Educational Administration: Theory and Practice
2024, 30(5), 9474-9480
ISSN: 2148-2403
https://kuey.net/

Research Article

National Guidelines For Stem Cell Research (2017) In India: A Legal Study

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Citation: Kavita Srivastava, et al (2024), National Guidelines For Stem Cell Research (2017) In India: A Legal Study, Educational Administration: Theory and Practice, 30(5), 9474-9480
DOI: 10.53555/kuey.v30i5.4595

ARTICLE INFO

ABSTRACT

Stem caller search plays aleadrolein the fast developing area of regenerative medicine, it has capability to treat, prevent and cure diseases by growing a promising (unlimited) number of specific cells for organtrans plantation and for various therapeutic procedures.
The guidelines for 'Stem cell research and therapy'2007 was the first landmark step to provide guidance and promotion of human stem cell research with restricting exploitation of vulnerable population .The primary goal of the guideline is to prohibit the early commercialization of presumed stem-cell therapies. But to develop new researches based on strong scientific reasoning and performing with all ethical considerations. NGSCR 2017 encourages safe, ethical, clinically approved and regulated translational stem cell research. This paper discusses the overview of national guidelines for stem cell research 2017.

Keywords: Stem cell, Research, Clinical translation, Regenerative, Guidelines.

Stem cell research holds great promise for improving human health by controlling degenerative diseases and restoring organ damage caused by various injuries; however, it also raises several ethical and social issues, such as the destruction of human embryos to create human embryonic stem cell lines, the potential for introducing commercialisation of human tissues and organs with inherent barriers to access for socio-economically deprived people, and the potential use of technological advances to improve human health. As a result, research in this sector must be regulated to achieve a balance[1].The DCGI established a specific section for stem cells to outcome the criticism of internal evaluation in 2012. The Indian government constituted National Apex Committee for 'Stem Cell Research and Therapy' (NAC-SCRT) to monitor research. These guidelines have no statutory backing from 2007, the concern parties recommended to update it with legislative measures. Thus the guidelines were modified as 'National Guidelines of Stem Cell Research (NGSCR) 2013'[2].

The DCGI also announced that it would update the 'Drugs and Cosmetics Act' to treat "stem cells and cell-based products" as new drugs in 2014. The 2013 guidelines ultimately known for big accomplishment, pioneering it updated the stem cell research in the country with focus on governance. Finally it communicated its medical, legal, social, and ethical challenges involved in stem cell reaserch to a large scale.
Recently India has amended guidelines for stem cell research and clinical translation named as 'National Guidelines for Stem cell research 2017' (NGSCR 2017),released by the Indian Council of Medical Research (ICMR), in association with the department of biotechnology (DBT). The modification reflects recent developments in stem cell science and other related fields. It covers ethical, social, and policy challenges that have developed since the previous amendments in 2013. Following the guidelines were amended in 2013 and 2017, the word *"therapy"* removed from the title. It states that "*stem cells are still not a part of the standard of care; hence there can be no guidelines for therapy until efficacy is proven and... any stem cell use in*

patients, other than that for hematopoietic stem cell reconstitution for approved indications, is investigational at present"

The stem cell repairs damaged tissue and regenerate new cells in human body, to replace those that die during a person's lifespan. It is commonly accepted that stem cell therapies would transform healthcare and provide hope to individuals suffering from a variety of diseases and injuries, for which limited or no treatment choices. Wound healing, stroke, heart regeneration, type I diabetes, multiple sclerosis, spinal cord injury, osteoarthritis, hepatic repair, graft versus host disease, and, more recently, therapeutic options for the management of COVID 19 patients are just a few instances of stem cell research.[3]

NGSCR 2017

The NGSCR 2017 is primarily focused on three areas: (i) monitoring mechanisms and regulatory pathways for basic, clinical, and product development based on research categorization and level of manipulation; (ii) procurement of gametes, embryos, and somatic cells for derivation and propagation of any stem cell lines, as well as their banking and distribution; and (iii) most importantly pay attention on international collaboration, cell/line exchange, and stakeholder education.

Stem cells and their products constitute definition of 'Drug', which is defined in the 'Drugs and Cosmetics Act 1940' and they were classified in the name of 'Investigational New Drug (IND)' or 'Investigational New Entity (INE)' once utilised for clinical applications

At present NGSCR ruled that umbilical cord blood banking is permissible which is licensed by the Central Drug Standard Control Organization (CDSCO), while "Commercial banking of other biological materials (is) not approved up to fresh notification".

Regulatory procedure in NGSCR 2017

S.N.	Regulator	Institution/Clinical trials
1.	CTRI registration	Clinical trial related to stem cell
2.	IC-SCR registration. Certificate is issued for the registration of the clinical trial objective.	Consent of NAC-SCRT for Institutions.
3.	IEC registration	Consent of CDSCO for Institutions
4	Mandatory approvals from IC-SCR, IEC and CDSCO	Clinical trials employing minimally manipulated autologous SSC's (ie. HSC's and MSC's) for non-homologous/Homologous use of any indication not listed in Annexure III
5.	Authorization from IC-SCR, IEC and CDSCO	Manipulated stem cells - prior to conducting Clinical trial
6.	Mandatory prior approval from IC-SCR, IEC and CDSCO	Clinical trials including allergenic SSC's and autologous SSC's (in degree of manipulation)
7.	Mandatory prior approval from IC-SCR, IEC and CDSCO	clinical trial using human pluripotent stem cells (hESC's or IPSC's) or their derivatives
8.	CDSCO approval	for any stem cell related product which is already approved and marketed outside India (for repeat trial in India)
9.	A clearance from IC-SCR and IEC with approval from CDSCO	clinical trial with a product preplanned to authorized for marketed.
10.	Specific approval is required from CDSCO proceeded by clearance from IC-SCR and IE Committee	For tissue designed or combination product

Given below here are the highlights /objective of "NGSCR 2017'[4] to avoid unproven stem cell therapies from being commercialised prematurely and to provide safe therapy to people.

Ethical consideration (Section 4. 1).

The general principles of stem cell research were affirmed in the "National Ethical Guidelines for biomedical and health research involving human participants, 2017",which is mandatory to follow in any stem cell research , and the other ethical considerations is laid down in Section 4.1. The donor's health, wellness, rights and safty are of supreme concern, as defined below in following conditions.

- Informed consent is required prior to the collection of biological material for the isolation of stem cells, which includes audio-visual recording in accordance with CDSCO standards of January 9, 2014 (schedule Y).[5]
- Full information to the doner about mandatory screening for communicable diseases (human immunodeficiency virus 1 and 2, hepatitis B virus, hepatitis C virus, Treponema pallidum cytomegalovirus and human T-lymphotropic virus) or other risk factors, such as genetic disease.
- Intellectual property rights of donated biological material should be shared rather than vesting with the donor. If commercialization results in any financial gain, it might be distributed to donors and /or the community.
- Annexure IV deals with screening of donors for Allergenic transplantation / inclusion and exclusion criteria for selection of doners.

Scientific consideration (Section 4.2)

To ensure the security/safty and quality assurance, of the scientific consideration, manipulation of cell sequence specify the manufacturing process. Annexure V provides details on the necessities for manufacturing of stem cells and their derivatives. The release criteria are explained in (Annexure VI) in the guidelines. It highlighted that stem cells or their products must be developed in a CDSCO-approved facility that follows GMP and also ensure, the rigour of quality control and quality assurance for product development, the cell processing and manufacturing phases must comply with the requirements of schedule M of the 'Drugs and Cosmetics Act, 1940' and Rules and for all clinical trials, this is required.

Evidence based research (S 4.2.3)

The commercial use of stem cells as elements of therapy is restricted, and also no stem cell administration to humans is permissible beyond the scope of clinical trials. Annexure III deals with the approved indications for Hematopoietic stem cell transplantation (HSCT).It means "every use of stem cells in patients outside of an approved clinical trial is considered unethical and shall be considered as malpractice". The Individual/ human participant enrolled for a clinical trial for any procedure(s) should not pay for hospital accommodation and laboratory investigations. The follow-up period should be at least two years or it may be longer as per requirment.

Evaluation and oversight (Section 5)

Two levels of evalution procedure has been formulated by the Annexure – I(Composition and functioning of NAC-SCRT and IC-SCR) of NGSCR 2017.The NAC-SCRT known for national level other IC-SCR is a self-regulatory system of review for institutional level. The NGSCR 2017 outlines a framework for evaluation and oversight. The latest guidelines of ICMR-DBT appears to have finally settled jurisdictional ambiguities about stem cell therapy governance. The procedure for reviewing and monitoring stem cell research will be carried out separately at the institutional and national levels.

NAC-SCRT manages and monitors national research efforts (basic and clinical research) as it is constituted by the Government of India (department of health research) and its committee constituted of experts from many fields of biomedical research, government organisations, and other stakeholders.[6]

The Institutional Committee for Stem Cell Research (IC-SCR) approves and monitors stem cell research (basic and clinical) in institution. IC-SCR a self-contained, independent body free of interference, partiality, or unjustified influence. In order to function properly, the committee must include at least 11 medical and nonmedical members.[7]

All stakeholders in stem cell research are required to create an IC-SCR and register it with the NAC-SCRT. These oversight committees ensure that all research projects in the field of stem cell research are reviewed, approved, and monitored in accordance with national criteria.

Level of stem cell manipulation (Section 7)

Before being used in clinical trials, transplantation, or translational research, The stem cell product and derivatives may be subjected to different extent of '*in vitro*' or '*ex vivo*' processing which can lead to contamination and changes in their qualities.

1.Minimal manipulation, processing has no effect on the number, biological properties, or function of the cells. The 'minimal' processing time must be less than 72 hours, and clearances from CDSCO, IC-SCR, and IEC are required.

2. Substantial or more than minimal manipulation of the cell population (enhancing or depletion of certain subsets) predicted for result in change of cell properties and its function requires permissions from CDSCO only after receiving approvals from IC-SCR and IEC.
3. Major Manipulation refers to the transient or permanent genetic and epigenetic manipulation of stem cells, and it requires CDSCO permission after NAC-SCRT and IC-SCR clearances and IEC.

Stem cell classification (Section 8)

The guideline categorize research into three categories, based on ethical and/or safety regarding stem cell sources and levels of manipulation

1. Permissible- In vitro studies using stem cells isolated from tissues, establishment of new human ESC lines from spare embryos or iPSC lines from fetal/adult somatic cells or SSCs from fetal or adult tissues, it can be done with the IC-SCR and IEC's prior clearance,

2. Restrictive -ESC lines are derived from human preimplantation embryos treated in IVF/LCSI/SCNT. Due to the sensitive nature, greater oversight/monitoring is required.

3. Prohibited- Research that involves human germline gene treatment and reproductive cloning, studies involving xenogeneic cells or hybrids, genome modified embryos for developmental propagation, implantation of any type of processed human cells/embryos into the uterus of humans/primates, or the development of chimeric gonadal cells are all in vitro studies of human embryos beyond 14 days of fertilisation or formation of primitive streak.

Basic Research involving stem cells (Section 10)

It states that apart from experiments using established human stem-cell lines registered with the IC-SCR, in vitro studies (mostly under the "permissible" category) require prior approval of the IEC and IC-SCR. Preimplantation human embryo in vitro research must be completed between 14 days following fertilisation or the establishment of the primitive streak. The IC-SCR and IEC must approve the creation of new ESC or iPSC lines from human embryonic or somatic cells, respectively. The implantation of modified cells into the uterus (human/animal) with the goal of creating a full organism is forbidden. The use of stem cells or cell lines developed for basic research in humans or clinical trials is prohibited.

Clinical trial and translational research (Sec 9, Section 11)

- To conduct a clinical trial related to stem cell therapy, only institutions/hospitals with registered IC-SCR (with NAC-SCRT) and IEC (with CDSCO) can conduct clinical trials (section 9.11). The cells or cell-based products used in the trial should be processed in a CDSCO-certified GLP and GMP facility (Schedule L1 and M of the Drugs and Cosmetic Act, 1940, and rules therein) (section 9.17).
- . The IEC for humans, the Institutional Animal Ethics Committee for small animals, and the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) for large/nonhuman primates, all give their approval for preclinical testing. IC-SCR, IEC, and CDSCO clearances are required, as well as registration with CTRI for clinical testing. .

Excluded in guideline (Sec 12)

Other than hematopoietic stem cell treatment (HSCT), there are currently no approved indications for stem cell treatment (Sec 12.2). Non-human stem cells and derivatives, as well as hematopoietic SCR, are prohibited under the recommendations. Guideline also exclude out SCR with protein-rich plasma and autologous stem cells, implantation of chondrocytes/osteocytes, because they are listed as "other cell-based applications" rather than "stem cell transplantation". Section 12.1 states other therapeutic uses of stem cells must be treated as investigational clinical trial and after regulatory approval. Otherwise, it is considered as unethical and illegal.

Banking of stem cell product and derivatives (Section 14)

According to guidelines umbilical card blood-derived hematopoietic stem cells (HSCs) can be used to treat a variety of haematological and immunological diseases. There are few public-funded UCB banks, but several private banks have emerged as busy in promising advertising, offering cord blood preservation with the assurence for future medicinal usage in India. The general public is frequently misled by such commercials advertisements, which lack complete information. Currently no scientific basis for storing cord blood for future self-use, this practise raises ethical and social challenges. Thus, banking of UCB or ESC/iPSC lines allowed only in institutions licenced by CDSCO. The other biological stuff cannot yet to be banked commercially. If a bank is participating in stem cell research, it must be an IC-SCR (NAC-SCRT registered) and have a standard operating procedure for banking and release. Biological materials can only be released to registered IC-SCR and IEC institutes.

Procurement and exchange of stem cell lines (Section 15, 16, 17)

- The procurement process will be reviewed and approved by the IEC and the IC-SCR. Approval and the NAC-SCR is required if cells/tissues were produced via the IVF technique. The stem-cell lines and related material have a ten-year archival period. Processes for procuring foetal or placental tissue must adhere to all requirements of the 'Medical Termination of Pregnancy Act of 1971'[8].
- According to ICMR Guidelines[9,] all overseas collaborations require clearance from the different funding agencies, with approval from the Health Ministry's Screening Committee (section 16).
- Importing stem-cell lines for basic research does not require a no objection certificate (17.1), But those from other countries do needed for clinical trials (section 17.4.4). IEC and IC-SCR approvals are required for the export of indigenously produced cell lines, and they must be secured and submitted with the MTA during the review of such research applications (section 17.4.2). The IC-SCR and IEC will review all proposals for the import/export of stem cells and their derivatives for research and development, including clinical trials (section17.4.3).

Publicity (Section19)

Direct-to-consumer advertising, the stem cell clinics attract patients by boasting overstated benefits of stem cell therapy, is another challenging key issue. According to the 'Indian Medical Council (Professional Conduct, Etiquette, and Ethics) Regulation' (Chapter 6)[10], doctors are not permitted to advertise or publicise the potential benefits of stem-cell therapy in any form. 'The Medical Council of India (MCI)' and state medical boards have been directed to take action against those physicians who violate the MCI's code of ethics, either on their own initiative or in response to any complaint they receive (section19.1). Furthermore, the 'Drugs and Magical Remedies (Objectionable Advertisements) Act' of 1954[11] prohibits misleading advertisements for drugs and magical remedies. Advertisements for the treatment of disorders classified

under Schedule J of the 'Drugs and Cosmetics Act, 1940'[12] and its Rules(Annexure VII), as well as any advertisement that violate the Advertising Standards Council of India's code for self-regulation in advertising, are banned. The advertising/publicity claiming a cure by stem-cell products and derivatives (SCPD) is strictly prohibited (section 19.3). The CDSCO and the DGHS and relevant state authorities have legislated power to take appropriate action for violation of publicity rules.

Stem cell derived product-definition

The gazet notification of Government of India under the 'New Drugs' and 'Clinical Trials Regulations 2019'[13], on March 19, legislated under 'Drugs and Cosmetics Act 1940'. According to NDCTR 2019 'Stem cell derived products' were included in definition of new drug without any exclusions being provided for 'minimally manipulated stem cells'. Any hospital or clinic that offers stem cell-based treatments would have to apply for a licence to continue operating under the NDCR 2019. This Rule initially appeared to close the governance gap in the legal framework governing stem cell activities. But it has simply increased misunderstanding. The core problem is that the term "stem cell derived products" is not defined in the NDCTR 2019.
The Health and Family Welfare Ministry, GSR No. 334 dated 04-04-2018[14] proposed amendment to exclude 'minimally manipulated stem cells' from definition of new drug. ICMR also has objection on same. With this exclusion, these cells won't need to undergo efficacy and safety testing in clinical studies before being approved for commercialization. The amendment contradicts the NGSCR 2017, because it is mentioned in guideline even if minimally manipulated stem cells are used for clinical application, it is obligatory that mandatory permissions for Stem Cell Research has been taken from the authorites of the Central Drugs Standard Control Organisation as well as Institutional Committee.

National Biotechnology Development Strategy 2021–2025

The 'National Biotechnology Development Strategy' 2021–2025, which was latest, announced by the department of biotechnology, is the second strategy statement for the advancement of biotechnology in India. It ensures that future medical advancements, such as stem cell therapy or regenerative medicine, will be encouraged. Through clinical trials, the Indian government hopes to develop full fledge stem cell research and therapy, making India a potential and relatively inexpensive stem cell therapy destination in the future.

The International Conference on Harmonization: The Guidelines of Good clinical practice (E6)

Good Clinical Practices (GCP) is a series of general principles that must be observed during the conduct of human experimentation. This GCP guideline provides a universal standard for procedural aspect of designing, conducting, recording, and reporting clinical experimentations that involve human subjects. Agreement with GCP guideline provides public satisfaction that the rights, health and well-being as well as confidentiality of the trial subjects are protected. The results of the study are trustworthy. GCP are part of the quality systems to cover the testing of medicinal products and devices, and conducting clinical studies in human beings.
Their objective of GCP is to give a unified standard for the United States, European Union, Japan, with consideration to existing GCPs of Australia, Canada, the Nordic Countries, including the World Health Organization. And also to facilitate the mutual acceptance of clinical data by the concerned regulatory authorities. It includes the minimum information that should be included in the information for mate to the investigator, which are the considered as essential in documentation, with aim, and procedure to file. Number of countries of the world have accepted these guidelines as their own. The ICH guideline on GCP (E6) recommends the 13 principles of good clinical practices. These principles are in line with the Nuremberg Code, the Declaration of Helsinki and the Belmont Report. These guidelines should be adopted by IRBs/IECs, sponsors, and clinical investigators for compliance of regulatory authorities who oversee or conduct clinical trials[15] .

Indian Good Clinical Practice (GCP) Guidelines-

The Central Drugs Standard Control Organization first issued the Indian Good Clinical Practice (GCP) guidelines in 2001. Latter these were amended in 2005 and notified as the law.

Points of diffirentiation in Indian GCP Guidelines are following:

1 Research on specific groups (paediatrics, or pregnancy),
2 In case of a foreign sponsor, the responsibility is delegated to a
CRO in writing. But the sponsor is finally responsible for the drug related trial
, Clinical Trials on vaccines, contraceptives, surgical procedures/medical devices,
diagnostic products and herbal remedies.
3. The Guidelines also include specific details about the format for submitting data for
rDNA based vaccines, diagnostics and other biologicals.

Indian GCP is modified the following points in comparison to ICH-GCP:

1.Trial related protocol(quality assurance (QA)/quality control (QC)) procedures ,

Finance and insurance
2. Composition of ethics committee
3. Informed consent
4 Compensation for research participation

The regulations of the NGSCR 2017 were set up to ensure that all human stem cell research in the country is carried out ethically and scientifically. As a result, all stakeholders must adhere to all regulatory standards relating to biomedical research in general and SCR in particular, as notified in the guidelines.[16] Government restricts stem cell banking and therapeutic use in order to protect people getting untested stem cell treatments. Despite having stringent stem cell therapy restrictions, India has been a popular destination for untested stem cell therapies. Indian clinics have been criticized for making false claims about the efficacy of a variety of stem cell treatments, as well as giving faked government permission declarations in some cases.[17,18] This is due to the fact that infringing these rules carries no legal ramification.[19] Furthermore, as international standards change as per scientific researches, new provisions will always be added. In India the stem cell research regulations are constantly improving to restrict resource exploitation and commercialisation of unproven stem cell therapy. The 2017 guideline is a substantial step. For future course of action. The concepts that should guide human stem cell research, clinical translation, and related research activities with proper ethical consideration are emphasised in the guidelines. The need of the present time is to make strict laws for the regulation of stem cell research in India, although this guide line have proper regulatory and monitoring mechanism, but guidelines cannot take place of legislation. Medical malpractices, negligence and quackery can be controlled only through proper implementation of legislation. The 2nd most important thing is that members with vested interest should not have voting rights in any type committees in relation to clinical trial or in any decision-making process. Proper laws should be implemented in stem cell banking for therapeutic use.

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