

Summary of The National Academies of Science 2008 Amendments for the Guidelines for Human Embryonic Stem Cell Research

Applicability of the Guidelines to non-embryonic human pluripotent stem cells:

- A portion of the guidelines should also apply to other types of human stem cell research including: 1) human pluripotent stem (hPS) cells derived from non-embryonic sources such as spermatogonial stem cells and induced pluripotent stem cells derived from somatic cells by introduction of genes or otherwise; 2) and other pluripotent cells yet to be developed.
- Institutional Review Boards (IRBs) should review all new procurements of gametes, blastocysts, or somatic cells for the purpose of generating new human embryonic stem (hES) or hPS cell lines.
- Investigators are encouraged to document how they will characterize, validate, store and distribute any new hPS cell lines.
- The derivation of non-embryo derived hPS cells are covered by existing IRB regulations concerning review and consent and no embryonic stem cell research oversight committee (ESCRO) review is required.
- The IRB review should consider proper consent for use of the derived hPS cells.
- Use of hPS cells purely for in vitro research should not require any review beyond what is necessary for any human cell line, with the exception of research designed to yield gametes, which would then be subject to ESCRO committee review.
- ESCRO committee and IACUC review is required for transplantation of non-embryo derived hPS cells into nonhuman animals at any stage of embryonic, fetal and postnatal development.
 - ESCRO committees should review the provenance of the hPS cell lines as they review the provenance of hES cell lines to ensure the cell lines were derived according to ethical procedures of informed consent as monitored by an IRB or equivalent oversight body.
 - Proposals for the use of hPS cells in animals should fall into one of three categories: 1) Permissible after currently mandated reviews and documentation, or experiments that only require IACUC review and not ESCRO review; 2) Permissible after additional review by an ESCRO committee and experiments in which there is a significant possibility that the implanted hPS cells could give rise to neural or gametic cells and tissues; 3) Should not be conducted at this time.
- ESCRO committees should decide whether they wish to review and monitor experiments with neural stem cells.
- No animal, into which hPS cells have been introduced such that they could contribute to the germline, should be allowed to breed.

- Institutions should consider the value of banking and distributing hPS cells using the guidance and rules that are already in place for hES cells and the value of including hPS cell lines in their registries.
- To determine if purely in vitro hES cell research that uses previously derived hES cell lines is permissible, a ESCRO committee may conduct an expedited review of such research proposals and allow the ESCRO committee chair or others designated by the committee chair to act on behalf of the ESCRO committee to determine if the hES cells have been acceptably derived.
- Investigators and stem cell banks are free to choose which cell lines to accept and are not obligated to accept cell lines for which maintaining information about specific research use prohibitions would be unduly burdensome
- New derivations of stem cell lines from banked tissues obtained prior to the adoption of the guidelines are permissible provided that the original donations were made in accordance with the legal requirements in force at the place and time of donation.

Public openness and ESCRO committee audits

- ESCRO committees should maintain registries of hES cell research and make this information (including project abstracts and sources of funding) available to the public and the media through the institution's website.
- An institution that maintains its own ESCRO committee should periodically audit the committee to ensure they are carrying out their responsibilities appropriately. An institution using an outside ESCRO committee should also ensure that their ESCRO committee is carrying out their responsibilities appropriately.

Clarification of policy regarding reimbursement of oocyte donors

- Examples of direct expenses that may be reimbursed for women undergoing AOP for research include costs associated with travel, housing, child care, medical care, health insurance and actual lost wages.
- No payments beyond reimbursement should be provided for donating oocytes or sperm for research or somatic cells used in NT.