

University of Connecticut ESCRO

Oversight Policy for Research using Induced Pluripotent Human Cells (iPS cells) (Approved May 21, 2008)

Definitions

1. **induced pluripotent human stem cell (iPS)** – a pluripotent stem cell that has been artificially created by reprogramming non-pluripotent human cells through techniques that do not involve oocytes or embryos, e.g. through inserting certain genes into a somatic cell.
2. **pluripotent stem cell** – a stem cell that has the potential to differentiate into any of the three germ layers of ectoderm, mesoderm, or endoderm, but not the potential to develop into a complete organism.
3. **totipotent cell** – a cell that has the potential to develop into a complete fetal or adult organism, e.g. an embryo.

ESCRO Oversight Policy:

1. **Derivation of new human iPS lines: no ESCRO oversight. IRB approval is required for new donations of human somatic cells and use of cell lines associated with personal identifiers of the donor.**
2. **Research using human iPS lines**
 - a. ***in vitro* research that does not involve the generation of human gametes, embryos, or other types of totipotent cells : no ESCRO oversight**
 - b. ***in vitro* research that involves the generation of human gametes: ESCRO notification is required, with review required for projects involving the generation of embryos or other types of totipotent cells. For reviewed projects, submit a completed ESCRO application form along with any related IRB and IBC approvals. All policies pertaining to hESC research apply to projects falling under category (b).**
 - c. ***in vivo* research that implants human iPS cells or derivatives into animal models: ESCRO notification is required, with review required for projects that inject human cells into pre-natal animals or into the central nervous system of post-natal animals. For reviewed projects, submit a completed ESCRO application along with any related IRB, IBC, and ACC/IACUC approvals. All policies pertaining to hESC research apply to projects under category (c).**

Table Summary of iPS ESCRO Oversight:

Activity	ESCRO OVERSIGHT
Derivation of iPS	NONE
<i>in vitro</i> research w/no genesis of gametes or totipotent cells	NONE
<i>in vitro</i> research w/genesis of gametes, or embryos and other totipotent cells	Notification for gamete genesis; Review for creation of embryos or other totipotent cells.
<i>in vivo</i> research	Notification; review of projects injecting human cells into prenatal animals or into the central nervous system of animals.