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Review Article

Ethical Issues in the Stem Cells Research- An Updated Review

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INTRODUCTION:-

Stem cells are undifferentiated biological cells that can differentiate into specialized cells and can divide (through mitosis) to produce more stem cells. They are found in multi-cellular organisms. They have the remarkable potential to develop into many different cell types in the body especially during early life and growth of an individual. In addition, they also serve as a sort of internal repair system in many tissues, to replenish other cells as long as the person or animal is still alive. Stem cells are distinguished from other cell types by two important characteristics. SELF RENEWAL AND POTENCY, which include the capability to renew themselves through cell division and under certain physiologic or experimental conditions, they can be induced to become tissue or organ-specific cells with special functions respectively. Diseases and conditions where the stem cells use is being investigated include; Diabetes mellitus, Rheumatoid arthritis, Parkinson's, Alzheimer's disease, Osteoarthritis, Stroke and traumatic brain injury repair, learning disability due to congenital disorder etc.

Different types of stem cells used for research activities. [1]

I. Multipotent Stem Cells

A. Cord blood stem cells B. Adult blood stem cells

II. Embryonic Stem Cell Research

A. Existing embryonic stem cell lines

B. New embryonic stem cell lines from frozen embryos

C. Ethical concerns about oocyte donation for research

III. Somatic Cell Nuclear Transfer (SCNT)

A. Ethical concerns about SCNT

IV. Fetal Stem Cells

V. Induced Pluripotent Stem Cells (iPS Cells)[i]

BACKGROUND OF THE STEM CELL RESEARCH:

Scientists had been working with embryonic stem cells derived from mouse embryos more than 30 years ago, till they discovered ways to develop two kinds of stem cells Embryonic and Non embryonic or somatic or adult stem cells from the early mouse embryos. The detailed study of the biology of mouse stem cells led to the discovery, in 1998, of a method to derive stem cells from human embryos and grow the cells in the laboratory. These cells are called **Human embryonic stem cells (hES)**. In 2006, a major breakthrough was identification of **induced pluripotent stem cells (iPSCs)** which are the specialized adult cells to be "reprogrammed" genetically to assume a stem cell-like state. Through the research studies scientists have started using stem cells to screen the new drugs and learn about the special characteristics of stem cells which make them different from specialised cell types along with identifying their contribution towards normal growth and identification of birth defects. Although stem cell research is one of the most fascinating areas of contemporary biology, it also raises sharp ethical and political controversies. With any hSC research, however, there are difficult dilemmas, including consent to donate materials for hSC research, early clinical trials of hSC therapies, and oversight of hSC research.[1]

AIMS AND OBJECTIVES OF THE STUDY:

This review commentary is basically aimed towards :

- ✓ Addressing the key ETHICAL issues surrounding the stem cells research and therapy.
- ✓ As well as it is aimed towards the listing or summarizing the basic guidelines released by various national and international organizations about the stem cells research.
- ✓ Finally the aim is also to clear the ambiguity between "**Stem cells research and therapy"** which is very much attention seeking in developing countries like India.

METHODOLOGY USED IN THIS STUDY:

The methodology to update this review involves the secondary research based upon library referencing from the year 2000 to 2016 through online search using key words as, "stem cells, stem cells research, stem cells research and therapy, ethics and stem cells, stem cells controversies, ethical guidelines and stem cells."

Discussion about the Ethical concerns related to different types of stem cell research:

I. Multipotent stem cells: Adult stem cells and cord blood stem cells do not raise special ethical concerns and are widely used in research and clinical care. However, these cells cannot be expanded in vitro and have not been definitively shown to be pluripotent.

A. Cord blood stem cells: Hematopoietic stem cells from cord blood can be banked and are widely used for allogenic and autologous stem cell transplantation in pediatric hematological diseases as an alternative to bone marrow transplantation. **B. Adult blood stem cells:** Adult stem cells occur in many tissues and can differentiate into specialized cells in their tissue of origin and also trans-differentiate into specialized cells characteristic of other tissues. For example, hematopoietic stem cells can differentiate into all three blood cell types as well as into neural stem cells, cardiomyocytes, and liver cells.

II. Embryonic Stem Cell Research: Pluripotent stem cell lines can be derived from the inner cell mass of the 5 to 7day-old blastocyst. However, human embryonic stem cell (hESC) research is ethically and politically controversial because it involves the destruction of human embryos. In the United States, the question of when human life begins has been highly controversial and closely linked to debates over abortion. As a matter of religious faith and moral conviction, they believe that "human life begins at conception" and that an embryo is therefore a person.[2] Few people, however, believe that the embryo or blastocyst is just a clump of cells that can be used for research without restriction. Many hold a middle ground that the early embryo deserves special respect as a potential human being and can be used for certain types of research provided there is good scientific justification, careful oversight, and informed consent from the woman or couple for donating the embryo for research.[3]

A.Ethical concerns related to embryonic stem cell research:

1. Informed consent for donation of materials for stem cell research: Since the Nuremburg Code, informed consent has been regarded as a basic requirement for research with human subjects. Consent is particularly important in research with human embryos.[4]

2. Waiver of consent: In the United States, federal regulations on research permit a waiver of informed consent for the research use of de-identified biological materials that cannot be linked to donors.[5] Thus, logistically it would be possible to carry out embryo and stem cell research on deidentified materials without consent. For example, during IVF procedures, oocytes that fail to fertilize or embryos that fail to develop sufficiently to be implanted are ordinarily discarded can therefore be used for research purpose without the need of any consent.

3. Consent from gamete donors: Frozen embryos may be created with sperm or oocytes from donors who do not participate any further in assisted reproduction or childrearing. Specific consent for stem cell research from both embryo and gamete donors was recommended by the National Academy of Sciences 2005 Guidelines for Human Embryonic Stem Cell Research and has been adopted by the California Institute for Regenerative Medicine (CIRM), the state agency funding stem cell research.[6]

4. Confidentiality of donor information: Confidentiality must be carefully protected in embryo and hESC research because breaches of confidentiality might subject donors to unwanted publicity or even harassment by opponents of hESC research.[7] Files containing the identities of persons whose gametes or embryos were used to derive hESC lines should be protected through heightened security measures.

B.Ethical concerns about oocyte donation for research : Concerns about oocyte donation specifically for research are particularly serious in the wake of the Hwang scandal in South Korea, in which widely hailed claims of deriving human SCNT lines were fabricated. In California, some legislators and members of the public have charged that infertility clinics downplay the risks of oocyte donation.[8] CIRM has put in place several protections for women donating oocytes in state-funded stem cell research.

C. Protections for women about oocyte donation for research:

1.Medical risks of oocyte retrieval: The medical risks of oocyte retrieval include ovarian hyperstimulation syndrome, bleeding, infection, and complications of anesthesia. These risks may be minimized by the exclusion of donors at high-risk for these complications, careful monitoring of the number of developing follicles, and adjusting the dose of human chorionic gonadotropin administered to induce ovulation or canceling the cycle.[9] Because severe hyperovulation syndrome may require hospitalization or surgery, women donating oocytes for research should be protected against the costs of complications of hormonal stimulation and oocyte retrieval.

2. Protecting the reproductive interests of women in infertility treatment: If women in infertility treatment share oocytes with researchers—either their own oocytes or those from an oocyte donor—their prospect of reproductive success may be compromised because fewer oocytes are available for reproductive purposes.[10] In this situation, the physician carrying out oocyte retrieval and infertility care should give priority to the reproductive needs of the patient in IVF. The highest quality oocytes should be used for reproductive purposes.

3. Payment to oocyte donors: Many jurisdictions have conflicting policies about payment to oocyte donors. Reimbursement to oocyte donors for out-of-pocket expenses presents no ethical problems because donors gain no financial advantage from participating in research. Furthermore, bans on payment for oocyte donation for research have been criticized as paternalistic, denying women the authority to make decisions for themselves.[11]

4. Informed consent for oocyte donation: In California, **CIRM** (CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE) has instituted heightened requirements for informed consent for oocyte donation for research. The major ethical issue is whether donors appreciate key information about oocyte donation, not simply whether the information has been disclosed to them or not. CIRM thus reasons that disclosure, while necessary, is not sufficient to guarantee informed consent.[8]

III. Somatic Cell Nuclear Transfer (SCNT): In SCNT, reprogramming is achieved after transferring nuclear DNA from a donor cell into an oocyte from which the nucleus has been removed. However, creating human SCNT stem cell lines has not only been scientifically impossible to date but is also ethically controversial.[12,13]

Ethical concerns about SCNT:

1. Objections to creating embryos specifically for research: Some people who object to SCNT believe that creating embryos with the intention of using them for research and destroying them in that process violates respect for nascent human life.

2. Objections to human reproduction using SCNT: There are several compelling objections to using SCNT for human reproduction. First, because of errors during reprogramming of genetic material, cloned animal embryos fail to activate key embryonic genes, and newborn clones misexpress hundreds of genes.[14,15]

3. Use of animal oocytes to create SCNT lines using human DNA: Because of the shortage of human oocytes for SCNT research, some scientists wish to use nonhuman oocytes to derive lines using human nuclear DNA. These so-called "Cytoplasmic Hybrid Embryos" raise a number of ethical concerns. Some opponents fear the creation of chimeras—mythical beasts that appear part human and part animal and have characteristics of both humans and animals.[16]

IV. Fetal Stem Cells: Pluripotent stem cells can be derived from fetal tissue after abortion. However, use of fetal tissue is ethically controversial because it is associated with abortion, which many people object to. Under federal regulations, research with fetal tissue is permitted provided that the donation of tissue for research is considered only after the decision to terminate pregnancy has been made.[17,18]

V. Induced Pluripotent Stem Cells (iPS Cells): Somatic cells can be reprogrammed to form pluripotent stem cells,[19,20] called induced pluripotential stem cells (iPS cells). These iPS cell lines will have DNA matching that of the somatic cell donors and will be useful as disease models and potentially for allogenic transplantation.. The President's Council on Bioethics called iPS cells "ethically unproblematic and acceptable for use in humans."[21]

Stem Cell Clinical Trials- transition from research to therapy- Ethical issues:

Transplantation of cells derived from pluripotent stem cells offers the promise of effective new treatments. However, such transplantation also involves great uncertainty and the possibility of serious risks. Some stem cell therapies have been shown to be effective and safe, for example hematopoietic stem cell transplants for leukemia and epithelial stem cell-based treatments for burns and corneal disorders.[21] However, "there are some clinics around the world already exploiting patients' hopes by purporting to offer effective stem cell therapies for seriously ill patients, typically for large sums of money, but without credible scientific rationale, transparency, oversight, or patient protections."[21] Although supporting medical innovation under very limited circumstances, the International Society for Stem Cell Research has decried such use of unproven hSC transplantation.

Ethical issues in the stem cell clinical trials and the hype of the stem cell therapy in INDIA:

Understandably, medical professionals and patients, the world over, are agog to see the effects of stem cell transplantation in the treatment of diseases where current remedies have failed. In countries where effective regulation ensures that medical practices remain ethical and scientific, the use of stem cells in the treatment of diseases such as those of the heart, liver, brain and spinal cord has remained in the experimental stage. Trials in animals have shown unexpected complications - such as the formation of tumours by the transplanted stem cells - in some cases. Very carefully controlled clinical trials in humans have been permitted in a few instances. The results are being closely monitored by experts not involved in the trials as well as those conducting them.

The National Institutes of Health, USA, notes, on its website: "Adult stem cells, such as blood-forming stem cells in bone marrow ... are currently the only type of stem cell commonly used to treat human diseases. Doctors have been transferring such cells in bone marrow transplants for over 40 years... The clinical potential of adult stem cells has also been demonstrated in the treatment of other human diseases that include diabetes and advanced kidney cancer. However, these newer uses have involved studies with a very limited number of patients."[22]

In India we see a marked contrast. Individuals and institutions offer stem cell therapy to all patients. Claims are made on successful use of stem cells in curing diseases of the heart, liver and other organs; spinal cords damaged by injury and even cancer. Take the following example reproduced verbatim from the website of Life Line Hospital in Chennai:

"Spinal Cord Damage": Stem cells have found use in Patients with Muscular or Bladder paralysis after Spinal Cord Injury. In patients with paraplegia this therapy is of maximum use in patients 1-2 years after Spinal cord injury. It could also be potentially of use for patients with other neurological diseases of the spinal cord. In the future the therapy may be useful for patients with Brain Damage also. Stem cell Injected directly into the Spinal fluid or around the spinal cord, at the site of injury has been found to improve nerve function. The Injection procedure is done under local anesthesia and is painless.[23]

Another section at this website is equally dramatic: **"Cancer" :** "Natural Killer cells (NK cells) which can be purified from the peripheral blood is found to be beneficial even in late cases of cancers like - Melanoma, Liver, pancreatic, lung and Gastric cancers." The website also claims: "All Stem cell (sic) trials in Life Line Hospital are registered with NIH, USA and ICMR, India." Dr Vasantha Muthuswamy, senior deputy director-general at the Indian Council for Medical Research (ICMR), informed in a personal communication: "We have not given any approval to Lifeline Hospital." She elaborated: "ICMR has not given recognition to any centre for clinical applications. The only centres which have been cleared for basic research on stem cell biology are Manipal Acunova at Bangalore and Niche in stem cell research and regenerative medicine at Chennai."

Here is another example: "November 16, 2005: In the midst of controversy over the use of embryonic stem cells therapy for treatment, a private clinic on Wednesday claimed to have improved medical condition of 100 patients suffering from Alzheimer, paralysis and Parkinson's disease using the technique but government was cautious saying it would set up more operational guidelines for the area. "The claim by Nu tech Mediworld, a registered in vitro Fertilisation and Genetic Centre in Delhi, was made in the presence of Union Health Secretary P K Hota."[24]

On January 23, 2006, The Hindu reported a follow-up story from New Delhi: "The Government has ordered an inquiry into the activities of clinic conducting embryonic stem cell therapy and warned of stringent action against those found violating the rules and guilty of playing with the health of unsuspecting patients, Health Minister Anbumani Ramadoss said, "Current practices suggest that we have a long way to go with which we can even approach the standards of scientific and ethical excellence that are the norm in many other countries. Our regulatory agencies are unwilling to act effectively when individuals or institutions flout required standards, especially when these are politically powerful." The risks and benefits should be outweighed properly and understood by everyone who is willing to be a part of stem cells research or claimed therapies.

A. Risks and prospective benefits in stem cell clinical trials: The risks of innovative stem cell-based interventions include "tumor formation, immunological reactions, unexpected behavior of the cells, and unknown long-term health effects".[21] Evidence of safety and proof of principle should be established through appropriate preclinical studies in relevant animal models or through human studies of similar cell-based interventions. Requirements for proof of principle and safety should be higher if cells have been manipulated extensively in vitro or have been derived from pluripotent stem cells.[21]

B. Informed consent in early stem cell clinical trials: Problems with informed consent are well documented in phase I clinical trials. Participants in cancer clinical trials commonly expect that they will benefit personally from the trial, although the primary purpose of phase I trials is to test safety rather than efficacy.[25] This tendency to view clinical research as providing personal benefit has been termed the "therapeutic misconception".[26]

DISCUSSION AND REVIEW OF LITERATURE:

The ethical dilemma about the stem cell research :

Embryonic stem cell research poses a moral dilemma. It forces us to choose between two moral principles:

- The duty to prevent or alleviate suffering
- The duty to respect the value of human life

In the case of embryonic stem cell research, it is impossible to respect both moral principles. To obtain embryonic stem cells, the early embryo has to be destroyed. This means destroying a potential human life. But embryonic stem cell research could lead to the discovery of new medical treatments that would alleviate the suffering of many people. So which moral principle should have the upper hand in this situation? The answer hinges on how we view the embryo.

Religious views :

Jewish view: According to Rabbi Levi Yitschak Halperin of the Institute for Science and Jewish Law in Jerusalem, embryonic stem cell research is permitted so long as it has not been implanted in the womb. Not only is it permitted, but research is encouraged, rather than wasting it. As long as it has not been implanted in the womb and it is still a frozen fertilized egg, it does not have the status of an embryo at all and there is no prohibition to destroy it. Similarly, the sole Jewish majority state, Israel permits research on embryonic stem cells.

Catholicism: The Catholic Church OPPOSES hES cell research calling it "an absolutely unacceptable act." however SUPPORTS research that involves stem cells from adult tissues and the umbilical cord, as it involves no harm to human beings at any state of development.[27]

3. Baptists: The Southern Baptist Convention OPPOSES hES cell research on the grounds that "Bible teaches that human beings are made in the image and likeness of God and protectable human life begins at fertilization." However, it SUPPORTS adult stem cell research as it does not require the destruction of embryos.[28]

4. Methodism: United Methodist Church OPPOSES hES cell

research"a human embryo, even at its earliest stages, commands our reverence." However, it SUPPORTS adult stem cell research**,** stating that there are "few moral questions" raised by this issue.[29]

5. Pentecostalism: OPPOSES hES cell research, saying, it "perpetuates the evil of abortion and should be prohibited." [30]

6. Islam: FAVORS the stance that scientific research and development in terms of stem cell research is allowed as long as it benefits society while using the least amount of harm to the subjects.[31]

Ethical controversy – The different views:

The status of the human embryo and human embryonic stem cell research is a controversial issue as, with the present state of technology, the creation of a human embryonic stem cell line requires the destruction of a human embryo. Stem cell debates have motivated and reinvigorated the pro-life movement, whose members are concerned with the rights and status of the embryo as an early-aged human life. They believe that embryonic stem cell research instrumentalizes and violates the sanctity of life and is tantamount to murder.[32] The fundamental assertion of those who oppose embryonic stem cell research is the belief that human life is inviolable, combined with the belief that human life begins when a sperm cell fertilizes an egg cell to form a single cell.

In August 2000, The U.S. National Institutes of Health's Guidelines stated: "Research involving human pluripotent stem cells, promises new treatments and possible cures for many debilitating diseases and injuries, including Parkinson's disease, diabetes, heart disease, multiple sclerosis, burns and spinal cord injuries. The NIH believes the potential medical benefits of human pluripotent stem cell technology are compelling and worthy of pursuit in accordance with appropriate ethical standards."[33] In 2006, researchers at Advanced Cell Technology of Worcester, Massachusetts, succeeded in obtaining stem cells from mouse embryos without destroying the embryos.[34] If this technique and its reliability are improved, it would alleviate some of the ethical concerns related to embryonic stem cell research.

Another technique announced in 2007 may also defuse the longstanding debate and controversy. Research teams in the United States and Japan have developed a simple and cost effective method of reprogramming human skin cells to function much like embryonic stem cells by introducing artificial viruses. While extracting and cloning stem cells is complex and extremely expensive, the newly discovered method of reprogramming cells is much cheaper. However, the technique may disrupt the DNA in the new stem cells, resulting in damaged and cancerous tissue. More research will be required before non-cancerous stem cells can be created.[35-37]

The planned treatment trials will focus on the effects of oral lithium on neurological function in people with chronic spinal cord injury and those that have received umbilical cord blood mononuclear cell transplants to the spinal cord. The interest in these two treatments derives from recent reports indicating that **umbilical cord blood stem cells** may be beneficial for spinal cord injury and that lithium may promote regeneration and recovery of function after spinal cord injury. Both lithium and umbilical cord blood are widely available therapies that have long been used to treat diseases in humans.

Ethical controversy – The advantages of research…..??

1. Endorsement:

Embryonic stem cells have the potential to grow indefinitely in a laboratory environment and can differentiate into almost all types of bodily tissue. This makes embryonic stem cells a prospect for **cellular therapies to treat a wide range of diseases.**

2. Human potential and humanity:

This argument often goes hand-in-hand with the **Utilitarian argument**, and can be presented in several forms:

- ✓ **Embryos are not equivalent to human life**…… incapable of surviving outside the womb (i.e. they only have the potential for life).
- ✓ More than a third of zygotes **do not implant** after conception.

3. Efficiency:

- ✓ IVF generates **large numbers of unused embryos** (e.g. 70,000 in Australia alone). Many of these are slated for destruction. **Using them for scientific research uses a resource that would otherwise be wasted.**

4. Superiority:

- ✓ **Counter-argument to using adult stem cells for** embryonic destruction.
- ✓ Embryonic stem cells **divide more rapidly than adult stem cells**,- Easier to generate large numbers of cells for therapeutic means.
- ✓ Have greater plasticity- to treat a wider range of diseases.
- ✓ Potential to cure chronic & degenerative diseases – current medicine ineffective.

5. Individuality:

- ✓ Since a fertilized egg has the potential to be two individuals or half of one, some believe **it can only be considered a potential person, not an actual one.** Those who subscribe to this belief then hold that destroying a blastocyst for embryonic stem cells is **ETHICAL**.

6. Viability:

- ✓ Standard under which embryos and fetuses have been regarded as human lives.
- ✓ In the United States, the 1973 Supreme Court case of **Roe v. Wade** defined viability as the point at which a fetus is "**potentially able to live outside the**

mother's womb, albeit with artificial aid." The point of viability was 24 to 28 weeks when the case was decided and has since moved to about 22 weeks due to advancement in medical technology.

- ✓ Embryos used in medical research for stem cells are well below development that would enable viability.

This argument is used by **opponents of embryonic destruction as well as researchers specializing in adult stem cell research**. Pro-life supporters often claim that the use of adult stem cells from sources such as umbilical cord blood has consistently produced **more promising results than the use of embryonic stem cells**. Furthermore, adult stem cell research may be able to make greater advances if less money and resources were channeled into embryonic stem cell research.

The ICMR guidelines about the ethical concerns in stem cells research and therapy:

General Principles:

Research on human subjects involving cells and tissues derived from human embryos and foetuses must safeguard human rights, dignity, and fundamental freedom. This includes processes related to obtaining human tissues and cells for research, diagnosis and therapy. The fundamental tenets of beneficence, non malfeasance, justice and autonomy should be adhered to in all research involving human subjects. To achieve these objectives, all research involving the use of stem cells must be guided by the general principles laid down in the "Ethical Guidelines for Biomedical Research on Human Participants" published in 2006 by the Indian Council of Medical Research (ICMR) and specific principles related to stem cells as detailed in these guidelines must be followed.

The general principles to be followed are given below:

- ➢ Principle of essentiality
- ➢ Principles of voluntariness, informed consent and community agreement
- ➢ Principle of non-exploitation
- ➢ Principle of privacy and confidentiality
- ➢ Principle of precaution and risk minimization
- ➢ Principle of professional competence
- ➢ Principle of accountability and transparency
- ➢ Principle of maximization of public interest and distributive justice
- ➢ Principle of institutional arrangements
- ➢ Principle of public domain
- ➢ Principle of totality of responsibility

Ethical Considerations Determining Specific Principles Related to Stem Cell Research:

Stem cells are unique in many ways. The two basic characteristics of stem pluripotent cells are their capacity for self-renewal and multi lineage differentiation. They may survive indefinitely and differentiate unpredictably when introduced into the human host. They may also give rise to tumours such as teratomas. Some of the major concerns that are specific to their collection, processing, storage and use, particularly of the human ES cells for translational research are listed below:

- ✓ Health and Safety of Donors
- ✓ Manufacture and Quality Assurance of Stem Cell Products
- ✓ Design of Clinical Trials:

  Planned carefully,

  With follow-up periods suitable for the subject being evaluated,

  Should also incorporate appropriate end points
- ✓ Intellectual Property Rights and Social Responsibility

CATEGORIES OF RESEARCH: (http://cdsco.nic.in/htm)

- o Permitted areas of research
- o Restricted Areas of Research
- o prohibited areas of research

ICMR-Ethical Guidelines for Biomedical Research involving Human Participants (http://www.icmr.nic.in/ethical)

Summary and conclusion: Use of stem cells in regenerative medicine holds promise for improving human health by restoring the function of cells and organs damaged due to degeneration or injury. Stem cell biology has potential application in several areas of biomedical research that includes drug development, toxicity testing, developmental biology, disease modelling, tissue engineering etc. Like many innovations, stem cell research also involves scientific, ethical and social issues. Apart from challenges of using appropriate stem cells for a particular condition, there are important issues related to the use of embryos for creating human embryonic stem (hES) cell lines. As these may lead to commoditization of human tissues and cells, there is inherent risk of exploitation of individuals particularly those belonging to the underprivileged groups, and challenges related to the contentious issue of human germ-line engineering and reproductive cloning. Premature use of stem cells for therapy before obtaining adequate data on their safety and efficacy has created an unprecedented problem related to therapeutic profligacy with vulnerable patients being exploited. The potential danger of tumorogenicity of stem cells considering their capacity for unlimited proliferation, possibility of genomic changes arising during in-vitro manipulations, and limitations related to immunological tissue incompatibility between individuals are all causes for concern. Of equal importance is the assurance of safety and rights of those donating stem cells of all types for basic and clinical research. Safeguards must be in place to protect subjects receiving stem cells through enrolment in clinical trials. Societal concerns regarding compensation for research related injuries and adverse effects are all also issues that need to be addressed.

As with any new scientific development having the potential for improving human health, research in this field must be regulated with special attention to these issues. The guiding

philosophy should be to promote scientific and ethical stem cell research while preventing premature commercialization and potential exploitation of vulnerable patients. In summary, hSC research offers exciting opportunities for scientific advances and new therapies, but also raises some complex ethical and policy issues. These issues need to be discussed along with scientific challenges to ensure that stem cell research is carried out in an ethically appropriate manner.

A wide range of ethical complications has come to light since interest first arose in the medical applications of stem cells. These problems have chiefly related to the means of procuring stem cells, especially techniques involving the destruction of human embryos. Other ethical problems have included the possibility of human cloning and the potential exploitation of embryo and egg donors, as well as the questions raised by the new alternative techniques for obtaining stem cells. The ethical acceptability of a particular research technique or medical procedure is not a matter for science alone to decide — it is not only a matter of empirical fact but also of moral judgment. Such moral judgments are not the exclusive domain of scientists or of experts in bioethics. Insofar as these matters impinge on public policy and on questions of the human future, they are deserving of public consideration and they rightly become matters not just of private conscience but of political deliberation.

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