



The University of South Dakota

Policy Number:	6.011
Originating Office:	Office of Research and Sponsored Programs
Responsible Executive:	Vice President for Research
Date Issued:	01/26/2011
Date Last Revised:	01/26/2011

Use of Human Stem Cells in Research

Policy Contents

I. Reason for this Policy.....	1
II. Statement of Policy	1
III. Definitions.....	2
IV. Procedures	2
V. Related Documents, Forms and Tools.....	3

I. REASON FOR THIS POLICY

This policy describes the legal limits on the use of human stem cells in research, and sets forth a procedure at USD through which researchers document their compliance with this policy and South Dakota codified law 34-14-18. This policy also distinguishes between human **embryonic** stem cells, the use of which are prohibited by law, and human **non-embryonic** (somatic or adult) stem cells, which are legal to use for approved purposes.

II. STATEMENT OF POLICY

All research conducted by USD researchers, whether at USD or in collaboration with other institutions, will conform to South Dakota's ban on the use of human embryonic stem cells.

SD Codified Law 34-14-18 states; "Use of cells or tissues obtained in violation of § 34-14-16 or 34-14-17 prohibited. **No person may use for research purposes cells or tissues that the person knows were obtained by performing the activities described in §§ 34-14-16 and 34-14-17.** A violation of this section is a Class 1 misdemeanor." (Source: SL 2000, ch 169, § 3)

The following text further explains §§ 34-14-16 and 34-14-17:

"34-14-16. Research that destroys human embryo prohibited--Violation as misdemeanor. **No person may knowingly conduct nontherapeutic research that destroys a human embryo.** A violation of this section is a Class 1 misdemeanor." (Source: SL 2000, ch 169, § 1)

"34-14-17. Research subjecting human embryo to substantial risk prohibited--Sale or transfer of embryos for research prohibited--Violation as misdemeanor. **No person may knowingly conduct nontherapeutic research that subjects a human embryo to substantial risk of injury or death. No person may sell or transfer a human embryo with the knowledge that the embryo will be subjected to nontherapeutic research.** A violation of this section is a Class 1 misdemeanor." (Source: SL 2000, ch 169, § 2)

III. DEFINITIONS

STEM CELLS are normal cells with potential to develop into many different cell types in the body during early life and growth. There are two kinds of stem cells in animals and humans, embryonic stem cells and non-embryonic "somatic" or "adult" stem cells, plus a third type (induced pluripotent stem cells) that can be stimulated under certain conditions; each is described below.

EMBRYONIC STEM CELLS, as their name suggests, are derived from embryos. Most embryonic stem cells are derived from embryos that develop from eggs that have been fertilized in vitro—in an in vitro fertilization clinic—and then donated for research purposes with informed consent of the donors. They are not derived from eggs fertilized in a woman's body.

The federal definition of human embryonic stem cell, as given in the National Institutes of Health Guidelines, is as follows: human embryonic stem cells "are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers."

EMBRYONIC STEM CELL LINES are embryonic stem cells that have been cultured under in vitro conditions (in a laboratory) that allow cell proliferation without differentiation (into more specialized cells) for months to years.

INDUCED PLURIPOTENT STEM CELLS are somatic (adult) cells reprogrammed to enter an embryonic stem cell–like state by being forced to express factors (molecules made by cells) important for maintaining the "stemness" of embryonic stem cells. Comparison of induced pluripotent stem cells and embryonic stem cells is being accomplished by researchers at the National Institutes of Health and elsewhere outside of South Dakota.

IV. PROCEDURES

Researchers planning the use of human non-embryonic somatic (adult) stem cells in research must provide to the vice president for research documentation from an official source affirming that the cells or tissue were not derived in violation of SDCL 34-14-18, or describing in sufficient detail the actual derivation of the cells or tissue so as to demonstrate unequivocally that SDCL 34-14-18 is not violated.

The documentation may be provided as a paper document with explanatory cover letter, or an email to orsp@usd.edu with explanatory narrative and official documents as attachments.

Provision of documentation, and review and certification of compliance by the Vice President for Research are required prior to purchase or transfer of stem cells to USD.

V. RELATED DOCUMENTS, FORMS AND TOOLS

SD Codified Law, Chapter 34-14, "MEDICAL RESEARCH".

<http://legis.state.sd.us/statutes/DisplayStatute.aspx?Statute=34-14&Type=Statute>

"Stem Cell Information", National Institutes of Health resource for stem cell research:

<http://stemcells.nih.gov/index.asp>

Federal Register, March 11, 2009, Part IV, Executive Order 13505, "Removing Barriers to Responsible Scientific Research Involving Human Stem Cells":

<http://edocket.access.gpo.gov/2009/pdf/E9-5441.pdf>