

**Q.1. Is there stem cell research activities going on India? In what way Government of India supported these activities?**

Yes.

The Government of India has been supporting basic as well as clinical research through national funding agencies like the Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT) and Department of Science and Technology (DST). This has resulted in the establishment of state-of-art infrastructure at over 40 premier health research and educational institutes in addition to supporting industry initiatives in India.

**Q.2. Are there any guidelines governing stem cell research in India?**

- Yes, since 2007 guidelines are available and any stem cell research has to be in compliance with these.
- MoHFW, Government of India is committed towards stem cell treatments that are safe and have proven efficacy. The Guidelines for Stem Cell Research and Therapy in 2007 was a step towards this commitment, which were revised after public consultations/opinion and released as National Guidelines for Stem Cell Research (NGSCR-2013).
- These were further revised to incorporate the recent technical advances and harmonized with the existing rules and regulations in the country to be released as The National Guidelines for Stem Cell Research, 2017 on 12<sup>th</sup> Oct 2017 as(available at [http://bic.icmr.org.in/nacsrt/downloads/National\\_Guidelines\\_for\\_Stem\\_Cell\\_Research\\_2017.pdf](http://bic.icmr.org.in/nacsrt/downloads/National_Guidelines_for_Stem_Cell_Research_2017.pdf) ).

**Q.3. What kind of stem cell research is covered by NGSCR 2017?**

- Both basic and clinical research involving any kind of human stem cells and their derivatives is to be done in compliance with NGSCR 2017.
- The guidelines do not apply to research using non-human stem cells and their derivatives.
- Further, these do not apply to use of hematopoietic stem cells for treatment of various haematological, immunological and metabolic disorders since these have already been established as a standard of medical care.
- Protein rich plasma (PRP) and autologous chondrocyte/osteocytes implantation does not fall under the purview of these guidelines as they are categorized as other cell based applications and not stem cell transplantation.

**Q.4. Who has to follow the NGSCR 2017?**

All stakeholders including individual researchers, organizations, sponsors, oversight/regulatory committees and all others associated with both basic and clinical research involving any kind of human stem cells and their derivatives.

**Q.5. What is the mechanism of monitoring the stem cell research activities in the country?**

- Two levels of monitoring mechanism have been established: one at the national level focusing primarily on policy and the other, a more self-regulatory system of review at the institutional level.
- The National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) has been constituted and notified by Department of Health Research (DHR), Ministry of Health and Family Welfare, Govt. of India as an independent body of experts representing diverse areas of biomedical research, concerned government agencies and other stakeholders.
- The Institutional Committee of Stem Cell Research (IC-SCR), on the other hand, operates at the institutional level with members having specific expertise as per these guidelines. It is mandatory for them to register with NAC-SCRT and submit periodic report on their scientific activities for effective functioning.
- All Clinical trial need approval of Cell Biology Based Therapeutic Drugs Evaluation Committee (CBBTDEC) of Central Drug Standards Control Organization (CDSCO).