

Propose a Regulatory Framework for Stem Cell Research based on Ethical Guideline

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ABSTRACT

Background: Stem cell research has emerged as one of the most promising research areas in modern biomedicine. However, despite much promise the use and derivation of these cells in many countries is ethically challenging. Stem cell laws are the law, rules, and policy governance concerning the sources, research, and use of stem cells in treatment of human diseases. These laws have been the source of much controversy and vary significantly by country.

Methods: Google search was used to find information on the Web about stem cell research in world countries and Iran.

Discussion: An ethical guideline in Iran has been recently approved. In compiling this guideline the accumulated experience of the governments and Islamic laws and Persian culture and special look to human health as well as the moral status of the human embryo has been used. Some part of this guideline is licensed research can only take place on embryos created *in vitro*: embryos that have developed from eggs fertilized outside the body. Most embryos used in stem cell research are embryos that initially created in order to use in fertility treatment, but not used. These 'surplus' IVF embryos, if donated with the full consent of the parents, can be used for research.

Conclusion: We propose a regulatory framework based on this moral guideline one of our suggestion for regulation of stem cell research is legal medicine organization.

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► *Implication for health policy/practice/research/medical education:* Propose a Regulatory Framework for Stem Cell Research based on Ethical Guideline

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1. Introduction:

Stem cells are cells found in most, if not all, multi-cellular organisms. A common example of a stem cell is the Hematopoietic stem cell (HSC) which is multipotent stem

cells that give rise to cells of the blood lineage. In contrast to multipotent stem cells, embryonic stem cells are pluripotent and are thought to be able to give rise to all cells of the body. Embryonic stem cells were isolated in mice in 1981, and in humans in 1998 (1).

Stem cell treatments are a type of cell therapy that introduce new cells into adult bodies for possible treatment

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of cancer, Somatic cell nucleartransfer, diabetes, and other medical conditions. Cloning also might be done with stem cells. Stem cells have been used to repair tissue damaged by disease (2).

Stem cell research has emerged as one of the most promising research areas in modern biomedicine. However, despite much promise the use and derivation of these cells in many countries is ethically challenging (3).

The proliferation of stem cell research, conflated with its ethical and moral implications, has led governments to attempt regulation of both the science and funding of stem cells. Due to a diversity of opinions and cultural viewpoints, no single policy or set of rules exist to govern stem cell research. Instead, each country has developed its own policy (4).

Stem cell laws are the law, rules, and policy governance concerning the sources, research,

Table 1: Regulation of stem cell research in Europe

Country	The laws
Regulation of stem cell research in Austria:	Research on embryos, including the derivation of embryonic stem cell lines, is banned. The use of imported embryonic stem cell lines is not addressed by Austrian law and is therefore permissible.
Regulation of stem cell research in Bulgaria	Embryonic stem cells can be derived legally from surplus embryos donated following IVF treatment.
Regulation of stem cell research in the Czech Republic	Embryonic stem cell research is permitted. Reproductive cloning is banned.
Regulation of stem cell research in Finland	Human embryonic stem cells can be derived legally from excess IVF embryos for up to 14 days after fertilisation.
Regulation of stem cell research in France	Embryonic stem cell research is not allowed except under certain specific conditions.
Regulation of stem cell research in Germany	The derivation of embryonic stem cells is banned but embryonic stem cell lines can be imported specifically for research if the line was generated before a defined cut-off date.
Regulation of stem cell research in Greece	Embryonic stem cells can be derived legally from surplus IVF embryos, for medical and research purposes.
Regulation of stem cell research in Ireland	There is no specific legislation dealing with stem cell research in Ireland.
Regulation of stem cell research in Italy	The derivation of embryonic stem cell lines is banned but it is permitted to use imported embryonic stem cell lines .
Regulation of stem cell research in Lithuania	Research on human embryos and the import and export of tissues of a human embryo, stem cells of a human embryo and lines thereof are prohibited.
Regulation of stem cell research in Portugal	The derivation of human embryonic stem cell lines from surplus IVF embryos is permitted.
Regulation of stem cell research in Spain	Spain has a comprehensive regulatory framework for stem cell research, with a series of laws and regulations applied to different aspects of research.
Regulation of stem cell research in Sweden	Regulation of stem cell research in Sweden The use of human embryos for research is comprehensively regulated. Human embryonic stem cells can be derived from excess IVF embryos and by somatic cell nuclear transfer (SCNT). Reproductive cloning is banned.
Regulation of stem cell research in Switzerland	Embryonic stem cells can be derived from surplus IVF embryos (up to 7 days old). Embryonic stem cell lines can be imported specifically for research purposes.
Regulation of stem cell research in the United Kingdom	The UK has a comprehensive and well-established regulatory framework for stem cell research. Embryonic stem cell research is allowed subject to a licence from the Human Fertilisation and Embryology Authority (HFEA).

Table 1: Regulation of stem cell research in Asia

Country	The lawes
China	China prohibits human reproductive cloning but allows the creation of human embryos for research and therapeutic purposes.
India	Banned in 2004 reproductive cloning, permitted therapeutic cloning .
Japan	In 2004, Japan's Council for Science and Technology Policy voted to allow scientists to conduct stem cell research for therapeutic purposes, though formal guidelines have yet to be released.
South Korean	The South Korean government promotes therapeutic cloning, but forbids cloning.
Saudi Arabia	Saudi Arabia religious officials issued a decree that sanctions the use of embryos for therapeutic and research purposes.
Canada	In March 2002, the Canadian Institutes of Health Research announced the first ever guidelines for human pluripotent stem cell research in Canada. The federal granting agencies, CIHR, Natural Sciences and Engineering Research Council, and Social Sciences and Humanities Research Council of Canada teamed up and agreed that no research with human IPSCs would be funded without review and approval from the Stem Cell Oversight Committee (SCOC) .In March 2004, Canadian parliament enacted the Assisted Human Reproduction Act (AHRA), modeled on the United Kingdom's Human Fertilization and Embryology Act of 1990. Highlights of the act include prohibitions against the creation of embryos for research purposes and the criminalization of commercial transactions in human reproductive tissues. In 2006, Canada enacted a law permitting research on discarded embryos from in vitro fertilization procedures. However, it prohibits the creation of human embryos for research.

and uses in treatment of stem cells in humans. These laws have been the source of much controversy and vary significantly by country (5).

In the early 2000, the Iranian stem cell research and technology had a relatively strong start that benefited from religious blessings, political and public support, as well as scientific endeavors on the part of non-governmental and public research organizations and universities (6).

In 2002, supreme leader of Iran, Ayatollah Sayed Ali Khamenei, openly supported human ESC research in issuing the 'stem cell fatwa', an official declaration that Shiite Islam is not only consistent with, but encourages human ESC technology for therapeutic uses (7).

In the European Union, stem cell research using the human embryo is permitted in Sweden, Finland, Belgium, Greece, Britain, Denmark and the Netherlands; however, it is illegal in Germany, Austria, Ireland, Italy, and Portugal. The United States enforcing a complete ban and others giving financial support (8).

In this literature review we look at some government regulatory framework and

compare them with together and our regulation.

Regulation of stem cell research in Europe is shown in (table1) (9).

Regulation of stem cell research in Asia is shown in (Table.2) (1).

2. Discussion:

Islamic Republic of Iran had a significant effort to reach this knowledge from the beginning of its formation and especially in the past decade. Iran is among the first countries which achieved to these technologies. The use of human embryonic stem cells or adult cell origin, has been hopeful to treat and reduce the severity of diseases and also has its ethical considerations such as the safety of the subjects and the respect of human embryos. Undoubtedly, proper and sustainable utilization of such researches depend on ethical considerations. An ethical guidelines has been recently approved. So we propose a regulatory framework based on this moral guideline.

The regulatory pathway for stem cell research in the UK is well established, and is documented for different research scenarios (human stem cells only) in the UK Stem Cell

Toolkit. Research ethics committee that considers all proposals for research on human subjects using cells from human stem cell lines have also examined and issued reports on ethical issues relating to stem cell research. (11)

An ethical guideline in Iran has been recently approved. In compiling this guideline the accumulated experience of the governments, Islamic laws, Persian culture and its special look to human health as well as the moral status of the human embryo has been used. Some part of this guideline is licensed research can only take place on embryos created *in vitro*: embryos that have developed from eggs fertilized outside the body. Most embryos used in stem cell research are embryos initially created for use in fertility treatment, but not used. These 'surplus' IVF embryos, if donated with the full consent of the parents, can be used for research. So we propose a regulatory framework based on this moral guideline. One of our suggestions for regulation of stem cell research is legal medicine organization.

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