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Letter To Editor

Indian National Guidelines for Stem Cell Research (2017): Summary

Sir,

India recently updated its guidelines on stem cell research, the National Guidelines for Stem Cell Research 2017 (NGSCR 2017),[1] complied by a collaborative effort from the Indian Council of Medical Research – Department of Biotechnology. The new guidelines are a part of a continuous endeavor to tackle scientific, technical, as well as perceived challenges in the field of SCR. It seeks to facilitate safe, ethical, and regulated translational and clinical SCR by engaging all stakeholders proactively.

The guidelines exclude SCR using nonhuman stem cells and their derivatives and hematopoietic SCR. They also exclude SCR involving protein-rich plasma and autologous chondrocyte/oteocyte implantation, since they are categorized as "other cell-based applications" and not stem cell transplantation.[1]

The NGSCR-2017 mainly focuses on three aspects as follows: (i) monitoring mechanism and regulatory pathway for basic, clinical research and product development based on categories of research and level of manipulation; (ii) procurement of gametes, embryos, and somatic cells for derivation and propagation of any stem cell lines, their banking and distribution; and (iii) important areas such as international collaboration, exchange of cell/lines, and education for stakeholders and advertisement. The major highlights of NGSCR 2017 include the following:

1. Mandatory registration of the Institutional Committee-SCR (IC-SCR) and Institutional Ethics Committee (IEC) with National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) and Central Drugs Standard Control Organization (CDSCO), respectively
2. Clinical trials only to be undertaken in institutes with registered IC-SCR, IEC associated with Good Manufacturing Practice, and Good Laboratory Practice-certified facilities for processing of stem cell products and derivatives (SCP&D). Institutes must obtain mandatory accreditation from National Accreditation Board for Testing and Calibration Laboratories (NABL), when processing SCP&D for human use
3. Mandatory video consenting as per the CDSCO guidelines for audio-visual recording (dated January 9, 2014 – Schedule Y)[2]
4. Mandatory screening for communicable diseases (human immunodeficiency virus 1 and 2, hepatitis B virus, hepatitis C virus, *Treponema pallidum*, human T-lymphotropic virus, and cytomegalovirus) or any other risk factors for genetic diseases
5. Elaboration on the existing categories of research: "Permissible" – research involving establishment of embryonic stem cell (ESC) and induced pluripotent stem cells (iPSCs); "Restrictive" – research involving human preimplantation embryos processed by *in vitro* fertilization (IVF)/intracytoplasmic sperm injection (ICSI)/somatic cell nuclear transfer to derive ESC lines; and "Prohibited" – research involving human germline gene therapy and reproductive cloning
6. Elaboration on "levels of manipulation" of stem cells: Minimal: processing period must be within 72 h; approvals from CDSCO, IC-SCR, and IEC; Substantial: CDSCO approval only after IC-SCR and IEC clearances; Major: CDSCO approval after clearances from NAC-SCRT through IC-SCR and IEC
7. *In vitro* studies (largely under "permissible" category) will require prior approval of IEC and IC-SCR, except studies involving established human stem cell lines registered with the IC-SCR. *In vitro* studies on preimplantation human embryos must be carried within 14 days of fertilization or formation of primitive streak, whichever is earlier
8. Preclinical testing: Requires approval from IEC (humans), Institutional Animal Ethics Committee (small animals), and Committee for the Purpose of Control and Supervision of Experiments on Animals (large/nonhuman primates). All SCP and D testing must include safety, biodistribution, immune rejection studies, single and repeat dose toxicity studies, tumorigenicity, genotoxicity, developmental toxicity studies, and bio-distribution studies
9. Clinical studies: Require clearances from IC-SCR, IEC, and CDSCO and must be registered with Clinical Trials Registry – India. Follow-up period of minimum 2 years is mandatory. Establishing Data Safety Monitoring Board is mandatory for each study. All adverse events must be reported to IEC, CDSCO, and NAC-SCRT through IC-SCR. Trial records must be maintained for a minimum of 15 years
10. Banking of umbilical cord blood or ESC/iPSC lines permitted only in institutions licensed by the CDSCO. Commercial banking of all other biological materials has been not permitted yet. Such banks, if involved in SCR, must constitute IC-SCR (NAC-SCRT registered) and have a standard operating procedure for banking and release. Biological materials can only be released to institutes with registered IC-SCR and IEC
11. Import of stem cell lines for basic research will not require no objection certificate, but those required for clinical trials and originating oversees require import clearance from the CDSCO
12. For export of indigenously developed cell lines, IEC and IC-SCR clearances must be obtained and submitted along with the material transfer agreement during the review of such research proposals.

The provisions under NGSCR 2017 were laid down to ensure that all researches with human stem cells in the country are conducted in an ethical and scientifically responsible manner. Therefore, all stakeholders are required to comply with all regulatory requirements pertaining to biomedical research, in general, and SCR, in particular, put forth in the regulations.

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Conflicts of interest

There are no conflicts of interest.

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