

Ethical Considerations for MSCRF/TEDCO Research Proposals

Both the MSCRF peer reviewers and the members of the MSCRF Commission (who conduct second-tier review of the proposals) are given the responsibility in the Maryland law to make sure that funded research will be done in conformity with high medical ethical standards. This may be the reason behind the separate “Ethics” section of the MSCRF grant applications. Please take this section seriously, as a simplistic response in this section such as “Not applicable because human ESCs are not used in this proposal” might lead to rejection of the grant; i.e., there are ethical considerations in use of human materials and animals, that the reviewers and Commission members feel deserve consideration by the principal investigator.

Please note the following:

1. The proposed MSCRF/TEDCO research must be approved by the University of Maryland School of Medicine’s Institutional Review Board (even if you are utilizing established cell lines). This is a quirk of the Maryland law that established the Maryland Stem Cell Research Fund. IRB approval can be accomplished just in time, after notification that you will be funded.
2. The University of Maryland School of Medicine has established an Embryonic Stem Cell Research Oversight (ESCRO) Committee. The proposed MSCRF/TEDCO research must be approved by the University of Maryland School of Medicine’s Embryonic Stem Cell Research Oversight (ESCRO) Committee (even if you are not utilizing ES cells). This is a second quirk of the Maryland law that established the Maryland Stem Cell Research Fund. ESCRO approval can be accomplished just in time, after notification that you will be funded, and can be sought in parallel with seeking IRB (and IACUC, if relevant).
3. If use of vertebrate animals is involved, the proposed MSCRF/TEDCO research must be approved by the University of Maryland School of Medicine’s IACUC.

MSCRF Requirements:

Below are the relevant sections of the State of Maryland Act of 2006, available at:

www.msccrf.org/content/aboutus/actof2006.cfm

§ 10-437.

*(a) A person who conducts State-funded stem cell research shall conduct the research in a manner that **considers the ethical and medical implications of the research.***

*(b) A person who conducts State-funded stem cell research **may not engage in any research that intentionally and directly leads to human cloning.***

§ 10-438

*(b) Any unused **material donated for State-funded stem cell research may not be an oocyte.***

*(c) An individual who donates any unused material for research purposes under subsection (a)(2) of this section shall provide the health care practitioner with **written consent for the donation.***

§ 10-440.

(a) A person may not conduct or attempt to conduct human cloning.

The NIH Guidelines for Stem Cell Research provide more information for your consideration.

A few key excerpts are noted below. For more information go to: stemcells.nih.gov/policy/2009guidelines.htm

Many of the guidelines are concerned with the process of obtaining consent from donors.

1. The July 7, 2009, NIH Guidelines for Human Stem Cell Research require written informed consent in all cases from the

individuals donating the embryos.

2. There should be documentation that "no payments, cash or in kind, were offered for the donated embryos."
3. The donor(s) must receive information that the research was not intended to provide direct medical benefit to the donor(s); that the results of research using the hESCs may have commercial potential, and that the donor(s) would not receive financial or any other benefits from any such commercial development.
4. No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

If you are introducing hESC or human iPS cells into animals, remember that NIH prohibits certain experiments, as indicated below. Noting that you are in compliance shows awareness of potential ethical issues. IF your experiments are not in compliance you must address the ethical implications directly.

NIH prohibits:

1. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
2. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.