Review Article

The National Guidelines for Stem Cell Research (2017): What academicians need to know?

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Abstract

India recently updated its guidelines on stem cell research (SCR), the National Guidelines for Stem Cell Research 2017. It was drafted under a collaborative effort from the Indian Council of Medical Research and 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.

Keywords: Cellular therapy, clinical translation, clinical trials, India, stem cells

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INTRODUCTION

India is one of the few countries to have formal guidelines on research involving stem-cell products and derivatives (SCPDs). While such efforts have been commended international community, significant concerns began to emerge from the mid-2000s over unproven stem-cell treatments being offered in clinics with apparently little by way of regulatory oversight. As a result, the requirements for carrying out stem cell research (SCR) were first outlined under the International Ethical Guidelines for Biomedical Research on Human Participants, published by the Indian Council of Medical Research (ICMR) in 2000 and later revised in 2006.[1] However, their recommendations are nonbinding and controversial.

To ensure ethical and good-quality SCR, the ICMR released "draft guidelines for SCR/regulation" in 2002, which was elaborately worked upon along with the Department of Biotechnology (DBT), resulting in the formulation of "Guidelines for Stem Cell Research and Therapy (2007)."[2] The 76-page document specified the ethical principles for SCR and recommended a process for formal committee approval of SCR activities and their periodic review/monitoring. It stipulated that the clinical use of stem cells was not permitted, and any use in clinical context (with the exception of already standardized use in autologous bone marrow transplantation and epithelial therapies for corneal disorders) must be the part of a clinical study, after due approval from the Institutional Committee for Stem Cell Research and Therapy (IC-SCRT), the relevant research ethics committee, and the Drugs Controller General of India (DCGI).

To encourage SCR, the Government of India focused on its policy on grants toward the infrastructure development and operational activities. In 2003, the Stem Cell Task

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Force was constituted, entrusted with the responsibility of evaluating project proposals, pushing the formulation of protocols, monitoring, and evaluating results. In fact, there was a proposal for "stem cell priority fund" with possibilities of including the ICMR, the Department of Science and Technology (DST), and the Defence Research and Development Organisation.

Consequently, in 2008, the Central Drugs Standard Control Organization (CDSCO) released a guidance document on submission requirements for new drug approvals for biotechnological/biological products, including SCPD.[3] Later in 2010, the CDSCO constituted the Cellular Biology Based Therapeutic Drug Evaluation Committee to review cell therapy-based clinical trials in the country.[4,5] Its formal recommendations were communicated in May 2011.

In 2012, the DCGI constituted a special division for stem cells in response to criticisms that it does not have any internal evaluation mechanism. The Government of India also set up a long-awaited National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) to oversee and monitor activities in this field. Since the 2007 guidelines lacked statutory backing, many scholars had been recommending providing it legislative weight. Concerns/inputs from key stakeholders were invited and addressed, and the guidelines were updated as National Guidelines for Stem Cell Research (NGSCR) 2013.[6] In 2014, the DCGI also announced that it would modify the Drugs and Cosmetics Act to treat "stem cells and cell-based products" as new drugs. In a nutshell, the 2013 guidelines were a landmark achievement, because, for the first time, it constituted the SCR in India as an object of governance. Moreover, it addressed complicated ethical, social, and legal issues involved SCR to a great extent.

Recently, on October 11, 2017, ICMR and DBT jointly updated the existing guidelines and released the NGSCR 2017.[7] The underlying guiding philosophy of the document was to prevent the premature commercialization of unproven stem-cell therapies and generation of new knowledge based on the sound scientific rationale while addressing all ethical concerns. An important aspect of the new rule is that it clarifies the ambiguity over who has legal jurisdiction over the uses of stem cell.

Table 1 provides an overview of the 2017 guidelines. Some major amendments in this guideline include mandatory registration of the Institutional Committee for Stem Cell Research and the Institutional Ethics Committee (IEC) with NAC-SCRT and CDSCO, respectively, undertaking clinical trials only at institutes with registered IC-SCR and IEC, conducting studies only at Good Manufacturing Practice (GMP)- and Good Laboratory Practice (GLP)-certified facilities and clinical research undertaken by medical professionals registered with the Medical Council of India (MCI) having an MCI-approved postgraduate qualification in the domain area of the specific trial. We further discuss some of the major provisions under the new rule.

ETHICAL AND SCIENTIFIC CONSIDERATION

Health, safety, and rights of the donor are of the utmost importance, and the following provisions in the new guidelines are committed to the same:

1. Mandatory video consent (as per the CDSCO guidelines dated January 9, 2014 – Schedule Y)[8]
2. Screening for six major transmittable diseases (HIV-1 and 2, hepatitis B virus, hepatitis C virus, *Treponema pallidum*, human T-lymphotropic virus, and cytomegalovirus) or any other risk factors for genetic disorders
3. Intellectual property rights of donated material will not vest with donor, but may be shared (to be mentioned in informed consent form). If commercialization brings any financial benefit, may be passed on to donor/community.

Key elaborations in manufacturing process and release criteria have been cited in the new guidelines, to ensure the safety and quality assurance:

1. Cell processing and manufacturing stages to be compliant with requirements as per the Schedule M of Drugs and Cosmetics Act, 1940 and Rules, to ensure the rigor of quality control and quality assurance for product development
2. SCPD can only be processed in a CDSCO-certified GLP and GMP facility (as per the Schedule L1 and M of Drugs and Cosmetics Act, 1940 and Rules, respectively)
3. For preclinical studies on animals, all laboratories must obtain GLP certification from the DST. Institutes or laboratories must also obtain the National Accreditation Board for Testing and Calibration Laboratories accreditation, when processing SCPD for human use.

MECHANISM FOR REVIEW AND OVERSIGHT

Table 2 summarizes the regulatory framework under NGSCR 2017. Jurisdictional ambiguities over the governance of stem-cell therapy seem to have finally been resolved with the ICMR-DBT in the latest guidelines. Yet, even well-ordered statutory laws require mechanisms for

Table 1: Overview of National Guidelines for Stem Cell Research 2017

Section (s)	Highlights
Ethical Consideration (Section 4.1)	Mandatory video consent (as per CDSCO guidelines dated January 19, 2014 - Schedule Y). Screening for 6 major transmittable diseases (HIV-1 and 2, HBV, HCV, Treponema pallidum, HTLV, CMV). Banking of donated material under exceptional circumstances. IPR of donated material will not vest with donor, but may be shared. If commercialization brings any financial benefit, may be passed on to donor/community
Scientific Consideration (Section 4.2)	Mandates requirement of appropriate safety measures to mitigate the risk of acquired mutation in PSCs. Short-term and long-term viability/potency testing of cryopreserved or stored products. CDSCO certified GLP and GMP facility (Schedule L1 and M) to process SCPD. For preclinical studies on animals, laboratory should have GLP certification from the DST. Institutional NABL accreditation mandatory, when processing SCPD for human use
Levels of Manipulation (Section 7)	3 levels: '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
Categorization of Research (Section 8)	3 categories: "Permissible" - Research involving establishment of ESC and iPSCs; "Restrictive" - Research involving human preimplantation embryos processed by in IVF/LCSI/SCNT to derive ESC lines; "Prohibited" - Research involving human germline gene therapy and reproductive cloning
Basic Research (Section 10)	*In vitro* studies (largely under "permissible" category) 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 out within 14 days of fertilization or formation of primitive streak, whichever is earlier. Derivation of new ESC or iPSC lines from human embryonic or somatic cells, respectively, must have prior approval of IC-SCR and IEC. Uterine implantation (human/animal) of manipulated cells with the intent of developing a whole organism is prohibited
Translational Research Including Clinical Trials (Section 11)	Preclinical testing: Requires approval from IEC (humans), IAEC (small animals), and CPCSEA (large/nonhuman primates). Product testing must include safety, biodistribution, immune rejection studies, single- and repeated-dose toxicity studies, tumorigenicity, genotoxicity, developmental toxicity studies, and biodistribution studies. Clinical studies: Require clearances from IC-SCR, IEC, and CDSCO, and must be registered with CTRI. Follow-up period of minimum 2 years is mandatory. Establishing DSMB is mandatory for each study. All adverse events must be reported to IEC, CDSCO, NAC-SCRT through IC-SCR. Trial records must be maintained for minimum of 15 years. Patient confidentiality is to be maintained by all means
Banking (Section 14)	Banking of UCB or ESC/iPSC lines permitted only in institutions licensed by CDSCO. Commercial banking of all other biological materials not permitted yet. Such banks, if involved in stem cell research, must constitute IC-SCR (NAC-SCRT registered), and have an SOP for banking and release. Biological materials can only be released to institutes with registered IC-SCR and IEC
Procurement (Section 15)	IEC and IC-SCR shall review and approve process of procurement. If cells/tissues have been developed utilizing IVF method, clearance from the NAC-SCR mandatory. Archival period for stem-cell lines and related information is 10 years. For procurement of fetal or placental tissue, processes must comply with all obligations under the MTP Act, 1971. The medical person responsible for patient care of and the investigator using the fetal material shall not be the same. The consent for fetal tissue donation should be obtained in advance and not just before or at the time of the procedure. If there is disagreement between parents, the mother's wish shall prevail. Consent for donation of blastocysts for establishment of human ESC lines should be obtained from the donor at least 24 hours in advance. Donors retain the right to withdraw consent until the blastocysts are actually used in cell line derivation
Exchange (Section 17)	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 CDSCO. For export of indigenously developed cell lines, IEC and IC-SCR clearances must be obtained and submitted along with the MTA during the review of such research proposals
Publicity (Section 19)	The advertising and publicity of any kind through any mode are not permitted and is a prosecutable offense

HIV=Human immunodeficiency virus, HBV=Hepatitis B virus, HCV=Hepatitis C virus, HTLV=Human T-lymphotropic virus, CMV=Cytomegalovirus, IEC=Institutional ethics committee, IC-SCR=Institutional Committee for Stem Cell Research, NAC-SCRT=National Apex Committee for Stem Cell Research and Therapy, GMP=Good Manufacturing Practice, GLP=Good Laboratory Practice, SOP=Standard operating procedure, ESC=Embryonic stem cell, iPSC=Induced pluripotent stem cells, NABL=National Accreditation Board for Testing and Calibration, PSC=Pleuripotent stem cells, SCPD=Stem cell products and derivatives, CDSCO=Central Drugs Standard Control Organization, HSC=Human stem-cell lines, UCB=Umbilical cord blood, MTA=Material transfer agreement, IVF=*In vitro* fertilization, ICSI=Intracytoplasmic sperm injection, SCNT=Somatic cell nuclear transfer, CTRI=Clinical Trial Registry of India, DSMB=Data Safety Monitoring Board, IPR=Intellectual Property Rights

enforcement. The process of reviewing and monitoring SCR will now be administered separately at institutional and national levels. The NAC-SCRT is to monitor research activities at the national level. The IC-SCR shall approve and monitor the SCR (basic and clinical) at the institutional level. It is mandatory for all the institutes and entities engaged in SCR to establish an IC-SCR and register the same with NAC-SCRT. The IC-SCR will provide periodic reports regarding the status of SCR to NAC-SCRT. The National Bioethics Committee has prepared the consent protocol for tissue collection for human SCR.

CATEGORIZATION OF RESEARCH INVOLVING STEM CELLS

As per the new rule, SCR is broadly categorized in three major areas, based on the ethical and/or safety concerns regarding the source of stem cells and levels of manipulation, which warrant additional review and monitoring as per the existing regulations, as follows:

1. "Permissible" – Research involving the establishment of new embryonic stem cell/induced pluripotent stem cell (iPSC) lines

Table 2: Regulatory framework as per the National Guidelines for Stem Cell Research 2017

Summary
The 2017 guidelines reiterate that any stem cell use in patients, other than that for hematopoietic stem cell reconstitution for approved indications, is investigational at present. The guidelines do not apply to research using (i) nonhuman stem cells and their derivatives; (ii) hematopoietic stem cells (where standard of medical care has been established), and (iii) PRP and autologous chondrocyte/osteocytes implantation (categorized as "other cell-based applications")
Clinical trials using stem cells should be in compliance with Schedule Y of Drugs and Cosmetic Act, 1940 as well as GCP guidelines of CDSCO and ICMR-ethical guidelines for biomedical research involving human participants (2017)
All international collaborations require approvals of the respective funding agencies followed by approval from the Indian health ministry's screening committee. In situation involving a conflict (scientific and/or ethical) between the collaborators, the existing Indian guidelines, acts, and regulations shall prevail for the work to be carried out in India
Stem cells and their derivatives fall under definition of "drug" as per the Drugs and Cosmetics Act 1940, and are categorized as "IND" or "INE" when used for clinical application
The investigator should follow the clinical trial template for protocol as per the given format (Annexure II, NGSCR 2017) and submit the application to the office of CDSCO in the Form 44. All clinical trials using stem cells must be registered with the CTRI (www.ctri.nic.in)
Review, approval, and monitoring of clinical studies involving stem cells will be done at two levels: (i) National (by NAC-SCRT) and (ii) Institutional (IC-SCR)
Clinical trials can be permitted only in institutions/hospitals having registered IC-SCR (with NAC-SCRT) and IEC (with CDSCO). For multicentric clinical trials, all participating sites should obtain approvals form their own IC-SCR and IEC
The IC-SCR shall not act as an IEC. Separate approvals must be obtained from both the committees for human stem cell-related projects
IC-SCR quorum will have minimum of eight members: Chairperson/vice-chairperson (≥10 years of experience), member secretary, experts from law, ethics (≥6-month training) and social sciences, community/lay-person and at least two stem cell/cell and molecular biology expert (≥5 years of experience) with appropriate expertise and no COI. In the absence of the chairperson, the vice-chairperson can conduct the meeting. The members of quorum except the member secretary should never have been affiliated to the institution
Subject experts with no COI and not affiliated to the same institute may be invited for specific projects. The invitee will not have voting rights. NAC-SCRT may nominate an observer on the IC-SCR to educate and to create awareness regarding existing guidelines and regulations. Ex-employees of the institute can become a member only after 2 years of leaving the institution
All clinical trial must have a medical specialist registered with MCI and holding MCI-approved postgraduate qualification in the subject domain of the trial. All medical professionals involved in clinical trials should have a valid GCP certification
Human participants enrolled for clinical trials are not liable to pay any charges toward procedures, investigations, and/or hospitalization related to the trial. Video consent shall be recorded as per the CDSCO guidelines for audio-visual recording dated January 9, 2014, (Schedule Y). Identity of the donor shall be kept confidential at all times
The advertising and publicity through any mode by clinicians are not permitted as per the Chapter 6 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation. The Drugs and Magical Remedies (Objectionable Advertisements) Act, 1954 prohibits misleading advertisements relating to drugs and magical remedies. CDSCO, DGHS, and relevant state authorities are mandated to take necessary action for violation of this act

IEC=Institutional Ethics Committee, SCR=Stem cell research; IC-SCR=Institutional committee for stem cell research; NAC-SCRT=National Apex Committee for Stem Cell Research and Therapy; COI=Conflict of interest; GCP=Good Clinical Practice, MCI=Medical Council of India; CDSCO=Central Drugs Standard Control Organization; DGHS=Directorate General of Health Services, PRP=Protein-rich plasma, IND=Investigational New Drug, INE=Investigational New Entity

2. "Restrictive" – Research involving human preimplantation embryos processed by *in vitro* fertilization (IVF)/intracytoplasmic sperm injection/somatic cell nuclear transfer to derive ESC lines
3. "Prohibited" – Research involving human germline gene therapy and reproductive cloning, *in vitro* studies of human embryos beyond 14 days of fertilization or formation of primitive streak, studies involving xenogeneic cells or hybrids, genome-modified embryos for developmental propagation, implantation of any type of processed human cells/embryos into uterus of humans/primates, or the development of chimeric gonadal cells.

LEVELS OF MANIPULATION INVOLVING STEM CELL RESEARCH

Before any clinical application/transplantation/translational research, the SCPDs may undergo variable degree of *in vitro* or *ex vivo* processing that carries the risk of contamination and may also lead to alteration in their properties, which may vary according to the degree and type of manipulation. Thus, different levels of manipulation used for SCR have been defined along with necessary approvals required for the same:

1. "Minimal" – Where the processing neither alters the number nor the biological characteristics, and function of the cells (or tissue) relating to their utility for reconstruction, repair, or replacement, for example, use of bone marrow/peripheral blood/umbilical cord blood (UCB)-derived mononuclear cells/bone marrow concentrate using any device by intravenous route
2. "Substantial" – *Ex vivo* alteration in the cell population (enhancement or depletion of specific subsets), expansion, cryopreservation, or cytokine-based activation, but one that is not expected to result in alteration of cell characteristics and function, for example, the adipose tissue may be more than minimally manipulated if the processing alters the original relevant characteristics of the tissue relating to its utility for reconstruction, repair, or replacement

3. "Major" – Genetic and epigenetic modification of stem cells, transient or permanent, or of cells propagated in culture leading to alteration not only in their numbers but also in biological characteristics and function, for example, transdifferentiation, transduction/transfection by retro/lentiviruses, or other gene delivery vehicles to achieve specific selection and expansion of cells of interest.

BASIC RESEARCH INVOLVING STEM CELLS

The guidelines for undertaking basic research involving stem cells include:

1. *In vitro* studies (which largely fall under "permissible" category) require prior approval of IEC and IC-SCR. Exemption: the studies involving established human stem-cell lines registered with the IC-SCR
2. *In vitro* studies on preimplantation human embryos must be carried out within 14 days of fertilization or formation of primitive streak, whichever is earlier
3. Derivation of new human embryonic stem cells (hESCs) or iPSC lines from human embryonic or somatic cells, respectively, shall adhere to the conditions for gamete, embryo, and somatic cell donation, and with prior approval of IC-SCR and IEC
4. Uterine implantation (human/animal) of manipulated cells with the intent of developing a whole organism is prohibited.

EXCLUSIONS

It must be noted that, in line with the previous guidelines, the 2017 guidelines also exclude the research involving non-human SCPD. Further, the guidelines also do not apply to hematopoietic SCR, indicated or approved in the treatment of various hematological, immunological, and metabolic disorders. Protein-rich plasma and autologous chondrocyte/osteocytes implantation also do not fall under the purview of these guidelines, as they are categorized as "other cell-based applications" and not stem-cell transplantation.

TRANSLATIONAL RESEARCH INCLUDING CLINICAL TRIALS INVOLVING STEM CELLS

The preclinical studies and clinical trials using SCPD, for repair or regeneration of damaged tissues and organs as well as other clinical applications in conditions, where use of stem cells has not yet reached the standard of medical care, must abide the following norms:

Preclinical testing

a. Requires prior approvals 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)
b. Product testing must include safety, biodistribution (local and systemic), and immune rejection studies
c. Single- and repeated-dose toxicity studies should be performed in relevant animal models. The risk for tumorigenicity, genotoxicity, and developmental toxicity must be assessed on the intended clinical use.

Clinical testing

a. Requires prior clearances from IC-SCR, IEC, and CDSCO and must be registered with CTRI. Any protocol amendments/deviations must have clearances from IC-SCR, IEC, and CDSCO
b. Follow-up period of minimum 2 years is mandatory
c. Establishing Data Safety Monitoring Board is mandatory
d. All adverse events occurring during clinical trials must be reported to IEC, CDSCO, and NAC-SCRT through IC-SCR
e. Trial records must be maintained for a minimum of 15 years.

BANKING OF INVOLVING STEM CELL PRODUCTS AND DERIVATIVES

The new guideline says that UCB is a rich source of CD34+ hematopoietic and mesenchymal (stromal) stem cells. The use of UCB-derived hematopoietic stem cells (HSCs) for the treatment of various hematological and immunological disorders is currently well established, particularly where a human leukocyte antigen-matched sibling is not available. However, there is a paucity of public-funded UCB banks in India. On the other hand, several private banks have come up, that engage themselves in promotional advertising, offering storage of cord blood with the promise of future therapeutic use. Such advertisements are often misleading for the public and lack comprehensive and accurate information.

As of now, there is no scientific basis for the preservation of cord blood for future self-use, and this practice therefore raises ethical and social concerns. Hence, under the new rule, banking of UCB or hESC/iPSC lines is only permitted in institutions currently licensed by CDSCO. Accordingly, commercial banking of all other biological materials is not permitted until further notification. Such institutions, if involved in SCR, must constitute the IC-SCR (and register it with NAC-SCRT) and have a standard operating procedures (SOPs) for banking and release. Moreover, the

biological materials can only be released to institutes with registered IC-SCR and IEC.

PROCUREMENT AND EXCHANGE OF STEM CELLS PRODUCTS AND DERIVATIVES

The procurement of SCPD is strictly regulated under the new guidelines, to prevent misuse and commercialization of unproven stem-cell therapy. The major provisions are:

1. Import of any type of SCPD requires license from CDSCO as per the established regulations
2. Clinical trials sponsored by multinationals, employing the cell products developed outside India, should have clearances from the regulatory authorities of the country of the origin and shall need prior approval from the CDSCO following clearance from both IC-SCR and IEC of the trial site
3. All international collaborations require approvals from the respective funding agencies followed by the approval from the Health Ministry's Screening Committee as per the Government of India guidelines[9]
4. In situation involving a conflict (scientific and/or ethical) between the collaborators, the existing Indian guidelines, acts, and regulations shall prevail for the work to be carried out in India
5. Biological material can be procured only from the institutions that have IEC. The IEC must ensure that the SOPs are in compliance with the guidelines
6. Only IEC and IC-SCR shall review and approve the process of procurement. If cells/tissues have been developed utilizing the IVF method, clearance from the NAC-SCR is mandatory
7. For procurement of fetal or placental tissue as a source of stem cells, termination of pregnancy must comply with all obligations under the Medical Termination of Pregnancy Act, 1971[10]
8. 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. 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.

PUBLICITY AND MALPRACTICE

The advertising and publicity of probable benefits of stem-cell therapy through any mode by clinicians are not permitted as per the Chapter 6 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulation.[11] The MCI and medical councils of respective states have been directed to initiate action on the erring clinicians for the violation of code of ethics prescribed by it either taking *suo motu* cognizance or acting on any complaint received by them. Moreover, the Drugs and Magical Remedies (Objectionable Advertisements) Act, 1954[12] also prohibits the misleading advertisements relating to drugs and magical remedies and mandates the Directorate General of Health Services and relevant state authorities to take necessary action for violation of this act.

Advertisement of treatment of several diseases as listed in Schedule J of Drugs and Cosmetics Act, 1940 and Rules[13] therein and any advertisement that violates the code for self-regulation in advertising, as adopted by the Advertising Standards Council of India, is not permissible. Hence, the publicity claiming available cure for conditions using SCPD is strictly prohibited.

CONCERNS

Recently, the ICMR has objected to amendments proposed by the Ministry of Health and Family Welfare to the Drugs and Cosmetics Rules, 1945, on the regulation of stem-cell procedures. The proposed amendments were notified on April 4, 2018,[14] with 45 days until May 20, 2018, given for objections and comments. The ICMR submitted its objections on April 29, 2018.

The amendments seek to exclude "minimally" manipulated stem cells, from being defined as new drugs. Such an amendment contradicts the 2017 guidelines and bypasses approval needs for clinical trials (from NAC-SCRT) for establishing the efficacy and safety before receiving the market approval. If passed, these amendments may legitimize the use of unproven stem-cell therapies in India.

Moreover, many commercial entities involved in UCB have asserted that people should have the right to preserve their biological materials for the future and questioned the new guidelines restricting commercial banking of biological materials. For instance, *LifeCell*, a Chennai-based company, has argued that "banking is mere storage – not utilization statement." If utilization was a concern, restrictions on the release of stored stem cells could easily have been prescribed, which has not even been considered."[15]

CONCLUSION

The vacuum around stem-cell activity in India – being a vacuum in governance or bioethical behavior – has always been more problematic than a simple failure to adequately enforce the guidelines through statutory or nonstatutory means. Thus, there is a requirement of more clarity about

the implications of the new rule, to be sought from the regulatory authorities. Moreover, the guidelines concerning SCR are ever evolving, and better provisions will always be required as per changing international standards. As of now, the current guideline is a significant step in this regard. It has tried to encompass the major government regulations, institutional oversight, and communications enclosing basic and translational SCR, largely catering to the regulatory ambiguity.

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Conflicts of interest

There are no conflicts of interest.

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