Updated guidelines for stem cell research released

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The National Academies today released amended guidelines for research involving human embryonic stem cells, revising those that were issued in 2005 and updated in 2007. The Academies originally produced the guidelines to offer a common set of ethical standards for the responsible conduct of research using human stem cells, an area that, due to an absence of comprehensive federal funding, was lacking national standards. Since their initial release, the guidelines have served effectively as the basis for oversight of this research in the United States. In addition, a standing advisory committee -- a joint project between the Academies' National Research Council and Institute of Medicine -- was established to monitor and review scientific advances and determine any need for revisions.

Embryonic stem cells have the potential to produce all of the body's cell types. Researchers are working to harness stem cells' ability both to regenerate themselves and produce specialized cells that may lead to medical treatments that replace certain types of cells damaged or lost to debilitating illness and injury, such as nerve cells.

One reason for the 2008 modifications is to provide guidance on the derivation and use of new human stem cells that were first developed last year. These cells -- called "induced pluripotent cells" -- are made by reprogramming nonembryonic adult cells into a stem-cell-like state, in which they can be manipulated to form a wide array of specialized body cells. Although induced pluripotent stem cells can be derived without using embryos, the ethical and policy concerns related to their potential

uses are similar to those pertaining to human embryonic stem cells. For example, issues arising from mixing human and animal cells in a single organism are relevant for stem cells from both embryonic and nonembryonic sources. However, derivation of induced pluripotent stem cells does not require special stem cell expertise and is adequately covered by current Institutional Review Board regulations, the report says.

At this time it is still undetermined which stem cell types will prove the most useful for regenerative medicine, as most likely each will have some utility, noted the committee that wrote the report. Therefore, the need for research with human embryonic stem cells still exists despite the availability of new cell sources.

The amended guidelines also clarify that "direct expenses" for reimbursement to women donating their eggs for use in stem cell research may include costs associated with travel, housing, child care, medical care, health insurance, and actual lost wages. This language extends the 2005 guidelines, which stated that women who undergo hormonal induction to generate eggs specifically for research purposes should be reimbursed only for "direct expenses" incurred as a result of the procedure, although they did not specify which expenses qualified as direct. The committee stressed that reimbursement for lost wages is not a payment for eggs; the intent is to leave all donors neither better off nor worse off financially.

To instill a high level of confidence that institutions and their researchers are conducting stem cell research responsibly, the guidelines recommend that the public be informed about the types of stem cell research under way and how the research conforms to the institution's established procedures. Moreover, the committee strongly suggested as a good management practice that institutions conducting human embryonic stem cell research carry out periodic audits of their embryonic stem cell

research oversight (ESCRO) committees to ensure proper performance and make the findings of the audits available to the public. The audits should document decisions regarding the acceptance of research proposals and verify that cell lines in use were acceptably derived.

Additionally, the new guidelines clarify that an institutional ESCRO committee may conduct expedited review for research done exclusively in a laboratory dish or test tube that does not create new lines of stem cells but uses previously derived human embryonic stem cell lines. The original guidelines stated that research is "permissible after currently mandated review and proper notification of the relevant research institution." However the word "notification" led some experts to question if the requirement could be fulfilled by merely informing ESCRO committees that the research would occur. Although allowing for expedited review, the guidelines still require an ESCRO committee to determine if the human embryonic stem cells have been acceptably derived.

Future committee deliberations will consider items for which additional information-gathering and more extensive debate and discussion may be necessary. For example, the National Institutes of Health determined that the human embryonic stem cell lines declared in 2001 by President George W. Bush to be eligible for federally funded research were derived from embryos donated with informed consent and without financial inducement. Based on this determination, the Academies' 2007 guidelines had deemed those lines to have been acceptably derived. However, questions about their derivation were raised when this report was near completion. In addition, a breakthrough in the ability to "reprogram" adult cells from one type to another in a living animal was recently announced. The committee will continue to monitor developments in stem cell research to decide whether any future changes to the guidelines are warranted.

Source: National Academy of Sciences