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Comprehensive stem cell policy soon

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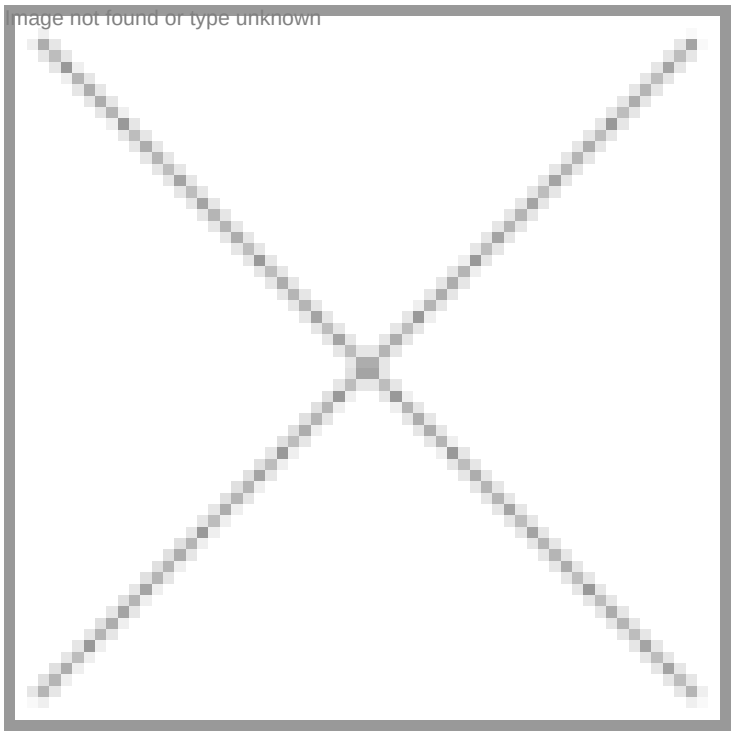

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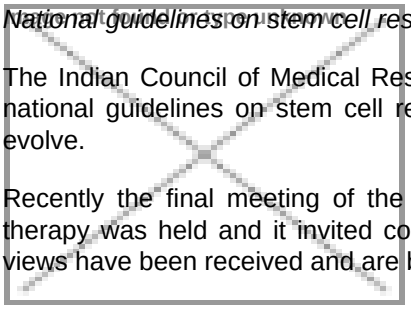

National guidelines on stem cell research and therapy are on the anvil

The Indian Council of Medical Research (ICMR) and the Department of Biotechnology (DBT) are jointly finalizing the draft national guidelines on stem cell research. The draft guidelines are expected anytime based on which the final policy will evolve.

Recently the final meeting of the expert committee in charge of framing the national regulatory guidelines for stem cell therapy was held and it invited comments from all stakeholders on the draft before finalizing the regulatory norms. These views have been received and are being incorporated.

The draft guidelines will be hosted on the ICMR/DBT website inviting comments from the general public. It is believed that the document will be available in the public domain for about three months, post which the comments will be collated, analyzed and incorporated, if required, in the final document.

These guidelines essentially provide a framework and practical guide for researchers after taking into account the scientific, ethical and legal aspects for derivation, propagation, banking and use of stem cells for research and therapy. It comprehensively addresses the entire gamut of issues related to not only the ethically sensitive embryonic stem cell arena but also the adult stem cells and the cord cells.

The national guidelines will reaffirm India's current stand in this arena that stem cell research should be promoted in the country with appropriate safeguards. They will be of a 'regulatory nature' and are aimed at giving a direction and thrust to stem cell research in the country, in view of its potential clinical use.

In the case of embryonic stem cell, the guidelines provide a complete oversight process that will ensure that the research is conducted in a responsible and ethically sensitive manner and complies with all the regulatory requirements pertaining to biomedical research in general and stem cell research in particular. They cover all derivations of human embryonic stem cell lines and research that uses such cells. A salient feature of the guidelines is setting up a of a high level committee which will clear any research proposal involving previously derived human embryonic stem cell lines; all proposals will have to be submitted to the committee which will review them speedily.

Besides elaborating on what areas of research are permitted, it also outlines, "what should not be done" or is not permissible. For example, embryonic stem cell research involving in vitro culture of any intact human embryo for longer than 14 days is not permitted nor is research involving introduction of embryonic cell into human or non-human primate blastocyst. The guidelines also ensure that only surplus embryos will be used for research after obtaining permission from the couple and generating embryos for the sole purpose of obtaining stem cells is strictly banned.

Some other prohibited research areas include transfer of blastocysts/human embryos generated by SCNT/parthogenetic to a human or non-human uterus; research involving the directed non-autologous donation of stem cell lines to an individual; research in which any cells of a pluripotent nature are combined/grafted with a human or non human embryo/foetus.

The document also outlines the criteria for derivation and study of human somatic stem cell lines from the umbilical cord and placenta or human somatic tissue; Research on anonymized human embryonic stem (ES) cell lines, embryonic gamete (EG) cell lines or somatic stem (SS) cell lines; Research involving the grafting of human ES, EC or SS cells into non human adults or legally competent humans. In addition, the guidelines elaborate on the related technical issues like the banking and distribution of human ES cell lines, the critical informed consent process, protecting the anonymity and privacy of the donor, etc.

Once the final guidelines take shape, it will be imperative to pass them as legislation so that the stipulated norms can be strictly enforced. The deterrent of punitive action will go a long way in preventing unethical and fraudulent research as was recently seen in the Korean stem cell researcher, Hwang Woo Suk's case. The national guidelines should thus become the Holy Grail of any future research foray in the stem cell arena.

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