

ISSCR statement on ethical standards for stem cell-based embryo models

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The ISSCR is updating its Guidelines for Stem Cell Research and Clinical Translation to respond to recent scientific advances that include the use of pluripotent stem cell (PSC) to create models of early human embryo development (see *Stem Cell Reports* 14:1-6). As the science continues to advance, it raises important scientific, clinical, ethical, and societal issues for researchers, regulators, and funding agencies. The ISSCR believes the scientific community must address these challenges to establish parameters for research in this area.

Stem cell-based models of early embryo development are important to enable researchers to study early [human development](#) without destroying [human embryos](#). The ability to model early embryo development through the culture of [stem cells](#) may also make it possible to ethically study periods of human development that are poorly understood or difficult to model using animal embryos. This area of research could improve fertility treatment and prevent the development of certain congenital diseases.

The ISSCR will develop detailed guidance on this area of research in the updated ISSCR Guidelines that will be released in early 2021. Until the Guidelines are released, the ISSCR encourages researchers and institutions to observe the following principles and current recommendations when considering research in this area:

- Research involving the culture of pluripotent stem cells (PSCs) to model the entire conceptus (the embryo and extraembryonic

structures) should be overseen and authorized by a special committee capable of evaluating the ethical and scientific justification of proposed research according to the Embryo Research Oversight (EMRO) process described in ISSCR Guidelines Recommendation 2.1.1;

- Multicellular structures derived from PSCs that do not model the entire conceptus (for example lacking extraembryonic structures and lack the potential to develop into an organism) are not [embryos](#) and should not be regulated as such. Proposed research using these models should be reported to an EMRO committee but does not require prior authorization;
- Models of the entire conceptus that have the potential to develop into an organism should not be maintained in culture beyond 14 days or the time at which the primitive streak develops (ISSCR Guidelines, Recommendation 2.1.3.3 Category 3);
- Models of the entire conceptus that are cultured as individual components such as germ layers or extraembryonic structures before 14 days, or when the primitive streak develops, can continue in culture but should be reported to an EMRO committee;
- Researchers using models involve combining human PSC-based embryo-like structures with other animal or human cells or tissues should endeavor to seek review by an EMRO process; and
- Multicellular structures derived from PSCs that seek to [model](#) certain aspects of the conceptus or the entire conceptus should not be transferred into the uterus of a human or animal (ISSCR Guidelines, Recommendation 2.1.3.3 Category 3).

More information: Insoo Hyun et al, Toward Guidelines for Research on Human Embryo Models Formed from Stem Cells, *Stem Cell Reports* (2020). [DOI: 10.1016/j.stemcr.2019.12.008](https://doi.org/10.1016/j.stemcr.2019.12.008)

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