UW–Madison Stem Cell Research Oversight Guidance for Documentation of Provenance (April 2019)

Researchers wishing to add lines to the UW–Madison Human Embryonic Stem Cell (hESC) Registry need to submit documentation to the SCRO Committee addressing each of the items listed below. This guidance is in addition to the consent requirements listed in Section 3 of the UW–Madison Policy for Human Embryo and Human Pluripotent Stem Cell Research.

1. Whenever it is practicable, the attending physician responsible for the infertility treatment and the investigator deriving or proposing to use hESCs will not be the same person.
2. No cash or in-kind payments may be provided for donating preimplantation embryos in excess of clinical need for research purposes.
3. Women who undergo hormonal induction to generate oocytes specifically for research purposes (such as for nuclear transfer) may be reimbursed for direct expenses incurred as a result of the procedure, as determined by an Institutional Review Board or appropriate institutional ethics committee. Oocytes and sperm donors may be compensated at a level consistent with compensation provided for *in vitro* fertilization donors at the locale where the donation occurs. In locales where reimbursement for research participation is allowed, there must be a detailed and rigorous review to ensure that reimbursement of direct expenses or financial considerations of any kind do not constitute an undue inducement. The study protocol should also consider the long-term effects of repeated ovulation induction.[1]
4. Potential donors of preimplantation embryos should be informed of all available options for the disposition of their embryos, including donation to others for reproductive purposes as well as destruction. Donors who may have specified their intent to donate embryos to research prior to completion of their clinical care must provide specific informed consent for donation to stem cell research after their clinical care has been completed.
5. The consent form must address the right to withdraw. Ideally, this language should specify the right to withdraw consent until the embryos are actually used to derive embryonic stem cells or until information which could link the identity of the embryo donor(s) with the embryo is no longer retained, if applicable. Embryo donors should be told, however, that once the embryos have been transferred to a researcher, they will no longer be usable for clinical purposes.
6. In the context of donation of gametes or preimplantation embryos for hESC research, the informed consent process should ideally provide the following information, although some variation is possible:
    a. A statement that the preimplantation embryo or gametes will be used to derive hESCs for research that may include research on human transplantation.
    b. A statement that the donation is made without any restriction or direction regarding who may be the recipient of transplants of the cells derived, except in the case of autologous donation.

[1] Based on International Society for Stem Cell Research, Guidelines for the Conduct of Human Embryonic Stem Cell Research Recommendations 11.5b(ii) and (v).

c. A statement as to whether the identities of the donors will be readily ascertainable to those who derive or work with the resulting hESC lines.

d. If the identities of the donors are retained (even if coded), a statement as to whether donors whose identities are retained wish to be contacted in the future to receive information obtained through studies of the cell lines.

e. An assurance that participants in research projects will follow applicable and appropriate best practices for donation, procurement, culture, and storage of cells and tissues to ensure, in particular, the traceability of stem cells. Traceable information, however, must be secured to ensure confidentiality.

f. A statement that derived hESCs and/or cell lines might be kept for many years.

g. A statement that the hESCs and/or cell lines might be used in research involving genetic manipulation of the cells or the mixing of human and non-human cells in animal models subject to approval of the appropriate institutional committee.[2]

h. Disclosure of the possibility that the results of study of the hESCs may have commercial potential and a statement that the donor will not receive financial or any other benefits from any future commercial development.

i. A statement that the research is not intended to provide direct medical benefit to the donor(s) except in the case of autologous donation.

j. A statement that embryos may be destroyed in the process of deriving hESCs.

k. A statement that neither consenting nor refusing to donate embryos for research will affect the quality of any future care provided to potential donors.

l. A statement of the risks to the donor.

m. An assurance that researchers have not asked members of the infertility treatment team to generate more oocytes than necessary for the optimal chance of reproductive success.

n. An assurance that an infertility clinic or other third party responsible for obtaining consent or collecting materials will not pay for or be paid for the material obtained (except for specifically defined cost-based reimbursements and payments for professional services.)

[2] This conforms to the 2009 NIH Guidelines provision II.A.2.