UCI Office of Research

Human Stem Cell Research Oversight (hSCRO) Provenance Policy

Version 2016

Proposed Material	Information, Examples, etc.	What You Need to Provide (Provenance)	Provide the Documentation To
Registered Pluripotent Cell Lines	• NIH Registered • CIRM Registered • UK Stem Cell Bank • UK Human Fertilization & Embryology Authority • Canadian National Stem Cell Oversight Committee • Japanese Guidelines for Derivation & Utilization of Human Embryonic Stem Cells	Appropriate registry name and registry number for each line. Some lines may require approval documentation from the registry.	UCI hSCRO Committee
Non-Registered Embryonic Pluripotent Cell Lines	Cell lines provided by a company, institution, or collaborator that do not appear on one of the above registration lists	1. A sample Consent Document 2. IRB (or equivalent) Approval Letter appropriate to the Consent document	UCI hSCRO Committee
Induced Pluripotent Cells (iPS)	Source Material: • Fresh Somatic Cells: see guidance below • Archived Somatic Cells: see guidance below	Please provide the appropriate documentation based on the source material.	UCI hSCRO Committee
Fresh Somatic Cells for the purpose of generating a) induced or re-programmed pluripotent cells, or b) NSC that will be used for in vivo transplantation	Usually in the form of tissue (e.g., punch biopsy, foreskin, residual tissue from surgical procedure, etc.)	1. A sample Consent Document 2. IRB (or equivalent) Approval Letter *(at UCI, hSCRO approval precedes UCI IRB review and approval)* 3. *In some instances*, a statement from the providing company or institution indicating specimens are de-identified, no access to the key code will be granted, and appropriate IRB (or equivalent) oversight was in place at the time of donation is acceptable.	UCI hSCRO Committee If subjects will be consented at UCI, or by a UCI investigator an IRB protocol must be in place.
Archived Somatic Cells for the purpose of generating a) induced or re-programmed pluripotent cells, or b) NSC that can be used for in vivo transplantation	Usually obtained from a tissue bank	Please provide written acknowledgement from provider (i.e., Tissue bank, Institution, etc.,) indicating specimens are de-identified, and you will not receive access to the key code under any circumstance.	UCI hSCRO Committee
Fetal Tissue-derived multipotent stem cells	Usually obtained from a tissue bank or academic institution	Please follow the guidance above for Fresh Somatic Cells	

Fetal Tissue	Aborted pregnancy materials, pathology samples	Provide the following statements as outlined in Code of California Regulations title 17 § 100085: Use of Fetal Tissue. • Statement signed by woman donating the material (usually in the form of an Informed Consent document) • Statement signed by attending physician (usually in the form of an Informed Consent document) • Statement signed by Principal Investigator	UCI hSCRO Committee If subjects will be consented at UCI, or by a UCI investigator an IRB protocol must be in place.
Embryos/Oocytes		1. Consent Document (either sample IRB-approved Consent or Consent document proposed for use) 2. In both instances (Embryos and Oocytes) IRB Approval is required	UCI hSCRO Committee If subjects will be consented at UCI, or by a UCI investigator an IRB protocol must be in place.