
FREQUENTLY ASKED QUESTIONS ON BASIC RESEARCH IN STEM CELLS

1) What is meant by basic research?

Basic fundamental research is an essential component of biomedical science, intended to enhance knowledge and understanding of a subject without necessarily leading to immediate practical solutions and/or therapeutic application.

2) What is the importance of basic research in field of stem cell and how it has been useful so far?

A focus on basic aspects of research in stem cell biology is important to advance our understanding on the mechanisms responsible for stemness, role of niche, dormancy, recruitment, plasticity and their ability to repair and regenerate etc.

3) What is included in the basic research?

It includes establishing *in vitro* cell culture systems to investigate stem cells and progenitors of different lineages and understand stages of cell differentiation. *In vivo* studies i.e. stem cell research in animals is also a part of basic research.

4) How basic research has been useful so far?

Research on human ESCs has led to new knowledge about embryo development. Breakthrough in iPSC technology has revolutionized the field of stem cell biology and has led to the generation of human disease specific models to understand the underlying pathophysiology. *In vitro* stem cell cultures have found application in drug discovery and toxicity screening.

5) In what way NGSCR 2017 applies to basic stem cell research?*

The basic stem cell research largely falls under the **permissible category** that can be conducted with prior approval of IC-SCR and Institutional Ethics Committee (IEC) or Institutional Animal Ethics Committee (IAEC) and includes

- *In vitro* studies using stem cells and/or established stem cell lines
- Establishment of new human ESC lines from spare embryos or iPSC lines from fetal/adult tissues or somatic stem cell lines from fetal or adult tissues.
- *In vivo* studies in experimental animals (other than primates), with established cell lines from any type of human pluripotent stem cells viz. ESCs, iPSCs, including their differentiated cells, and human SSCs (fetal, neonatal or adult) from any tissue, are permitted with the prior approval of IC-SCR and IAEC.

Basic research studies falling under **restrictive area of research** require additional arm of oversight/monitoring (such as IAEC/CPSCEA/ISBC/RCGM/NAC-SCRT approvals, as applicable) due to contentious issues involved. It includes:

- Creation of human pre-implantation embryos by *In vitro* fertilization (IVF), Intracytoplasmic Sperm Injection (ICSI), Somatic Cell Nuclear Transfer (SCNT) or any other method with the specific aim of deriving ESC lines for any purpose.
- Research involving introduction of human ESC/iPSC/SSCs into animals (including primates), at embryonic or fetal stages of development for studies designed to understand the patterns of differentiation and integration of human cells into non-human animal tissues.
- Studies on chimeras where stem cells from two or more species are mixed together at any stage of early development (embryonic or fetal), for understanding patterns of development and differentiation.
- Genome modification including gene editing (for example by CRISPR-Cas9 technology) of stem cells, germ-line stem cells or gamete and human embryos is restricted only to *in vitro* studies.

The following areas of fall under the **prohibited area of research** and cannot be done pursued under any circumstances:

- Research related to human germ line gene therapy and reproductive cloning.
- *In vitro* culture of intact human embryos, regardless of the method of their derivation, beyond 14 days of fertilization or formation of primitive streak, whichever is earlier.
- Research involving implantation of human embryos (generated by any means) after *in vitro* manipulation, at any stage of development, into uterus in humans or primates.
- Breeding of animals in which any type of human stem cells have been introduced at any stage of development, and are likely to contribute to chimeric gonadal cells.

**Please refer to NGSCR 2017 for complete details.*
