## News



# Stem cell research & regulatory framework

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Over the decade, stem cell research has emerged as a new and innovative field in the life sciences. These cells have become promine candidates for medical therapies with a potential to change the way therapy happens in human body.

Stem cells are found in most, if not all, multi-cellular organisms. These cells are self renewable and essentially the building blocks of h and is pluripotent (cells can form any cell types-over 200). Some of the much talked about indications for stem cell technology include r tissues/organs, repair of defective cell types, acute myocardial infarction, stroke, spinal cord injury, Alzheimer's disease, Parkinson's dis marrow transplants and skin grafts resulting from severe burns.

Stem cell research was started way back in 1954 as John Enders received a Nobel Prize in Medicine for growing polio virus in human kidney cells and gained momentum since 1960s around the world.

**Advantage India**

The Government of India had felt that there was a need for regulatory framework on ethical, social and legal issues while promotin research & therapy to follow world-class standards of ethics regulation and engage all stakeholders and the society at large in terms of g consensus. With this intent, the Department of Biotechnology (DBT) under the Ministry of Science and Technology and Indian Council Research (ICMR) jointly formulated "National Guidelines of Stem Cell Research and Therapy 2007" to lay down general principles on ethi cell research and therapy. One of the salient features of the guidelines is the classification of stem cell research under permissible, res prohibited categories. These guidelines address both ethical and scientific concerns to encourage responsible practices in the area o research and therapy. For marketable products, clearance from Drug Controller General of India (DCGI) is necessary since stem cells biological drugs. It has also set standards for the collection, processing and storage of cells intended for clinical use

India has made great strides in stem cell research in recent years creating several cell lines and published more than 100 publications in th field. Therefore, India has a distinct opportunity to focus the stem cell research as no country so far has a clear advantage on stem cell res therapy; there is enough evidence to prove that India is at par with the developed nations in the global arena.

Global Market Watch has reported that the largest growth in terms of drug discovery applications using stem cells is expected from A during 2009-2015. India and China are poised to play a key role in the scientific, clinical and commercial development of stem cell rese region. As per the report, India is a significant contributor to the global market for stem cells and is growing at a rate of 15%. Further, in Indi cell research market is expected to touch estimated $ 540 million by 2015. The therapy business segment is about $ 10 billion in the ne years. According to Stem Cell Global Foundation, the stem cell banking business will grow more than 35% over the next year to 140 crores

India may be still at a nascent stage as compared to some countries like U.K., however, has a huge population base with genetic versati demand is high. Moreover India is well positioned to emerge as a significant player in the global stem cell research and clinical applica vibrant biopharmaceutical companies, a large intellectual pool of scientific talent and a mature information technology industry.

Indian researchers and doctors are particularly working in the clinical application of stem cells in ophthalmology, cardiology, diabetes, and repair. There are more than 40 research institutes, hospitals and firms involved in stem cell research in India. Government of India recog cell research as niche area and initiated the process by allocating funds for infrastructure development and operational activities.

With such a tremendous growth potential, stem cell research raises many ethical, legal, scientific and policy issues that are of concern t makers and public at large. ICMR has proposed a sizeable "stem cell priority fund" to finance research activities in this promising therap Excellent groundwork is being carried out at public and private research institutes under the sponsorship of DBT; ICMR etc. have set up a

centre for stem cell research, therapy and storage.

**The way forward to strengthen regulations**
ICMR is all set to tighten the regulations by establishing National Apex Committee (NAC) for effective monitoring and review the crucial r stem cell therapy.

The National Apex Committee for Stem cell Research and Therapy (NAC-SCRT) will monitor and review the stem cell research, te techniques and clinical practices. Once it starts operating, all institutions conducting stem cell research have to compulsorily register unde having their own institutional committee on stem cell research and therapy (IC-SCRT). Further, the National Apex Committee will serve to the stem cell research centres, available stem cell lines in India, including the newly developed ones, and ongoing clinical stem cell t country. Further, stem cell storage and banking will come under the purview of regulatory framework

Thus, the Indian Government is playing a proactive role in guarding research ethics. To evolve consensus on the 'Guidelines for Stem Cel Regulation', ICMR had public consultations in various regions among stakeholders on this document. Various stakeholders participa consultation. Evolving consensus on the document is essential because even though stem cell research holds promise for improving hea regeneration and restoration of damaged organs by various injuries and disease, it also raises several ethical, legal and social issues.

**Conclusion**
As stem cells are considered the next big thing in modern therapeutics around the world, India has the advantage of large patient p spectrum of diseases, highly skilled clinicians, young paramedical, world class researchers and favourable regulations, besides governm and funding that will significantly help the country to develop as a global player in stem cells market. India should aim to develop mu therapies to many chronic diseases prevalent in its population, and to make progress towards becoming a knowledge driven economy.

However, it is equally important to make stem cell treatment less expensive so that it is affordable to common man. Further, a concret policy will facilitate to put all research institutions under radar prescribing establishment of facilities for good manufacturing practices (G Lab Practices (GLP) and Good Tissue Practices (GTP). Since the research guidelines cannot be legally enforced,it is unclear what reco be taken against those found operating outside these guidelines. A penalty provision for non-compliance with the guidelines should also indicated.

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