Human cloning and international governance

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Presentation by L. Ahrlund-Richter

Member of ISSCR

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ISSCR international Human Embryonic Stem Cell Research Task Force.

ISSCR

International Society for Stem Cell Research

Guidelines for the Conduct of Human Embryonic Stem Cell Research

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POLICY FORUM

ETHICS

The ISSCR Guidelines for Human Embryonic Stem Cell Research

The International Society for Stem Cell Research describes major principles that should guide ethical stem cell research.

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Human embryonic stem (ES) cells are valuable for biomedicine, but differing cultural, political, legal, and religious perspectives are potential barriers to international collaboration in this fledgling field. Recognizing the need for scientists to act transparently, to serve the public interest, and to preserve public trust, the International Society for Stem Cell Research (ISSCR) convened a task force to formulate guidelines for human ES cell research. The ISSCR guidelines were written by scientists, ethicists, and legal experts from 14 countries (*1*).

The ISSCR guidelines encompass the core values put forth by the Committee on Guidelines for Human ES Cell Research of the U.S. National Academy of Sciences (U.S. NAS) (*2*) and the Regulations of the California Institute for Regenerative Medicine (*3*), and acknowledge thoughtful governmental regulations already in place in several countries, particularly that of the Human Fertilisation and Embryology Authority of the United Kingdom (*4*). The ISSCR is the principal scientific society for stem cell scientists and transcends institutional, regional, and national political boundaries.

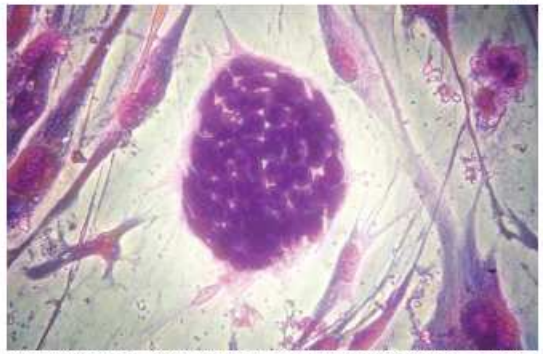
The ISSCR guidelines focus on research pertinent to derivation and use of pluripotent human stem cell lines and are not meant to encompass somatic (adult) stem cell research or human embryo or fetal tissue research. The ISSCR guidelines aim to facilitate international collaboration by encouraging investigators and institutions to adhere to a uniform set of practices. The ISSCR guidelines are subservient to all applicable laws and regulations of the country or region where the actual research takes place.

Major Principles

Call for oversight. Biomedical research is already subject to regulation and oversight. However, because human ES cell research raises unique and sensitive issues and requires specialized expertise to judge both scientific merit and ethical propriety, the ISSCR guidelines call for a specialized oversight process to complement existing institutional review boards. In contrast to the U.S. NAS guidelines, which stipulated that institutions engaged in human ES cell research should form an ES cell research oversight (ESCRO) committee, the ISSCR guidelines do not specify the precise form of stem cell research oversight (SCRO). The ISSCR guidelines specify the key elements of a single rigorous review at the institutional, regional, national, or international level, thereby eliminating redundancy and allowing flexibility for varied oversight mechanisms in different countries.

Permissible and impermissible research. The ISSCR guidelines prohibit (i) all experiments that lack a compelling scientific rationale or raise strong shared ethical concerns—in particular human reproductive cloning; (ii) in vitro culture of human embryos beyond 14 days or the formation of the primitive embryonic streak; and (iii) the interbreeding of animals likely to harbor human gametes.

The "14-day limit," first articulated in 1984 by the Warnock committee of the U. K. Human Fertilisation and Embryology Authority (*5*), is widely accepted by researchers in the human stem cell and fertility fields. It recognizes the significant biological distinctions between the earliest human embryos,



COURTESY OF M. WILLIAM LENGERICH, CHILDREN'S HOSPITAL BOSTON

How can ethical principles for research encompass cultural differences? Shown is a human embryonic stem cell colony, on a background of mouse embryonic fibroblast feeder cells, stained with Wright-Giemsa to highlight the individual cells of the colony.

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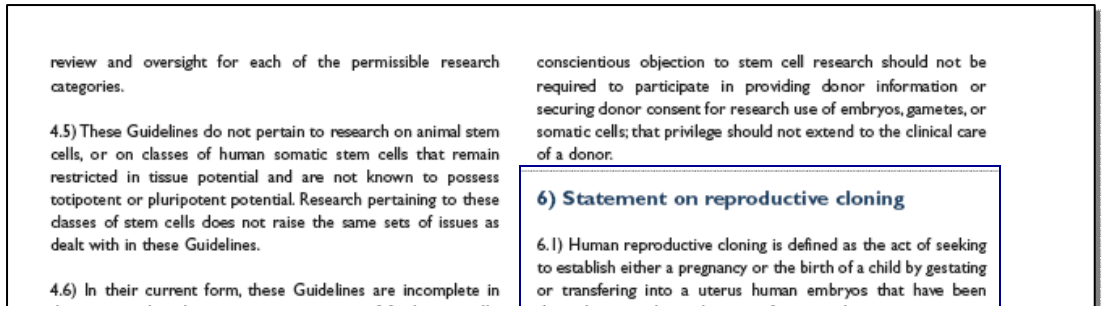

review and oversight for each of the permissible research categories.

4.5) These Guidelines do not pertain to research on animal stem cells, or on classes of human somatic stem cells that remain restricted in tissue potential and are not known to possess totipotent or pluripotent potential. Research pertaining to these classes of stem cells does not raise the same sets of issues as dealt with in these Guidelines.

4.6) In their current form, these Guidelines are incomplete in

conscientious objection to stem cell research should not be required to participate in providing donor information or securing donor consent for research use of embryos, gametes, or somatic cells; that privilege should not extend to the clinical care of a donor.

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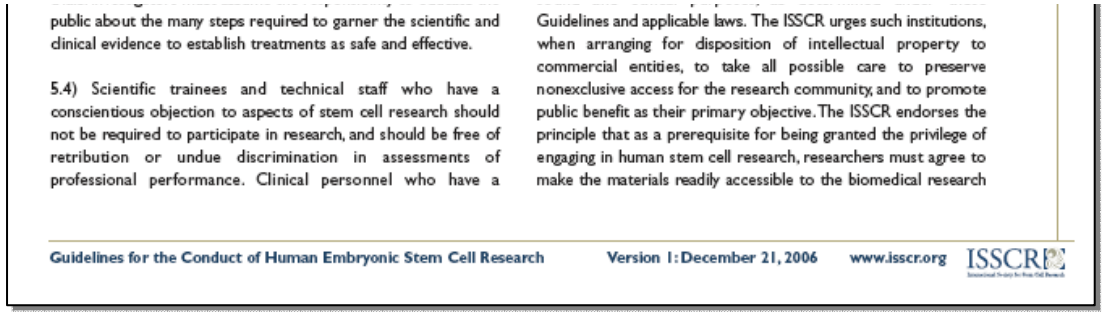
6.1) Human reproductive cloning is defined as the act of seeking to establish either a pregnancy or the birth of a child by gestating or transfering into a uterus human embryos that have been derived in vitro by nuclear transfer or nuclear reprogramming. Given current scientific and medical safety concerns, attempts at human reproductive cloning should be prohibited.



public about the many steps required to garner the scientific and clinical evidence to establish treatments as safe and effective.

5.4) Scientific trainees and technical staff who have a conscientious objection to aspects of stem cell research should not be required to participate in research, and should be free of retribution or undue discrimination in assessments of professional performance. Clinical personnel who have a

Guidelines and applicable laws. The ISSCR urges such institutions, when arranging for disposition of intellectual property to commercial entities, to take all possible care to preserve nonexclusive access for the research community, and to promote public benefit as their primary objective. The ISSCR endorses the principle that as a prerequisite for being granted the privilege of engaging in human stem cell research, researchers must agree to make the materials readily accessible to the biomedical research

1. In August 2001 the Permanent Missions of France and Germany requested the Secretary-General of the United Nations to include an additional item on the agenda of the 56th Session of the General Assembly entitled “International Convention against the Reproductive Cloning of Human Beings”. After years of debates, instead of a convention, a legally non-binding United Nations Declaration on Human Cloning was adopted on 8 March 2005. Three years later, is there any scientific, social or political change that would justify a new initiative at the international level?

2. The United Nations University Institute of Advanced Studies report entitled *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance* states that “international regulation is a necessity in this area...” and offers three possible options:

a. the International Bioethics Committee of UNESCO (IBC) takes up the issue of reproductive and research cloning, in the context of resolution A/RES/59/280 and also in the context of the Universal Declaration on Bioethics and Human Rights, adopted by the General Conference of UNESCO on 19 October 2005;

b. the sixth committee of the General Assembly takes up the issue of customary international law on cloning;

c. dissemination, discussion and debate on cloning issues at the international level, so that all countries including the developing and least developed countries can participate and put forward their concerns regarding this new technology.

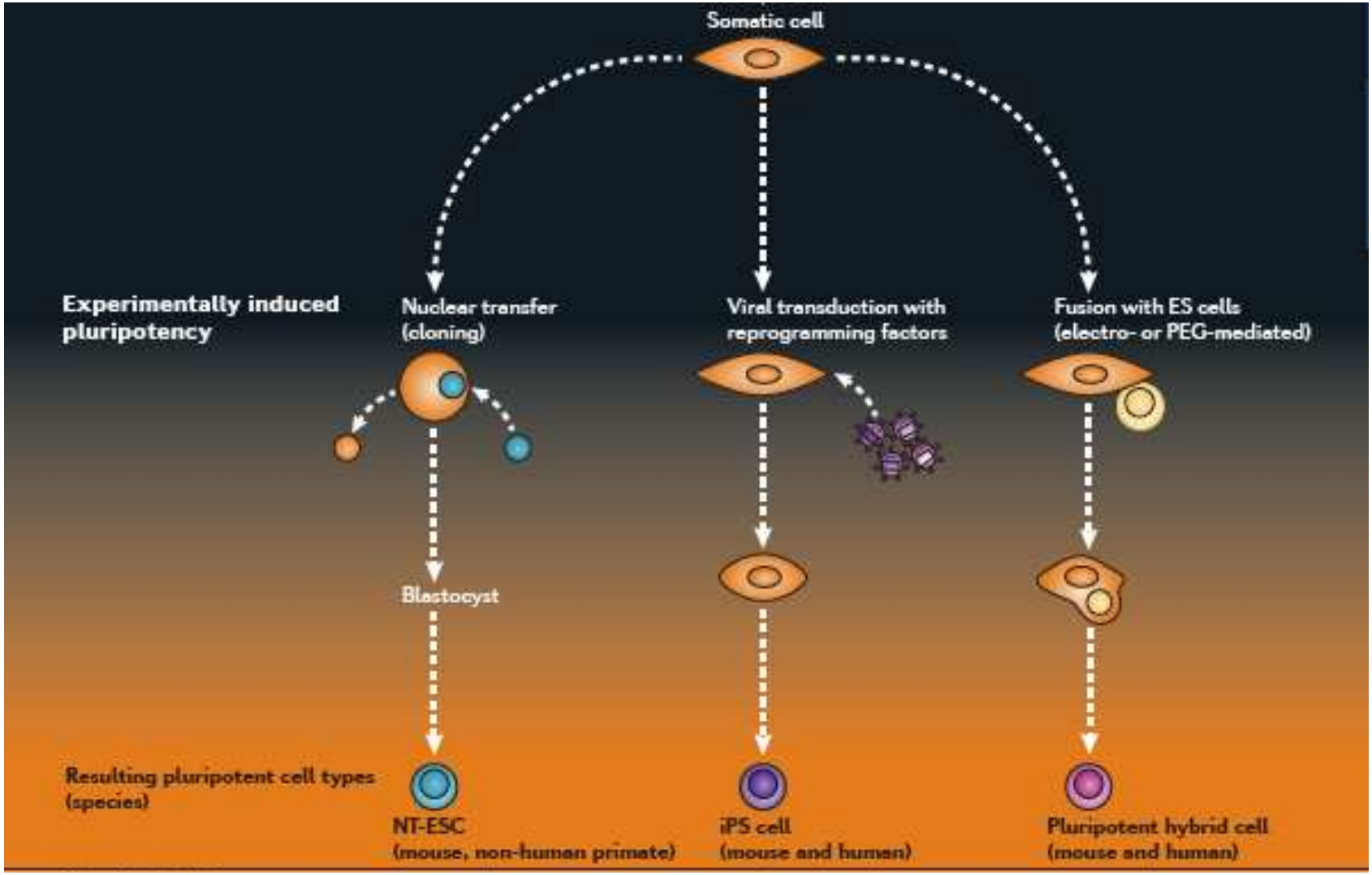
Would any of these actions be realistic in terms of different cultural, religious and social backgrounds of UN Member States and their interests in developing medical research towards treatment of numerous incurable diseases?

3. The same UNU document describes the following options available for regulation of cloning:

a) total ban on all cloning research
b) ban on reproductive cloning
c) ban on reproductive cloning and allow research cloning
d) ban reproductive cloning, allow research cloning for 10 years
e) place a moratorium on all cloning research.

For further actions within the United Nations system, what options could be feasible and serve the interests of Member States in the best possible way?

4. The terms and definitions we use can themselves start leading the discussion and build boundaries. Do the words “reproductive cloning” and “therapeutic cloning” introduced into bioethical debates several years ago still adequately describe the technical procedures scientists use (and are potentially able to use) today?



nature REVIEWS MOLECULAR CELL BIOLOGY

Pluripotent cell isolation for regenerative medicine

Christopher Lengner and Rudolf Jaenisch

Pluripotent cells offer great promise to the future of regenerative medicine and tissue engineering. Nuclear transfer, direct reprogramming and cell fusion can be used to experimentally induce pluripotency in somatic cells. To date, no naturally occurring pluripotent cell has been identified in the mammalian soma, and cells with pluripotent potential in the early embryo or germ lineage are difficult to isolate from patients. This makes methods of experimentally induced pluripotency in readily available somatic cells (such as skin biopsies) invaluable for the generation of patient-specific stem cells.

Our scientific opinion is that research on stem cells of all types should be pursued with the goals of reducing human suffering and better understanding human physiology.

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ISSCR Statement on New Advances in Human Pluripotent Stem Cell Research

New studies have been published in leading peer-reviewed scientific journals, demonstrating for the first time that human skin cells can be transformed into embryonic stem cell-like cells. The technology used to create these cells, induced pluripotent stem cells or iPS cells, holds great promise for creating patient- and disease-specific pluripotent stem cells for both research purposes and longer-term possible clinical use.

The ISSCR Ethics and Public Policy Committee, along with the ISSCR leadership support iPS cell research, as we do the many other paths in stem cell research being blazed by the members of the organization. We note that scientific advances cannot eliminate all ethical controversy, but for those who believe it is unethical to destroy human preimplantation embryos, finding other paths toward pluripotency is a positive move forward.

We know that the scientists that did the research have considered the challenges ahead—including the need to understand how to make iPS cells safe for potential clinical use. The process uses retroviruses to insert genes into somatic cells, and in some cases genes that can cause cancer. Furthermore, the use of viruses to transport the reprogramming genes into the adult human cells causes mutations that predispose these cells to cancer, a technical problem that will have to be solved before the iPS cells can be used clinically. The technology does, however, immediately offer a valuable research tool.

It is premature to suggest that the use of iPS cells can replace the derivation of embryonic stem cells from embryos or by nuclear transfer. We believe that research on human embryonic stem cells, somatic cell nuclear transfer and "adult" or tissue-specific stem cells needs to continue in parallel. All are part of a research effort that seeks to expand our knowledge of how cells function, what fails in the disease process, and how the first stages of human development occur. It is this general knowledge that will ultimately generate safe and effective therapies.

Further reading:
This position is expanded in a recent article in *Cell Stem Cell* co-authored by the lead researchers who developed this technology in the mouse and Dr Hyun, Chair of the ISSCR Ethics and Public Policy:

Hyun, I., Hochedlinger, K., Jaenisch, R. and Yamanaka, S. (2007). **New Advances in iPS Research Do Not Obviate the Need for Human Embryonic Stem Cells**. Cell Stem Cell *1* 367-368