

**HUMAN STEM CELL RESEARCH AND LAWS: AN OVERVIEW OF
INTERNATIONAL PERSPECTIVE****Dr. Rajinder Verma*****1. Introduction**

Stem cells are cells which can give rise to many different types of cells and are able to replicate infinitely (or for a very long time). They are present in embryonic, fetal, or adult. Embryonic stem (ES) cells had been derived from mouse blastocysts since 1981. In 1997, the cloning of Dolly the sheep, using a technique called somatic cell nuclear transfer (SCNT) enabled a means of generating ES cells with defined genetic makeup. In 1998, James Thomson and co-workers became the first scientists to derive and successfully culture human embryonic stem cells (hES cells) from a human blastocyst, an early human embryo of approximately 200 cells, donated by a couple who had completed infertility treatments. In the same year, John Gearhart (Johns Hopkins University) derived germ cells from cells in fetal gonadal tissue (primordial germ cells).

United Nations' instruments provide for various basic rights of the human beings. Everyone has the right to life, liberty and security of person.¹ No research or research applications concerning the human genome in particular in the fields of biology, genetics and medicine, should prevail over respect for the human rights, fundamental freedoms and human dignity of individuals or, where applicable, of groups of people.² The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.³ No one shall be arbitrarily deprived of his life.⁴

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¹ Universal Declaration of Human Rights, 1948, Article 3.

² Universal Declaration on the Human Genome and Human Rights, 1997, Article 10.

³ International Covenant on Economic, Social and Cultural Rights, 1966; Article 12(1).

⁴ International Covenant on Civil and Political Rights, 1966, Article 6(1).

Apart from United Nations, various bodies in the medical sphere have also contributed to the Guidelines to regulate the research on human subjects and related areas.

In February 1980, the Indian Council of Medical Research released a 'Policy Statement on Ethical Considerations involved in Research on Human Subjects' for the benefit of all those involved in clinical research in India under the chairmanship of Hon'ble Justice H R Khanna. These guidelines were revised in 2000 as the 'Ethical Guidelines for Biomedical Research on Human Subjects' under the chairmanship of Hon'ble Justice M N Venkatachaliah.⁵ Considering the recent advances in the field of Assisted Reproductive Technologies, separate guidelines have been brought out by the Indian Council of Medical Research as 'National Guidelines for Accreditation, Supervision and Regulation of ART Clinics in India' in 2005. In view of the new developments in the field of science and technology, another revision was carried out as Ethical Guidelines for Biomedical Research on Human Participants in 2006.⁶ The Guidelines contain both General and Specific Principles.

This article shall discuss the international developments briefly.

2. INTERNATIONAL LEGAL POSITION VIS-À-VIS STEM CELL RESEARCH -

The legal provisions must facilitate scientific research in view of potential benefits of stem cell research for human health and well-being, without ignoring ethical assessment of its justifiability.⁷ The first International Code of Ethics for Research involving human subjects - 'The Nuremberg Code' in 1947 laid down standards for carrying out human experimentations, emphasizing the subject's voluntary consent. It was a response to the cruelties committed by Nazi Research Physicians revealed at the Nuremberg war crimes trials. Thus, it was intended to

⁵ Available at

http://ethics.ncdirindia.org/asset/pdf/Ethical_guidelines_for_biomedical_research_on_human_subject-2000.pdf.

⁶ Available at https://www.icmr.nic.in/sites/default/files/guidelines/ethical_guidelines_0.pdf.

⁷ Rosario M. Isasi¹ and Bartha M. Knoppers, "Beyond the permissibility of embryonic and stem cell research: substantive requirements and procedural safeguards", available at <http://humrep.oxfordjournals.org/cgi/content/full/21/10/2474>.

prevent any repetitions by physician of such attacks on the rights and welfare of human beings that human research ethics came into being.

2.1 International Instruments regulating Stem Cell Research

Based on the preliminary efforts of the Council for International Organisations of Medical Sciences (C.I.O.M.S.) in 1964 at Helsinki, the World Medical Association formulated general principles on use of human subjects in medical research in addition to specific guidelines for biomedical research, known as the Helsinki Declaration which was revised from time to time. The Declaration of Helsinki was revised in 1983 , 1989 and 2002.

C.I.O.M.S., in association with W.H.O., undertook its work on ethics in biomedical research in the late 1970s. The outcome of the C.I.O.M.S./W.H.O. collaboration was entitled Proposed International Ethical Guidelines for Biomedical Research Involving Human Subjects.

In 1982, the World Health Organisation (W.H.O.) and the CIOMS issued the 'Proposed International Guidelines for Biomedical Research involving Human Subjects.' Subsequently the C.I.O.M.S. brought out the 'International Guidelines for Ethical Review in Epidemiological studies' in 1991 and 'International Ethical Guidelines for Biomedical Research involving Human subjects' in 1993. The 1993 Guidelines of C.I.O.M.S. were revised in 2002.

“Research involving human subjects includes: studies of a physiological, biochemical or pathological process, or of the response to a specific intervention , whether physical, chemical or psychological in healthy subjects or patients; controlled trials of diagnostic, preventive or therapeutic measures in larger groups of persons, designed to demonstrate a specific generalizable response to these measures against a background of individual biological variation; - studies designed to determine the consequences for individuals and communities of specific preventive or therapeutic measures; and - studies concerning human health-related behaviour in a variety of circumstances and environments. Research involving human subjects may employ either observation or physical, chemical or psychological intervention; it may also either generate records or make use of existing records containing biomedical or other information about individuals who may or may not be identifiable from the records or information. The

research may be concerned with the social environment, manipulating environmental factors in a way that could affect incidentally-exposed individuals. It is defined in broad terms in order to embrace field studies of pathogenic organisms and toxic chemicals under investigation for health-related purposes. All research involving human subjects should be conducted in accordance with three basic ethical principles, namely respect for persons, beneficence and justice.”⁸

To develop guidelines for the conduct of human embryonic stem cell (ESC) research that address the international diversity of cultural, political, legal and religious perspectives, the I.S.S.C.R. assembled a task force composed of experts in science and medicine, ethics and law from 14 countries. The I.S.S.C.R. Guidelines for the Conduct of Human Embryonic Stem Cell Research specify rigorous ethical standards for scientists working with human ESCs, and seek to promote responsible, transparent and uniform practices worldwide. Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo.⁹ The creation of human embryos for research purposes is prohibited.¹⁰

⁸ International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002 ; available at <https://cioms.ch/shop/product/international-ethical-guidelines-for-biomedical-research-involving-human-subjects-2/>.

⁹ Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 1997 , Article 18(1).

¹⁰ *Ibid*, Article 18(2).

Table 1 – Human Stem Cell Research under International Instruments

S.No.	International Instrument	Formulating Body
1.	Helsinki Declaration,1964	World Medical Association
2.	International Guidelines for Ethical Review in Epidemiological studies, 1991	Council for International Organisations of Medical Sciences (C.I.O.M.S.)
3.	International Ethical Guidelines for Biomedical Research involving Human subjects, 1993	Council for International Organisations of Medical Sciences (C.I.O.M.S.)
4.	United Nations Declaration on Human Cloning,2005	United Nations
5.	Guidelines for the Conduct of Human Embryonic Stem Cell Research ,2006	The International Society for Stem Cell Research (I.S.S.C.R.)
6.	Guidelines for the Clinical Translation of Stem Cells ,2008	The International Society for Stem Cell Research (I.S.S.C.R.)

United Nations Declaration on Human Cloning declares the following: (a) Member States are called upon to adopt all measures necessary to protect adequately human life in the application of life sciences; (b) Member States are called upon to prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life; (c) Member States are further called upon to adopt the measures necessary to prohibit the application of genetic engineering techniques that may be contrary to human dignity; (d) Member States are called upon to take measures to prevent the exploitation of women in the application of life sciences; (e) Member States are also called upon to adopt and implement without delay national legislation to bring into effect paragraphs (a) to (d); (f) Member States are further called upon, in their

financing of medical research, including of life sciences, to take into account the pressing global issues such as HIV/AIDS, tuberculosis and malaria, which affect in particular the developing countries.¹¹ The text of the 2005 United Nations Declaration on Human Cloning blurred the line separating reproductive and therapeutic cloning. The Universal Declaration on Human Genome and Human Rights, 1997), The International Declaration on Human Gene Data, 2003 and Universal Declaration on Bioethics and Human Rights , 2005 are also relevant.

2.2 Provisions dealing with patents of human stem cells

Patenting is a fundamental attack on this understanding of life as interconnected, mutually dependent and a gift of God which is given to all. It is also at variance with the Judeo-Christian conviction that freedom, openness and possibility are the hallmarks of life in God's creation. Various religious objections raised against the principle of patenting life forms certainly deserve to be respected.¹²

Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.¹³ An area of patent law that is still developing relates to the kind of information that must be included in the patent application of a biotechnology-related invention in order to sufficiently identify and distinguish its characteristics from other subject matter.¹⁴

¹¹ Available at http://5859d7f0f30e9c1373ac-76f52f45edd080d6d6d41139c312cfe3.r43.cf2.rackcdn.com/uploaded/u/0e2950803_1393615745_unonhumancloning.pdf. It was approved by the United Nations General Assembly on March 8, 2005.

¹² Graham Dutfield, IPR and the Life Science Industries- A Twentieth Century History, Aspgate Publishing Ltd., (2003) , p.164.

¹³ TRIPS, 1994, Article 27(2).

¹⁴ John J. Doll, "The Patenting of DNA", *Science* , May 1998, Vol. 280. no. 5364, pp. 689 - 690.

3. HUMAN RIGHTS PERSPECTIVE OF STEM CELL RESEARCH

In a bio society or bio technocracy, biological advances often dictate our life on their own terms affecting the basic human rights and traditional social structure.¹⁵ Human blastocysts have moral value equivalent to that of persons, which in turn suggests that researchers should not do to blastocysts anything that they would not do a person. The freedom of scientific research is not unlimited. Scientific research is obliged to respect human dignity and life, physical integrity and freedom of the person.¹⁶ The major justification for the non grant of patent to life forms has been based on the absence of effective system for distinguishing between formal and informal system for assessing its impact on public order and morality.¹⁷

Human life is sacred from its very beginning, since from conception it is ensouled existence.¹⁸ As such, it is personal existence, created in the image of God and endowed with a sanctity that destines it for eternal life. According to Jewish law, full human status does not occur until birth, but fetuses re considered potential human life .The plurality of philosophical and religious views has led to a general consensus that the human embryo has a special moral status, less than that of born human person but greater than that of other collections of cells.

Most positions on embryonic stem cell research rest at least in part on the relative moral weight accorded to embryos and that accorded to the prospect of saving, prolonging, or improving others' lives.¹⁹

¹⁵ Kshitj Kumar Singh, "Human Genome and Human Rights: An Overview", *Journal of Indian Law Institute*, Vol. 50(1), Jan – March (2008), p. 67.

¹⁶ Christian Starck, "The German Embryo Protection Act and the Stem Cell Act ", *German Law Journal*, July 1, (2006).

¹⁷ Abhinav Kumar, "Towards Patentability of Essentially Biological Processes", *Journal of Intellectual Property Rights*, vol 13, Mar 2008, p. 129.

¹⁸ Embryonic Stem Cell Research in the Perspective of Orthodox Christianity available at <http://www.oca.org/Docs.asp?ID=50&SID=12>.

¹⁹ Judith A. Johnson & Erin Williams, Stem Cell Research, CRS Report for Congress, August 13, (2004)

4. CONCLUSION

Most technological innovations that are there to make daily life easier are outcomes of the underlying wish in our culture not to respect the limits nature sets to human freedom. Great possibilities for improvements in human health are offered by research using human stem cells. The need for uniform ethical guidelines for research on human subjects is universally recognised.

Over the years, various international bodies and respective national bodies have laid down general and specific principles in specific areas of scientific research entailing the use of human beings as subjects in medical research. The national Codes inspired from the international codes and the universal principles underlying them outline 'guidelines' to be followed in their respective jurisdictions. The main instruments are Helsinki Declaration, 1964 ; International Guidelines for Ethical Review in Epidemiological studies, 1991 ; International Ethical Guidelines for Biomedical Research involving Human subjects, 1993 ; United Nations Declaration on Human Cloning, 2005 Guidelines for the Conduct of Human Embryonic Stem Cell Research, 2006 and Guidelines for the Clinical Translation of Stem Cells, 2008 . Similarly, in India, I.C.M.R. brought out a policy document in 1980, which was revised in 2000 and further revised in 2006.

While on one hand, research involving human participants must not violate any universally applicable ethical standards, on the other hand, a researcher needs to consider local cultural values when it comes to the application of the ethical principles to individual autonomy and informed consent. Stem cell research should not be allowed to be pursued solely on its scientific potential with no weight given to the fact that whether research requires destruction of blastocytes and purpose for which they are used. With the emergence of new technologies and knowledge that can potentially transform society, it has become necessary to constantly update the ethical guidelines to protect the rights and safety of the research participants involved in clinical research.