

Position on Human Pluripotent Stem Cell Research

Background

Human induced pluripotent stem cells (iPSCs) are immature unspecialized cells, derived from somatic cells from adults, 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, iPSCs promise to expand our understanding of normal physiologic processes such as cell growth and differentiation. They also enable new insights into disease, which may lead to new ways to prevent, diagnose and treat a wide variety of disorders. Additionally, iPSCs 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. Further, iPSCs can be used as a source to differentiate cells that are applicable for cancer therapy. Besides iPSCs, other types of stem cells derived from somatic cells from human adults can be used for research and as therapies for a number of diseases (e.g., Mesenchymal Stem Cells [MSCs] or Hematopoietic Stem Cells [HSCs]).

Significant scientific progress has been made in the area of human somatic (adult) stem cells and iPSCs. Moreover, 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 (2021), the National Academies Guidelines (2010), and the US National Institutes of Health (NIH) Guidelines (2009). These precedents establish an ethical framework to guide the Johnson & Johnson operating companies in our 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 well-being of the people we serve—patients and customers—must come first. We adhere to these values and maintain high ethical standards in our scientific research methods and programs. We also comply with the appropriate regulatory and industry guidelines as we seek to break new ground with advances in science and

technology. Our commitment to bring innovative, life-changing products and services to patients, doctors and customers requires thoughtful consideration of new science and research.

Our Position

In recognition of the potential importance of stem cells in fundamental research and in the development of innovative therapies for patients, Johnson & Johnson established the Committee on Advanced Therapies (“the Committee”) to ensure that the highest scientific and ethical standards are maintained in all research programs involving such cells. If human somatic, adult-derived stem cells and no other viable scientific and appropriate options to support groundbreaking therapies are available, and where such research offers the prospect of highly significant scientific or clinical benefit to address unmet medical needs, studies involving human embryonic stem cells may be considered following Committee and other appropriate review (with the exception of cord blood-derived stem cells). Such decisions will be reviewed by the Committee, whose membership includes seasoned scientists from across the Johnson & Johnson Enterprise who are relevant subject matter experts aware of emerging technologies.

The Committee has established the following 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.

About the Johnson & Johnson Committee on Advanced Therapies: The Committee serves as an advisory body that provides guidance to the development and use of advanced therapy products in research programs and therapeutic applications involving the use of fetal tissue, in order to ensure that all relevant scientific, legal and ethical standards are met.

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. Research programs using 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, and protocols employing these classes of stem cells need not be reviewed by the Committee.

Use of iPSCs according to principles outlined by the National Academy of Sciences (2010) is permissible and need not be reviewed by the Committee. Informed consent must apply to the procurement and use of tissues for derivation of iPSCs, 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 serves as an advisory body for research programs that employ human embryonic stem cells. Use of established human embryonic stem cell lines derived according to the principles articulated in the US NIH 2009 Guidelines is permissible.

Use of human embryonic stem cell lines that have not yet been vetted by the US NIH but have been derived according to the Guidelines for Stem Cell Research and Clinical Translation developed by the ISSCR (2021) or the National Academy of Sciences (2010) will be considered by the Committee, and their use will be subject to rigorous scientific justification and ethical permissibility.

Johnson & Johnson will adhere to prohibitions against other research articulated in the Guidelines for Stem Cell Research and Clinical Translation developed by the ISSCR (2021), the National Academy of Sciences (2010), and the US 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](#). These Guidelines will be reviewed in the event of any change in applicable international rules and regulations or at any time upon the request of the Committee.

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