johnson & Johnson conforms to current international standards of scientific and ethical oversight, and that all scientists and employees of the Johnson & Johnson Family of Companies adhere to these ethical principles when conducting human pluripotent stem cell research.

Scope of the guidelines: These guidelines pertain to use of human pluripotent stem cells. All research programs/protocols involving human pluripotent stem cells must conform to international standards for procurement of human cells and tissues under strict principles of informed consent. In addition, Johnson & Johnson research activities will comply with all applicable laws and regulations of the country or region where the specific research project is performed.

Permissible and Impermissible Research:

- Research programs using non-pluripotent stem cells derived from adult human tissue (such as bone marrow, muscle, and skin), placenta, or umbilical cord tissue or blood are broadly permissible and subject to standard procedures for research oversight. Protocols employing these classes of stem cells need not be reviewed by the committee.
- Use of human-induced pluripotent stem cells (hiPS cells) in accordance with principles outlined by the National Academies (2010) is permissible and need not be reviewed by the committee. Securing informed consent is obligatory for the procurement and use of tissues for derivation of hiPS cells, including disclosure of the possibility for genetic manipulation of human pluripotent stem cells, transplantation of these cells and their products into animals and humans, and their potential for commercial product development.
- The committee must review and approve research programs that employ human embryonic stem cells before they may commence. Use of established human embryonic stem cell lines derived according to the principles articulated in the U.S. NIH 2009 Guidelines is permissible. Use of human embryonic stem cell lines that have not yet been vetted by the U.S. NIH but have been derived according to the Guidelines for Human Embryonic Stem Cell Research developed by the ISSCR (2016) or the National Academies (2010) will be considered by the committee and their use will be subject to rigorous scientific justification.

- Johnson & Johnson will adhere to prohibitions against impermissible research articulated in the Guidelines for Human Embryonic Stem Cell Research developed by the ISSCR (2006)¹, the National Academies (2010), and the U.S. NIH (2009), which include prohibitions against human reproductive cloning.

Application

This position is relevant for the Johnson & Johnson Family of Companies, as detailed in our [governance materials](#). It is anticipated that the above guidelines may be reviewed periodically.

Last Updated: June 2020

¹ The ISSCR guidelines were originally created in 2006 and updated in 2016.