COMMENTARY

Indian Stem Cell Research Governance after dissolution of the National Apex Committee

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Abstract

The Government of India recently disbanded the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT). This decision followed expert and public consultations held last year and will significantly alter the review processes for human stem cell research in India. The NAC-SCRT played a crucial role in crafting and updating regulatory guidelines, fostering research and national discourse in human stem cell research, and defining safety and quality standards. The Institutional Ethics Committees are now being tasked to review stem cell research at the organisation level after due inclusion of two stem cell experts. The decision to merge regulatory frameworks is a welcome step, reflecting a dynamic regulatory landscape that is responsive to scientific advancements and aims to reduce the compliance burden. The effective implementation of the revised mechanism, however, necessitates further clarity on which agency will now be responsible for tasks earlier mandated to NAC-SCRT.

Keywords: *stem cell research, ethics committees, regulatory compliances, biomedical ethics*

Introduction

The dissolution of the National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT) marks a significant shift in the regulatory landscape of stem cell research in India. Recently, the Department of Health Research (DHR) and the Indian Council for Medical Research (ICMR) decided to disband the NAC-SCRT, which served as the apex body overseeing and regulating human stem cell research across the nation [1]. This decision followed expert consultations in 2023 and public consultations, which cited "several difficulties faced during the implementation of the mechanism" [2].

In 2017, the ICMR and the Department of Biotechnology (DBT) jointly introduced the National Guidelines for Stem Cell Research (NGSCR) to provide a framework for the ethical conduct of research in India involving human pluripotent stem cells [3]. These guidelines were crafted in alignment with international ethical standards and provided clear directives regarding permissible, restrictive, and prohibited areas of study. Additionally, the guidelines defined the requirements for the establishment of stem cell banks and outlined measures to combat misleading advertisements and the promotion of unproven stem cell therapies.

The National Apex Committee for Stem Cell Research and Therapy (NAC-SCRT)

The establishment of a two-tier review mechanism, consisting of the NAC-SCRT at the national level, and the Institutional Committee for Stem Cell Research (IC-SCR, formerly known as the Institutional Committee for Stem Cell Research and Therapy) at the institutional level, was initially introduced in the "Guidelines for Stem Cell Research and Therapy" in 2007 and implemented from 2010 [4]. This dedicated review mechanism was adopted at a time when the field of stem cell research was still nascent in India and presented complex ethical, social, and legal challenges [4]. Also, before the introduction and widespread adoption of induced pluripotent stem cell (iPSC) technology, the primary source of stem cells was spare human embryos from in-vitro fertilisation clinics, which raised additional ethical and moral concerns [5].

The NAC-SCRT secretariat was located within the ICMR headquarters and the overarching role of the committee was to advise the government on the promotion and facilitation of stem cell research in the country, review stem cell therapeutics, create policies to curb unethical activities, and examine the complex and controversial ethical issues regarding research or therapeutics using stem cells [3]. The committee also took up issues of national interest concerning stem cells from a scientific, technical, ethical, legal, and social perspective [3].

The NAC-SCRT played a pivotal role in regulating stem cell research in the country. In alignment with its mandate, the committee was also responsible for updating guidelines, overseeing IC-SCRs, reviewing research in restrictive areas, maintaining a database of institutions involved in stem cell research, and defining standards for safety, efficacy, quality control, and procedural protocols [3].

Institutional Committee for Stem Cell Research (IC-SCR)

The IC-SCR mechanism was created to facilitate self-regulation of research at an institutional level by an independent, and multi-disciplinary committee. The committee reviewed both basic and clinical research and ensured compliance with the NGSCR. The IC-SCR also

maintained a registry of pluripotent stem cell lines available at the institution and acted as an intermediary between investigators and NAC-SCRT. The NGSCR guidelines also made a very clear distinction between the IC-SCR and the Institutional Ethics Committee (IEC), and advocated for separate approvals from both these committees for human stem cell-related projects [3].

Requirements such as a minimum of 11 members to constitute the committee and presence of over seven members to meet the quorum made it challenging to formulate and organise meetings of these committees. The guidelines also mandated that only the member secretary of the committee could be an internal member, and all other members were mandated to be external to the host institution. The committee had to be registered with the NAC-SCRT and required its approval before the committee could be functional. The registration required renewal every three years [3]. Such rigorous provisions made it challenging for smaller institutions or institutions with smaller stem cell research programmes to invest significant resources in formulating and running IC-SCRs at the institutional level.

Dissolution of the NAC-SCRT

In a significant development on March 3, 2024, an order was issued by DHR granting IECs the authority to evaluate and approve stem cell research proposals [1]. This order mandates the inclusion of at least two stem cell experts in the IEC review process, with at least one being external to the host organisation [1]. Additionally, the order states that "no regulatory role is anticipated to be carried out by DHR related to stem cell research". This shift signifies a broader decentralisation of stem cell research oversight, allowing institutions greater autonomy while maintaining rigorous ethical standards.

The dissolution of NAC-SCRT, along with the IC-SCR, is seen as a positive step that alleviates the compliance burden for Indian stem cell researchers. As awareness of stem cell research grew and more experts and organisations were engaged in the field, the need to reassess the requirement for a separate review mechanism became apparent. However, any such significant restructuring of the regulatory landscape should be approached with careful deliberation, supported by comprehensive stakeholder consultations and a clearly articulated transition plan to ensure clarity and mitigate ambiguity.

Moving forward, as IECs assume the responsibility for reviewing research involving human stem cells, there is a need for clarity and guidance to ensure adherence to the National Guidelines for Stem Cell Research, 2017. The IECs fall within the broad framework of the National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, 2017 (NEGBHR) [6] and therefore may not have a comprehensive understanding of NGSCR.

The following aspects require attention to facilitate the effective implementation of the new review mechanism:

a. Training

Comprehensive training on the National Guidelines for Stem Cell Research, 2017 is essential for all IEC members, including stem cell experts, to gain proficiency and a holistic perspective to assess research proposals and ensure compliance. The NGSCR details the important ethical and quality control aspects of stem cell research and categorically defines permissible, restrictive, and prohibited areas of study. The IEC members are generally trained in NEGBHR, and may not have awareness about unique ethical concerns such as personhood, chimeric animals, and the irreversibility of stem cell therapies [5,7]. In addition to including stem cell experts on the IEC; laypersons, lawyers, ethicists, social scientists, and other IEC members may need specialised training before reviewing stem cell research proposals. There is an urgent need to develop and implement short training modules, delivered either online or offline, on the NGSCR. These modules should aim to enhance the capacity of all IEC members to engage effectively in deliberations on stem cell research, recognising the critical role these members play within the IEC framework. Looking ahead, the incorporation of NGSCR training modules should become a mandatory component of the registration and renewal process for IECs of institutions conducting stem cell research. Furthermore, the expertise of "stem cell experts" in NGSCR must be validated through certified training programmes to uphold and safeguard the ethical standards of stem cell research in India.

b. Regular update of NGSCR

The role of the NAC-SCRT in updating the national stem cell research and therapy guidelines has been crucial. With the exclusion of DHR from regulatory oversight of stem cell research, clarity regarding the entity responsible for promptly revising the guidelines in alignment with evolving technical, social, and ethical standards is required.

The ethical aspects of stem cell research are an evolving area of international discourse and the guidelines need to be regularly updated to ensure that Indian research is not lagging behind. The International Society of Stem Cell Research (ISSCR) is a leading international collective that regularly publishes stem cell research guidelines to keep up with the enhanced technical and ethical understanding of stem cell research. While the

NGSCR has not been updated since 2017, the ISSCR guidelines were revised in 2021, following significant technological advancements, including the creation of stem-cell-based embryo models and the possibility of inducing in vitro gametogenesis [8,9]. The guidelines also further the discussion on the "14-day rule" to grow and study human embryos in vitro and advocate for extending this deadline in the case of non-integrated embryo models [8,10]. Considering the rapid and difficult-to-predict advances in the field, the forward-looking ISSCR 2021 guidelines may also need further revision in the near future and Indian regulation needs to align with these changes [10]. Any lag in updating the regulation might restrict the ability of Indian stem =cell researchers to compete globally in light of the evolving global stem cell regulation discourse.

c. The Role of NGSCR

The March 2024 order does not explicitly state whether the "National Guidelines for Stem Cell Research, 2017" will continue to guide IEC reviews of stem cell studies [1]. While the March 2024 order proposes the revised review mechanism, clarity on the applicability of the NGSCR to IEC reviews may need explicit mention to avoid any confusion among researchers and IEC members.

d. Safety and quality control standards

The NAC-SCRT was also responsible for defining standards for safety, efficacy, quality control, and procedural protocols for stem cells or their products being studied in clinical trials for therapeutic purposes [3]. There is a need for clarity on which agency is responsible for defining these important standards previously drafted and overseen by the NAC-SCRT.

e. Role of Department of Health Research

The March 2024 order explicitly states that "No regulatory role is anticipated to be carried out by DHR related to stem cell research" [1]. However, all the IECs involved in the review of "biomedical research" are registered with DHR through the Naitik portal (www.naitik.gov.in); and the IEC governing regulation (NEGBHR) is also notified by DHR and ICMR. Therefore, the statement on the role of DHR may require further clarification.

f. Registry of human pluripotent stem cell lines

NAC-SCRT, with the help of IC-SCRs, was also mandated to maintain a registry of pluripotent stem cell lines derived or imported by Indian investigators [3]. The registry, if made available in the public domain, can help avoid duplication of efforts in the creation of multiple embryonic or induced pluripotent stem cell lines and facilitate inter-institutional sharing of stem cell lines. Most widely used human stem cell lines in research originate from non-Indian sources. Therefore, establishing quality-controlled stem cell lines from the Indian population is essential to enable detailed studies on India-specific genetic backgrounds. It is also unclear if this registry will still be maintained and, if so, who will be the custodian in the absence of NAC-SCRT.

Conclusion

The disbanding of NAC-SCRT is a significant move to reduce the compliance burden in Indian stem cell research. By redistributing regulatory responsibilities, this restructuring aims to foster innovation while safeguarding ethical practices. Ensuring clarity in these revised roles will help align Indian stem cell research with global standards and accelerate its contributions to the field. Additional clarity is needed on how the responsibilities previously mandated to NAC-SCRT or IC-SCRs will be redistributed. This will ensure that the unique technical, legal, and social aspects of stem cell research are given due importance in the new mechanism. Currently, biomedical research proposals undergo multiple reviews by committees for biosafety, animal ethics, human ethics, and international cooperation, leading to redundancy. Empowering institutional committees with broader mandates and streamlining review processes can accelerate life sciences research in the country. These regulatory decisions are welcome and encouraged as they foster a more conducive environment for research.

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