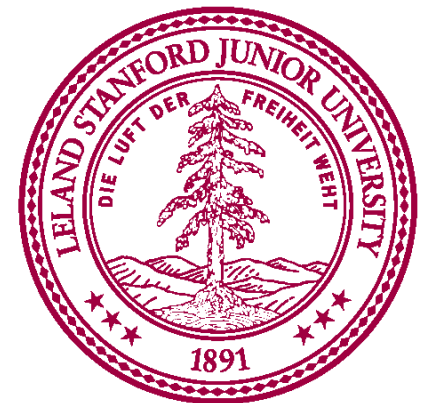


Provenance in Stem Cell Research

IRB/SCRO Panel Meeting
October 11, 2011



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Provenance Definition

- Origin of the tissues or the stem cell lines



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Documentation of Provenance

- IRB or IRB equivalent approval letter
- Template Informed Consent used for the collection of biological material
- Assurance from the Principal Investigator or organization responsible that all applicable laws were followed in the collection of the tissue for research purposes



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Types of Research Material that Require Acceptable Provenance

- Fetal Tissue funded by CIRM
- Induced Pluripotent Stem Cells or their cellular derivatives are intended to be used in human therapies
- hESC lines: need to be listed on the Stem Cell Matrix



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The Use of Fetal Tissue with CIRM Funds

- Signed statements are needed from the following individuals
 - Woman donating the tissue
 - Attending physician
 - Principal Investigator

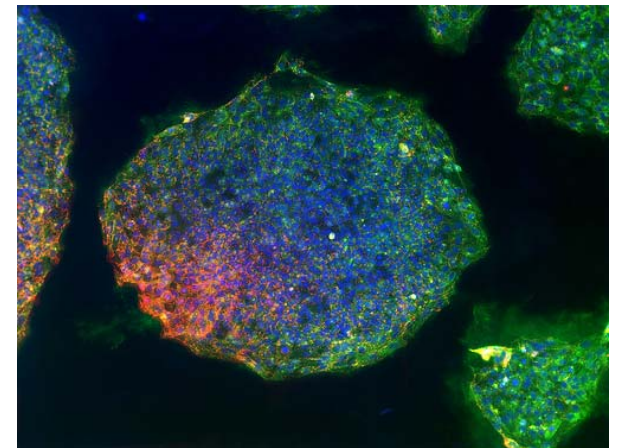


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Consent Recommendations for Future Research involving Somatic Tissue

- Genetic modification of cells
- Injection of iPS cells or derivatives into nonhuman animals
- Large-scale genome sequencing
- Sharing cell lines with other researchers
- Patenting discoveries and therapies, with no sharing of royalties with donors



Frozen iPS

Reference: Aalto-Setälä K, Conklin BR, Lo B (2009) Obtaining Consent for Future Research with Induced Pluripotent Cells: Opportunities and Challenges. PLoS Biol 7(2): e1000042. doi:10.1371/journal.pbio.1000042



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Donation of Embryos or Gametes

- Specific language requirements for the donor's voluntary consent
 - Information about the uses and restrictions of the tissue must be disclosed
- Payment is limited to Permissible Expenses as defined by regulations



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stem_cell_matrix (4).xlsx - Microsoft Excel

Home Insert Page Layout Formulas Data Review View Add-Ins Acrobat

Cut Copy Paste Format Painter Clipboard

Arial 10 Font

Wrap Text Merge & Center Alignment

General Number

Conditional Formatting Styles

Format as Table Cell Styles

Insert Delete Format Cells

AutoSum Fill Clear Editing

Sort & Find & Filter

J4

1 **Stem Cell Matrix**

2 All of the human embryonic stem cell lines listed can be used at Stanford. Eligible funding for each stem cell line is listed. Additional restrictions to funding eligibility can be found in the *Comments* column.

3 **Attention:** The "yes" boxes under *NIH Funding* have been grayed-out to reflect the preliminary injunction issued on August 23, 2010, by U.S. District Judge Royce Lamberth.

4 **Note:** There may be other hESC lines that are eligible for use, but are not listed. This matrix is updated continually. If the hESC line you would like to use is not listed, provide the IRB protocol and the informed consent form used to obtain the embryo as proof of provenance.

5 SCRO Contact: Mario McKay Garcia at mario.garcia@stanford.edu

6 Search as desired by drop-down menu. Updated 7/27/2011.

Cell Line Name	Approval Status	Organization	Provider	NIH Funding	CIRM Funding	Other Funding	Comments
201B1	Japan Approved	Kyoto University		no	yes	yes	
201B2	Japan Approved	Kyoto University		no	yes	yes	
201B3	Japan Approved	Kyoto University		no	yes	yes	
201B6	Japan Approved	Kyoto University		no	yes	yes	

Master Sheet2 Sheet3

Ready 115%



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Questions?



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HIPAA TRAINING

- STARS notification has been sent regarding completion of HIPAA Training
- Provide 45 days from notification
- Stanford University requirement
- Contact Privacy Office or Bertha deLanda



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