Matthew Jennings, BSC Coordinator, CDC, Coordinating Office for Terrorism Preparedness and Emergency Response, 1600 Clifton Road, NE., Mailstop D–44, Atlanta, Georgia 30333, Telephone (404) 639–7357.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 17, 2009.

Elaine L. Baker,

Director, Management Analysis and Service Office, Centers for Disease Control and Prevention.

[FR Doc. E9–9331 Filed 4–22–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft National Institutes of Health Guidelines for Human Stem Cell Research Notice

SUMMARY: The National Institutes of Health (NIH) is requesting public comment on draft guidelines entitled ''National Institutes of Health Guidelines for Human Stem Cell Research'' (Guidelines).

The purpose of these draft Guidelines is to implement Executive Order 13505, issued on March 9, 2009, as it pertains to extramural NIH-funded research, to establish policy and procedures under which NIH will fund research in this area, and to help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH research involving human stem cells.

These draft Guidelines would allow funding for research using human embryonic stem cells that were derived from embryos created by *in vitro* fertilization (IVF) for reproductive purposes and were no longer needed for that purpose. Funding will continue to be allowed for human stem cell research using adult stem cells and induced pluripotent stem cells. Specifically, these Guidelines describe the conditions and informed consent procedures that would have been required during the derivation of human embryonic stem cells for research using these cells to be funded by the NIH. NIH funding for research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not allowed under these Guidelines.

NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Consolidated Appropriations Act, 2009, Pub. L. 110–161, 3/11/09), otherwise known as the Dickey-Wicker Amendment.

According to these Guidelines, there are some uses of human embryonic stem cells and human induced pluripotent stem cells that, although those cells may come from allowable sources, are nevertheless ineligible for NIH funding.

For questions regarding ongoing NIH-funded research involving human embryonic stem cells, as well as pending applications and those submitted prior to the issuance of Final Guidelines, see the NIH Guide *http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-085.html.*

DATES: Written comments must be received by NIH on or before May 26, 2009.

ADDRESSES: The NIH welcomes public comment on the draft Guidelines set forth below. Comments may be entered at: *http://nihoerextra.nih.gov/stem_cells/add.htm.* Comments may also be mailed to: NIH Stem Cell Guidelines, MSC 7997, 9000 Rockville Pike, Bethesda, Maryland 20892–7997. Comments will be made publicly available, including any personally identifiable or confidential business information they contain.

SUPPLEMENTARY INFORMATION: On March 9, 2009, President Barack H. Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.* The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

The purpose of these draft Guidelines is to implement Executive Order 13505, issued on March 9, 2009, as it pertains to extramural NIH-funded research, to establish policy and procedures under which NIH will fund research in this area, and to help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH research involving human stem cells.

Long-standing Department of Health and Human Services regulations for Protection of Human Subjects, 45 CFR part 46, establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. When research involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 CFR part 46. Applicants should consult *http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm.*

As described in these draft Guidelines, human embryonic stem cells are cells that are derived from 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. Although human embryonic stem cells are derived from embryos, such stem cells are not themselves human embryos.

Studies of human embryonic stem cells may yield information about the complex events that occur during human development. Some of the most serious medical conditions, such as cancer and birth defects, are due to abnormal cell division and differentiation. A better understanding of the genetic and molecular controls of these processes could provide information about how such diseases arise and suggest new strategies for therapy. Human embryonic stem cells may also be used to test new drugs. For example, new medications could be tested for safety on differentiated somatic cells generated from human embryonic stem cells.

Perhaps the most important potential use of human embryonic stem cells is the generation of cells and tissues that could be used for cell-based therapies. Today, donated tissues and organs are often used to replace ailing or destroyed tissue, but the need for transplantable tissues and organs far outweighs the available supply. Stem cells, directed to differentiate into specific cell types, offer the possibility of a renewable source of replacement cells and tissues to treat diseases and conditions, including Parkinson's disease, amyotrophic lateral sclerosis, spinal cord injury, burns, heart disease, diabetes, and arthritis.

NIH currently funds ongoing research involving human embryonic stem cells as detailed under prior Presidential policy. Under that policy, Federal funds have been used for research on human embryonic stem cells where the derivation process was initiated prior to 9 p.m. EDT August 9, 2001, the embryo was created for reproductive purposes, the embryo was no longer needed for these purposes, informed consent was obtained for the donation of the embryo, and no financial inducements were provided for donation of the embryo.

These draft Guidelines would allow funding for research using only those human embryonic stem cells that were derived from embryos created by *in vitro* fertilization (IVF) for reproductive purposes and were no longer needed for that purpose. Funding will continue to be allowed for human stem cell research using adult stem cells and induced pluripotent stem cells. Specifically, these Guidelines describe the conditions and informed consent procedures that would have been required during the derivation of human embryonic stem cells for research using these cells to be funded by the NIH. NIH funding for research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not allowed under these Guidelines.

Please note that, for NIH funded research using the permitted human embryonic stem cells, the requirements of the Department's protection of human subjects regulations, 45 CFR part 46, may or may not apply, depending on the nature of the research. For further information, see *Human Embryonic Stem Cells, Germ Cells and Cell Derived Test Articles:* OHRP Guidance for Investigators and Institutional Review Boards.

NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Consolidated Appropriations Act, 2009, Pub. L. 110–161, 3/11/09), otherwise known as the Dickey-Wicker Amendment.

According to these Guidelines, there are some uses of human embryonic stem cells that, although those cells may come from allowable sources, are nevertheless ineligible for NIH funding.

In developing these draft Guidelines, the NIH consulted its Guidelines issued in 2000, as well as the thoughtful guidelines developed by other national and international committees of scientists, bioethicists, patient advocates, physicians and other stakeholders, including the U.S. National Academies, the International Society for Stem Cell Research, and others.

As directed by Executive Order 13505, the NIH shall review and update these Guidelines periodically, as appropriate.

The Draft Guidelines Follow:

National Institutes of Health Guidelines for Human Stem Cell Research

I. Scope of Guidelines

These Guidelines describe the circumstances under which human embryonic stem cells are eligible for use in extramural NIH-funded research, and they also include a section on uses of human embryonic stem cells or human induced pluripotent stem cells that are ineligible for NIH funding.

For the purpose of these Guidelines, ''human embryonic stem cells'' are cells that are derived from 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. Although human embryonic stem cells are derived from embryos, such stem cells are not themselves human embryos.

II. Guidelines for Eligibility of Human Embryonic Stem Cells for Use in Research

A. The Executive Order: Executive Order 13505, *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells,* states that the Secretary of the Department of Health and Human Services (DHHS), through the Director of the NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell research, to the extent permitted by law.

B. Eligibility of Human Embryonic Stem Cells Derived from Human Embryos: Human embryonic stem cells may be used in research using NIH funds, if the cells were derived from human embryos that were created for reproductive purposes, were no longer needed for this purpose, were donated for research purposes, and for which documentation for all of the following can be assured:

1. All options pertaining to use of embryos no longer needed for reproductive purposes were explained to the potential donor(s).

2. No inducements were offered for the donation.

3. A policy was in place at the health care facility where the embryos were donated that neither consenting nor refusing to donate embryos for research would affect the quality of care provided to potential donor(s).

4. There was a clear separation between the prospective donor(s)'s decision to create human embryos for reproductive purposes and the prospective donor(s)'s decision to donate human embryos for research purposes.

5. At the time of donation, consent for that donation was obtained from the individual(s) who had sought reproductive services. That is, even if potential donor(s) had given prior indication of their intent to donate to research any embryos that remained after reproductive treatment, consent for the donation should have been given at the time of the donation. Donor(s) were informed that they retained the right to withdraw consent until the embryos were actually used for research.

6. Decisions related to the creation of human embryos for reproductive purposes were made free from the influence of researchers proposing to derive or utilize human embryonic stem cells in research. Whenever it was practicable, the attending physician responsible for reproductive clinical care and the researcher deriving and/or proposing to utilize human embryonic stem cells should not have been the same person.

7. Written informed consent was obtained from individual(s) who sought reproductive services and who elected to donate human embryos for research purposes. The following information, which is pertinent to making the decision of whether or not to donate human embryos for research purposes, was in the written consent form for donation and discussed with potential donor(s) in the informed consent process:

a. A statement that donation of the embryos for research was voluntary;

b. A statement that donor(s) understood alternative options pertaining to use of the embryos;

c. A statement that the embryos would be used to derive human embryonic stem cells for research;

d. Information about what would happen to the embryos in the derivation of human embryonic stem cells for research;

e. A statement that human embryonic stem cells derived from the embryos might be maintained for many years;

f. A statement that the donation was made without any restriction or direction regarding the individual(s) who may receive medical benefit from the use of the stem cells;

g. A statement that the research was not intended to provide direct medical benefit to the donor(s);

h. A statement as to whether or not information that could identify the donor(s) would be retained prior to the derivation or the use of the human embryonic stem cells (relevant guidance from the DHHS Office for Human Research Protections (OHRP) should be followed, as applicable; see OHRP's *Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell-Derived Test Articles* and *Guidance on Research Involving Coded Private Information or Biological Specimens,* or successor guidances); and

i. A statement that the results of research using the human embryonic stem cells may have commercial potential, and a statement that the donor(s) would not receive financial or any other benefits from any such commercial development.

C. Prior to the use of NIH funds: Funding recipients must ensure that: (1) The human embryonic stem cells were derived consistent with sections II.A and B of these Guidelines; and (2) the grantee institution maintains appropriate documentation demonstrating such consistency in accordance with 45 CFR 74.53, which also details rights of access by NIH. The responsible grantee institutional official must provide assurances with respect to (1) and (2) when endorsing applications and progress reports submitted to NIH for projects that utilize these cells.

III. Research Using Human Embryonic Stem Cells and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come From Allowable Sources, Is Nevertheless Ineligible for NIH Funding

This section governs research using human embryonic stem cells and human induced pluripotent stem cells, *i.e.,* human cells that 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. There are some uses of these cells that, although they may come from allowable sources, are nevertheless ineligible for NIH funding, as follows:

A. Research in which human embryonic stem cells (even if derived according to these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.

B. Research involving the breeding of animals where the introduction of human embryonic stem cells (even if derived according to these Guidelines) or human induced pluripotent stem cells may have contributed to the germ line.

IV. Other Non-Allowable Research

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Consolidated Appropriations Act, 2009, Pub. L. 110–161, 3/11/09), otherwise known as the Dickey-Wicker Amendment.

B. NIH funding for research using human embryonic stem cells derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not allowed under these Guidelines.

Dated: April 17, 2009.

Raynard S. Kington,

Acting Director, NIH.

[FR Doc. E9–9313 Filed 4–22–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of Federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301/496–7057; fax: 301/402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

On-Demand In Vitro Assembly of Protein Microarrays

Description of Technology: Protein microarrays are becoming an indispensable biomedical tool to facilitate rapid high-throughput detection of protein-protein, protein-drug and protein-DNA interactions for large groups of proteins. The novel Protein Microarray of this invention is essentially a DNA microarray that becomes a protein microarray on demand and provides an efficient systematic approach to the study of protein interactions and drug target identification and validation, thereby speeding up the discovery process. The technology allows a large number of proteins to be synthesized and immobilized at their individual site of expression on an ordered array without the need for protein purification. As a result, proteins are ready for subsequent use in binding studies and other analysis.

The Protein Microarray is based on high affinity and high specificity of the protein-nucleic acid interaction of the Tus protein and the Ter site of E. coli. The DNA templates are arrayed on the microarray to perform dual function: (1) Synthesizing the protein in situ (cell-free protein synthesis) in the array and (2) at the same time capturing the protein it synthesizes by DNA-protein interaction. This method utilizes an expression vector containing a DNA sequence which serves a dual purpose: (a) Encoding proteins of interest fused to the Tus protein for in vitro synthesis of the protein and (b) encoding the Ter sequence, which captures the fusion protein through the high affinity interaction with the Tus protein.

Applications:

- Simultaneous analysis of interactions of many proteins with other proteins, antibodies, nucleic acids, lipids, drugs, etc, in a single experiment.
- Efficient discovery of novel drugs and drug targets.

Development Status: The technology is in early stages of development.

Inventors: Deb K. Chatterjee, Kalavathy Sitaraman, James L. Hartley, David J. Munroe, Cassio Baptista (NCI).

Patent Status:

U.S. Patent Application No. 11/252,735 filed 19 Oct 2005 (HHS Reference No. E–244–2005/0–US–01).

U.S. Patent Application No. 12/105,636 filed 18 Apr 2008 (HHS Reference No. E–244–2005/1–US–02).

Licensing Status: Available for licensing.

Licensing Contact: Jeffrey A. James, Ph.D.; 301–435–5474; *jeffreyja@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Protein Expression Laboratory is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or