

ISSCR Registry of Human Embryonic Stem Cell Line Provenance

The Registry

Clear documentation of the source, ethical review and permitted uses of human embryonic cell lines is critical if the lines are to be widely employed in the biomedical research community. The ISSCR is developing an international, centralized registry of human embryonic stem cell lines whose ethical derivation and permitted uses have been documented and evaluated. This information will be broadly accessible, providing support to the individual researcher, the stem cell research oversight process and other agencies, such as granting and publishing, in assessing research proposals for ethical merit. This registry will extend the work of the ISSCR 'Guidelines for the Conduct of Human Embryonic Research' in cultivating transparent and well-regulated practice of human embryonic stem cell research.

The Registry will acquire documentation of:

- Basic cell line and deriver information
- Informed consent
- Human subjects/patient rights protection review (IRB, ERB)
- The stem cell research oversight mechanism(s) in place
- Minimal biological data (optional)

The Registry is not intended to replace the stem cell research oversight mechanism(s) currently in place for a given locale, rather provide broad access to the information required for review and deliberation. Inclusion in the Registry will indicate that a minimum level of information has been collated and that there has been a targeted review of provided documents to confirm that the cell line was derived under the authority of human subjects and applicable stem cell research oversight, and in compliance with all applicable laws and regulations.

The ISSCR hopes through collaborations to strengthen the support the Registry can offer to individual agencies, and move towards standardized systems for oversight.

Progress

A *Registry Advisory Panel* including representatives from major banking, registry and stem cell funding efforts was convened to identify the parameters and process for data acquisition and evaluation (listed below). Patrick Taylor was appointed to chair the registry efforts and is working with Heather Rooke, ISSCR Science Editor, to further this project. Further consultation with this group is planned in the closing steps of development and in finalizing review processes.

The Registry has been developed in multiple platforms; a data submission platform, administrative and review platforms, and a registry listing. Access to the platform for data submission is expected to open on June 15, 2009. At this time, the ISSCR will reach out to the research community to submit data on the provenance of derived lines. Direct requests will be made to key investigators and institutions, alongside open calls.

A *Registry Review Committee* will provide a pre-determined targeted review of the documentation to confirm that the cell line was derived under the authority of human subjects and applicable stem cell research oversight, and in compliance with all applicable laws and

regulations. It is anticipated that this review committee will draw from the ISSCR Standards Committee and beyond where additional expertise is demanded.

Collaborations

The Registry includes a mechanism to collaborate specifically with individual jurisdictions or funding agencies in the registration and evaluation of lines in the ISSCR Registry. An agreement has been developed with the California Institute of Regenerative Medicine (CIRM) that seeks to involve them in the process of data procurement and evaluation, invite comment on future developments to the registry, and provide lists of lines that are eligible for CIRM funding. The ISSCR is pursuing similar collaborations with other states and funding groups to maximize the value of the registry to individuals, institutions and funding groups.

Collaborations with other registry/database efforts are being explored to coordinate data acquisition and provide integrated platforms and/or links to and from other registries that offer in-depth biological or distribution information. This will allow all groups to provide maximum utility to the research community.

ISSCR Registry Advisory Panel:

Advisory role in establishing parameters and process for data acquisition and evaluation

Chair:

Patrick Taylor, JD, Children's Hospital Boston, USA

Staff:

Heather Rooke, PhD, ISSCR Science Editor

Members:

Peter Andrews, DPhil, MBA, University of Sheffield, UK

Lars Ahrlund-Richter, PhD, Karolinska Institute, Sweden

Joeri Borstlap, Berlin-Brandenburg Center for Regenerative Therapies, Germany
(Technical Coordinator, European Human Embryonic Stem Cell Registry)

Dan Kaufman, MD, PhD, University of Minnesota, USA

Bartha Knoppers, JD, University of Montreal, (Chair, International Stem Cell Forum Ethics Working Party)

Story Landis, PhD, National Institute of Neurological Disorders and Stroke, USA (Chair, NIH Stem Cell Task Force)

Geoff Lomax, PhD, California Institute of Regenerative Medicine, USA

P. Pearl O'Rourke, MD, Partners Healthcare Systems, USA

Miodrag Stojkovic, DVM, PhD, Centro de Investigación Príncipe Felipe, Spain

Anna Veiga, PhD, Barcelona Stem Cell Bank at the Center of Regenerative Medicine
Barcelona, Spain (Scientific Coordinator, European Human Embryonic Stem Cell Registry)

Ex officio:

George Daley, MD, PhD, Immediate Past President, ISSCR