Adopt 17 Cal. Code of Regs. section 100110 to read:

§ 100110. Fairness and Diversity in Research.

CIRM grantees shall comply with the California Health Research Fairness Act, California Health and Safety Code, sections 439.900-439.906, and Inclusion of Women and Minorities in Clinical Research Act, Health and Safety Code, sections 100237-100239.

Note: Authority cited: Article XXXV, California Constitution; Section 125290.40(j), Health and Safety Code. Reference: Sections 439.900-439.906, 100237-100239, 125290.40, 125290.55, Health and Safety Code.

Deleted: 4

Adopt 17 Cal. Code of Regs. section 100120 to read:

§ 100120. Record Keeping.

(a) In addition to any other reporting or record retention obligations required by the CIRM, each grantee's institution shall also maintain records documenting:

(1) Review or notification requirements as described in Title 17, California Code of Regulations, section 100070;

(2) The final disposition of gametes, embryos and, somatic cells donated for CIRM-funded research or products of SCNT. For donated materials used to derive a covered stem cell line this record must demonstrate compliance with section 100080, subdivision (a).

(b) Such records shall be made available at CIRM's request.

Note: Authority cited: California Constitution, article XXXV; Section 125290.40(j), Health and Safety Code.

Reference: Sections 125290.35, 125290.40 and 124290.55, Health and Safety Code.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

January 11, 2002

MEMORANDUM

TO: Dr. Ruth Kirchstein
Acting Director, National Institutes of Health

FROM: Alex M. Azar II
General Counsel

SUBJECT: Compliance of the President's Embryonic Stem Cell Decision with the Dickey Amendment for Fiscal Year 2002

The National Institutes of Health plan soon to initiate federal funding of research on existing human embryonic stems cells in accordance with the policy announced by the President on August 9, 2001. Prior to the initiation of such funding, you have asked the Office of the General Counsel to provide advice on the legality of the President's policy under the Dickey Amendment to Public Law Number 107-116 (signed Jan. 10, 2002), the appropriations act funding the Department of Health & Human Services (the "Department") for fiscal year 2002.

It is our conclusion that the President's policy comports with the plain language of the Dickey Amendment. This reading is further buttressed by Congress's recent reenactment of the Dickey Amendment and, hence, ratification of the President's policy and by the legislative history accompanying the most recent reenactment of the Dickey Amendment.

The President's Policy

On August 9, 2001 at 9:00 p.m. EDT, President George W. Bush announced his decision to allow federal funds to be used for research on existing human embryonic stem cell lines as long as, prior to his announcement, (1) the derivation process (which commences with the removal of the inner cell mass from the blastocyst) had already been initiated, and (2) the embryo from which the stem cell line was derived no longer had the possibility of development as a human being.

As the President noted, "the life and death decision ha[d] already been made" with respect to those "existing human embryonic stem cell lines." This decision, as the President stated, "allows

us to explore the promise and potential of stem cell research without crossing a fundamental moral line, by providing taxpayer funding that would sanction or encourage further destruction of human embryos that have at least the potential for life." Remarks by the President on Stem Cell Research, Aug. 9, 2001, http://www.whitehouse.gov/news/releases/2001/08/print/20010809-2.html.

The President established the following additional criteria that had to be met for embryonic stem cell research to receive federal funding: (1) the stem cells must have been derived from an embryo that was created for reproductive purposes; (2) the embryo was no longer needed for such purposes; (3) informed consent must have been obtained for the donation of the embryo; and (4) no financial inducements were provided for donation of the embryo. Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry, Nov. 7, 2001, NOT-OD-02-005, Office of the Director, NIH, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html; NIH Human Embryonic Stem Cell Registry, http://escr.nih.gov. Pursuant to the President's policy, federal funds will not be used for (1) the derivation or use of stem cell lines derived from newly destroyed embryos; (2) the creation of any human embryos for research purposes; or (3) the cloning of human embryos for any purpose. Fact Sheet, Embryonic Stem Cell Research, Aug. 9, 2001, http://www.whitehouse.gov/news/release/2001/08/print/20010809-1.html.

Pursuant to the President's policy, on August 27, 2001, Secretary Thompson announced the creation of a registry of the embryonic stem cell lines meeting the President's eligibility criteria, such that research on stem cell lines listed on the Registry would be eligible for federal funding. He stated that:

> [t]he NIH wants to expedite this work and is aggressively pursuing several initiatives to facilitate research on all forms of stem cells. The NIH is creating a registry of the embryonic stem cell lines that meet the eligibility criteria so that researchers can contact the owners and gain access to them. The registry will contain basic information about the cells, a unique identifier, the name of the company or laboratory that derived the cells, and contact information about that company or lab. The registry will list these 10 laboratories as well as any other owners of stem cell lines meeting the eligibility criteria who come forward in the future.

Statement by Tommy G. Thompson, Secretary of Health & Human Services, Aug. 27, 2001, http://www.hhs.gov/new/press/2001pres/20010827a.html; *see also* Tommy G. Thompson, Secretary of Health & Human Services, Testimony before the Senate Committee on Health, Education, Labor & Pensions, Sept. 5, 2001, at 4 (discussing NIH's development of "a stem cell registry" and the intent to "mak[e] it available so scientists know exactly what lines are eligible and who they can approach for access" and to post the registry on the NIH website),

http://www.hhs.gov/news/speech/2001/010905.html.

In an NIH Update, the NIH noted that the laboratories or companies that derived the cells listed on the registry that it was creating would provide "a signed assurance that the derivation process was initiated prior to 9:00 p.m. EDT on August 9, 2001, informed consent was obtained for the donation of the embryo, the cells were derived from an excess embryo that was created for reproductive purposes, and there were no financial inducements for the donation of the embryo for research." NIH Update on Existing Human Embryonic Stem Cells, Aug. 27, 2001, at 2-3, http://www.nih.gov/news/stemcell/082701list.html. Shortly thereafter, the NIH entered into a memorandum of understanding with one of the entities that possesses such embryonic stem cell lines, to permit access to those lines by NIH scientists to conduct research and to permit scientists pursuing research funded by the NIH to negotiate access to those lines under the same terms and conditions. *See* NIH Press Release, National Institutes of Health and WiCell Research Institute, Inc. Sign Stem Cell Research Agreement, Sept. 5, 2001, http://www.nih.gov/news/pr/sep2001/od-05.html; Memorandum of Understanding between WiCell Research Institute, Inc. and Public Health Service, US Department of Health & Human Services, effective as of Sept. 5, 2001, http://www.nih.gov/news/stemcell/WicellMOU.pdf; *see also* Tommy G. Thompson, Secretary of Health & Human Services, Testimony before the Senate Committee on Health, Education, Labor & Pensions, Sept. 5, 2001, at 4 (announcing negotiation of the memorandum of understanding permitting research use of WiCell's "five existing stem cell lines that meet the eligibility criteria"), http://www.hhs.gov/news/speech/2001/010905.html.

On November 7, 2001, the NIH posted the Registry of embryonic stem cell lines that comply with the President's policy as announced on August 9, 2001. *See* NIH Human Embryonic Stem Cell Registry, http://escr.nih.gov; Notice of Criteria for Federal Funding of Research on Existing Human Embryonic Stem Cells and Establishment of NIH Human Embryonic Stem Cell Registry, Nov. 7, 2001, NOT-OD-02-005, Office of the Director, NIH, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html.

The Dickey Amendment

In construing the meaning of a statute, the starting point of the analysis is the language of the statute. *See, e.g., Central Bank of Denver NA v. First Interstate Bank of Denver NA*, 511 U.S. 164, 173 (1994) (the statutory language is "'the starting point in every case involving construction of a statute'"); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 409 (1993) ("The starting point in interpreting a statute is its language, for '[i]f the intent of Congress is clear, that is the end of the matter.'"); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 197 (1976) ("'The starting point in every case involving construction of a statute is the language itself.'"); *Kaiser Aluminum & Chem. Corp. v. Bonjorno*, 494 U.S. 827, 834-44 (1990) (same); *Meredith v. Federal Mine Safety & Health Review Comm'n*, 177 F.3d 1042, 1053 (D.C. Cir. 1999) ("As always, the

starting point of analysis is the text of the statute.").

Since 1995, the Dickey Amendment has been enacted in each of the annual appropriations acts for the Department. For fiscal year 2002, the Amendment provides:

> (a) None of the funds made available in this Act may be used for–
>
> (1) the creation of a human embryo or embryos for research purposes; or
>
> (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
>
> (b) For purposes of this section, the term 'human embryo or embryos' includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Pub. L. No. 107-116, § 510. This language is unchanged from the fiscal year 2001 Dickey Amendment.

The President's policy is consistent with the plain language of the Dickey Amendment. The Dickey Amendment contains two basic restrictions. The first prohibits the use of federal funds for "the creation of a human embryo or embryos for research purposes." *See* Pub. L. No. 107-116, § 510(a)(1). It is clear that, under the President's policy, no federal funds will be used for the creation of human embryos for research purposes. *See* Fact Sheet, Embryonic Stem Cell Research, Aug. 9, 2001, http://www.whitehouse.gov/news/release/2001/08/print/20010809-1.html (federal funds will not be used for "creation of any human embryos for research purposes"). Thus, the President's policy comports with the first restriction contained in the Dickey Amendment.

The second restriction of the Dickey Amendment prohibits the use of federal funds for *"research in which* a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero . . . ." H.R. 3061, § 510(a)(2) (emphasis added). The term "research in which" is not defined in the statute, and our research has not located any cases in which such a term is defined. As such, it is appropriate to look to ordinary and common usage when interpreting those terms. *See FDIC v. Meyer*, 510 U.S. 471, 476 (1994) ("In the absence of such a definition [in the act], we construe a statutory term in accordance with its ordinary or natural meaning."). The word "which," when "[u]sed as a relative pronoun preceded by *that* or a preposition in a clause that defines or restricts the antecedent" means "[t]he thing, animal, group of people, or event previously designated or implied, specifically." *See* The American Heritage Dictionary, New College Edition 1459

(1976). Dictionaries define "in" as meaning "within the confines of; inside"; "within the area covered by"; "during the course of or before the expiration of"; "during or part of the act or process of"; "within the category or class of." *See id.* at 663; *see also* Black's Law Dictionary 683 (5th ed. 1979) (a preposition "expressing relation of presence, existence, situation, inclusion, action, etc.; inclosed or surrounded by limits . . .; also meaning for, in and about, on, within etc.; and is synonymous with expressions 'in regard to', 'respecting', 'with respect to', and 'as is'"). Under the President's policy, federal funding for human embryonic stem cell research is limited to a discrete set of stem cell lines with respect to which the life and death decision had been made prior to the announcement of his policy. The President's policy provides no incentives for the destruction of additional embryos. Moreover, these derivation processes were not funded with federal dollars. So limited, the President's policy does not provide federal funding for "research in which [during the course of, during or part of the act or process of, or within the category or class of] embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero" within the ordinary, common usage of those terms. The policy is, thus, consistent with the second restriction of the Dickey Amendment.

Congressional Ratification of the Legality of the President's Policy

This plain meaning reading of the Dickey Amendment is bolstered by Congress's reenactment of the Dickey Amendment in identical form after the President's announcement on August 9, 2001. As discussed below, Congress was fully aware of the President's policy decision and the Secretary's steps in implementing that decision. With that knowledge, Congress reenacted the Dickey Amendment in identical form, clearly evidencing its concurrence that the President's policy is consistent with the Dickey Amendment. *See Lorillard v. Pons*, 434 U.S. 575, 580-81 (1978) ("Congress is presumed to be aware of an administrative or judicial interpretation of a statute and to adopt that interpretation when it re-enacts a statute without change."); *Central Bank of Denver*, 511 U.S. at 185-86 ("When Congress reenacts statutory language that has been given a consistent judicial construction, we often adhere to that construction in interpreting the reenacted statutory language."); *Pierce v. Underwood*, 487 U.S. 552, 567 (1988) (same); *City of Pleasant Grove v. United States*, 479 U.S. 462, 468 (1987) ("Congress was aware of the Attorney General's view . . . and implicitly approved it, when it reenacted the Voting Rights Act . . . ."); *San Huan New Materials High Tech, Inc. v. International Trade Comm'n*, 161 F.3d 1347, 1355 (Fed. Cir. 1998) ("The legislative history shows that Congress was fully aware of the agency regulations and practices [regarding consent decrees] at the time of legislating in their area, and absent some special circumstances the failure to change or refer to existing practices is reasonably viewed as ratification thereof.") .

Legislative History of the Dickey Amendment Contained in Pub. L. No. 107-116

The legislative history of the current reenactment of the Dickey Amendment in the appropriations act providing funding for Department for fiscal year 2002 further confirms that Congress understood the contours of the President's policy and believed that the policy complies with the requirements of the Dickey Amendment.

The Committee Report on H.R. 3061, the House version of the Act, published exactly two months after the President's announcement states:

> *Human Stem Cell Research*- The Committee received testimony from NIH institute and center directors, representatives of scientific and medical societies, and members of voluntary health organizations about the potential of both adult and embryonic stem cells for improving the lives of those who suffer with a host of disorders, including diabetes, Alzheimer's, Parkinson's, and cardiovascular disease. The Committee understands that a great deal of basic research is required to determine whether this potential can be realized.
>
> *It is the Committee's intent, that the NIH move ahead expeditiously to implement the President's policy concerning support of scientifically meritorious research involving both adult and human embryonic stem cells.* The Committee commends the NIH for moving quickly to negotiate material transfer agreements *with holders of existing embryonoc [sic] cell lines*. The Director is requested to keep the Committee apprised of program initiatives as well as research progress concerning both adult and embryonic stem cells.

H.R. Rep. 107-229, at 98 (Oct. 9, 2001) (emphases added). In addition, the Committee noted in connection with section 510, the Dickey Amendment, the following:

> Sec. 510. The Committee continues a provision to prohibit the use of funds in the Act concerning research involving human embryos. However, *this language should not be construed to limit federal support for research involving human embryonic stem cells listed on an NIH registry and carried out in accordance with policy outlined by the President.*

H.R. Rep. 107-229, at 180 (Oct. 9, 2001) (emphasis added). The Joint Explanatory Statement of the Committee of Conference directed that "in implementing this agreement [on appropriations], the Departments and agencies should comply with the language and instructions set forth in House Report 107-229 and Senate Report 107-84." *See* Joint Explanatory Statement of the Committee of Conference, H.R. Rep. 107-342, Conference Report on H.R. 3061, at 55 (Dec. 19, 2001). Thus, it would be appropriate to accord to H.R. Rep. 107-229 the weight customarily

given to conference committee explanatory statements. *See Northern Colorado Water Conservancy Dist. v. Federal Energy Regulatory Comm'n*, 730 F.2d 1509, 1518-19 (D.C. Cir. 1984) ("Statements in a conference report, because commended to the entire Congress, carry greater weight than comments from floor debates by individual legislators."); *Vitrano v. Marshall*, 504 F. Supp. 1381, 1383 (D.D.C. 1981) ("Perhaps the most useful document illuminating Congressional purpose is a Conference Report which bears on the final draft that is used by the conferees in explaining to the entire Congress why the bill should pass.").

As a whole, this legislative history expresses the Congress's support for the President's policy and unambiguously confirms that the President's decision is consistent with the Dickey Amendment. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 209 (1994) ("The legislative history of the Mine Act confirms this interpretation."); *see also San Huan New Materials*, 161 F.3d at 1355 ("The legislative history leaves no doubt that Congress was aware of, and approved of, the Commission's consent order procedure as it existed at the time of the 1988 amendments.").

In sum, whatever legal challenges might be brought, the President's policy is consistent with the Dickey Amendment as evidenced by the plain language of the statute, Congress's reenactment ratification of the President's policy, and the legislative history reflecting Congress's full understanding of the precise contours of the President's policy and that policy's compliance with the Dickey Amendment.

As we move forward with implementation of the President's decision, it should be noted that federal funding of research in the following areas remains barred: (1) the derivation of new stem cells from human embryos; (2) research in which human embryonic stem cells are used to create or contribute to a human embryo; (3) research in which human embryonic stem cells are derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; (4) research using human embryonic stem cells that were derived using somatic cell nuclear transfer, i.e., the transfer of a human somatic cell nucleus into a human or animal egg; (5) research in which human embryonic stem cells are combined with an animal embryo; and (6) research in which human embryonic stem cells are used in combination with somatic cell nuclear transfer for the purposes of reproductive cloning of a human. *See* National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, Part III ("Areas of Research Involving Human Pluripotent Stem Cells that are Ineligible for NIH Funding", listing the above categories of research), 65 FR 51976 (effective Aug. 25, 2000), corrected, 65 FR 69951 (Nov. 21, 2000), www.nih.gov/news/stemcell/stemcellguidelines.html, withdrawn as to those sections pertaining to research involving human pluripotent stem cells derived from human embryos that are the result of in vitro fertilization, are in excess of clinical need, and have not reached the stage at which the mesoderm is formed, Notice of Withdrawal of NIH Guidelines for Research Using Pluripotent Stem Cells, Nov. 7, 2001, NOT-OD-02-007, Office of the Director,

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

January 15, 1999

TO: Harold Varmus, M.D.
Director, NIH

FROM: Harriet S. Rabb

SUBJECT: Federal Funding for Research Involving Human Pluripotent Stem Cells

The Office of the General Counsel of the U.S. Department of Health and Human Services (HHS) has prepared the following in response to your request for a legal opinion on whether federal funds may be used for research conducted with human pluripotent stem cells derived from embryos created by *in vitro* fertilization or from primordial germ cells isolated from the tissue of non-living fetuses. This inquiry arises from the recently reported research of: (1) Dr. James A. Thomson of the University of Wisconsin-Madison, who isolated pluripotent stem cells from embryos donated for research by persons undergoing fertility treatment[1]; and (2) Dr. Michael Shamblott of the Johns Hopkins University School of Medicine, who derived pluripotent stem cells from primordial germ cells from non-living fetuses.[2] The research described in these two published reports was not funded by HHS.

Summary Answer

The statutory prohibition on the use of funds appropriated to HHS for human embryo research would not apply to research utilizing human pluripotent stem cells because such cells are not a human embryo within the statutory definition. To the extent human pluripotent stem cells are considered human fetal tissue by law, they are subject to the statutory prohibition on sale for valuable consideration, the restrictions on fetal tissue transplantation research that is conducted or funded by HHS, as well as to the federal criminal prohibition on the directed donation of fetal

[1] James A. Thomson et al., Embryonic Stem Cell Lines Derived from Human Blastocysts, Science, vol. 282, November 6, 1998, pp. 1145-1147.

[2] Michael J. Shamblott et al., Derivation of Pluripotent Stem Cells from Cultured Human Primordial Germ Cells, 95 Proc. Nat'l. Acad. Sci. USA 13726 (Nov. 1998).

tissue. Research involving human pluripotent stem cells excised from a non-living fetus may be conducted only in accordance with any applicable state or local law. Finally, the Presidential Directive banning federal funding of human cloning would apply to pluripotent stem cells, only if they were to be used for that purpose.

Analysis

I. Prohibition on Federal Funding for Human Embryo Research

In the appropriations provision for the Departments of Labor, Health and Human Services, and Education, and Related Agencies in the Omnibus Consolidated and Emergency Supplemental Appropriations Act, Fiscal Year 1999, Public Law 105-277, section 511 provides that none of the funds made available in that appropriation may be used for:

> (1) the creation of a human embryo or embryos for research purposes; or
> (2) research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 U.S.C. 289g (b)).

The term "human embryo or embryos" is defined in the statute to include "any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells."

Pluripotent stem cells are not a human "organism" as that term is used in the definition of human embryo provided by statute. The term "organism" is not itself defined by law, and the question of what is an organism calls for a science-based answer. According to the McGraw-Hill Dictionary of Scientific and Technical Terms (hereinafter McGraw-Hill), an organism is "[a]n individual constituted to carry out all life functions."[3] Pluripotent stem cells are not organisms

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[3] McGraw-Hill Dictionary of Scientific and Technical Terms 1408 (5th edition 1994). See also N. Campbell, Biology, (4th edition 1996) pp. 8-9, which defines organism as follows:

> While cells are the units of organisms, it is organisms that are the units of life. It's an important distinction. Except for unicellular life, 'cell' does not equal 'organism.' A single-celled organism such as an amoeba is analogous not to one of your cells, but to your whole body. What the amoeba accomplishes with a single cell -- the uptake and processing of nutrients, excretion of wastes, response to environmental stimuli, reproduction, and other functions -- a human or other multicellular organism accomplishes with a division of labor among specialized tissues, organs, and organ systems. Unlike the amoeba, none of your cells could live for long on its own. The organism we recognize as an animal or plant is not a

and do not have the capacity to develop into an organism that could perform all the life functions of a human being -- in this sense they are not even precursors to human organisms.[4] They are, rather, human cells that have the potential to evolve into different types of cells such as blood cells or insulin producing cells.

Moreover, a human embryo, as that term is virtually universally understood, has the potential to develop in the normal course of events into a living human being. The scientific definition of embryo, as described in McGraw-Hill, is "[t]he product of conception up to the third month of human pregnancy."[5] Pluripotent stem cells do not have the capacity to develop into a human being, even if transferred to a uterus.[6] Therefore, in addition to falling outside of the legal definition provided by statute, pluripotent stem cells cannot be considered human embryos consistent with the commonly accepted or scientific understanding of that term. Thus, based on

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collection of unicells, but a multicellular cooperative with the emergent properties of 'whole organism.'

[4] At a December 2, 1998, stem cell research hearing before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee, Senator Tom Harkin asked five scientists, two bioethicists, and a theologian testifying before the committee if, in their view, stem cells were organisms. All of the experts who responded concluded that human pluripotent stem cells are not organisms. Use of Fetal Tissue in Brain Stem Cell Research: Hearing Before the Subcomm. on Labor, Health and Human Services, and Education of the Senate Appropriations Comm., 105th Cong. (December 2, 1998) available in LEGI-SLATE, Transcript No. 983360015 [hereinafter Stem Cell Hearing] (statement of Dr. Harold Varmus, Director, National Institutes of Health; Dr. John Gearhart, Johns Hopkins University School of Medicine; Dr. James Thomson, Wisconsin Primate Research Center, University of Wisconsin; Dr. Michael West, Advanced Cell Technology; Dr. Thomas Okarma, Geron Corporation; Dr. Arthur Caplan, Center for Bioethics, University of Pennsylvania Health System; and Mr. Richard Doerflinger, Associate Director for Policy Development, Secretariat of Pro-Life Activities, National Conference of Catholic Bishops). One expert, Dr. Eric Meslin, Executive Director of the National Bioethics Advisory Commission, stated that he could not speak on behalf of the Commission because it had not considered the question. Stem Cell Hearing, supra, (statement of Dr. Eric Meslin).

[5] McGraw-Hill Dictionary, supra note 3, at 673.

[6] See Letter from the Chair of the National Bioethics Advisory Commission, to the President of the United States, response to question no. 2, November 20, 1998; National Institutes of Health, Report of the Human Embryo Research Panel, Sept. 1994, p. 26. See also Stem Cell Hearing, supra note 4, (statements of Dr. Michael West, Advanced Cell Technology; Dr. Thomas Okarma, Geron Corporation; and Dr. Arthur Caplan, Center for Bioethics, University of Pennsylvania Health System).

an analysis of the relevant law and scientific facts, federally funded research that utilizes human pluripotent stem cells would not be prohibited by the HHS appropriations law prohibiting human embryo research, because such stem cells are not human embryos.

II. Restrictions on the Use of Human Fetal Tissue

There are a number of potential sources of human pluripotent stem cells; some of these stem cells may fall within the legal definition of human fetal tissue and would, therefore, be subject to federal regulations. Section 498A of the Public Health Service Act specifies that fetal tissue "means tissue or cells obtained from a dead human embryo or fetus after a spontaneous or induced abortion, or after a stillbirth." 42 U.S.C. 289g-1(g). Some stem cells, for example those derived from the primordial germ cells of non-living fetuses, would be considered human fetal tissue for purposes of Section 498A.

The Public Health Service Act (hereinafter "The Act") contains three relevant provisions governing the use and transfer of human fetal tissue: (1) a criminal prohibition against the sale of human fetal tissue for valuable consideration; (2) restrictions on fetal tissue transplantation research supported by federal funds; and (3) a prohibition on the directed donation of fetal tissue for transplantation. We explore each of these restrictions in turn.

Section 498B(a) of the Act states that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration,[7] if the transfer affects interstate commerce.[8] 42 U.S.C. 289g-2(a). It is common practice for scientists throughout the United States to share research materials through transactions that result in such materials crossing state boundaries. Such exchanges, as well as transactions within the District of Columbia, or exchanges within a state that "affect interstate commerce" would meet the statutory criterion of affecting interstate commerce, but would not fall within the scope of the criminal

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[7] The term "valuable consideration" encompasses both monetary and non-monetary payments. Section 498B (d)(3) provides that the term does not include "reasonable payments associated with the transportation, implantation, processing, preservation, quality control, or storage of human fetal tissue."

[8] The statute adopts the definition of interstate commerce in section 201(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(b): ". . . commerce between any State or Territory and any place outside thereof, and . . . commerce within the District of Columbia or within any other Territory not organized with a legislative body." The statute does not define what "affects" interstate commerce, but, in interpreting similar language in another criminal statute the Supreme Court found that "affecting interstate commerce" is an expression of Congress' intent to broadly exercise its Commerce Clause power under the Constitution. Scarborough v. United States, 431 U.S. 563, 571-72 (1977).

prohibition unless the scientist providing the materials sought payment in excess of the expenses included in the statutory definition of "valuable consideration."

In addition, the law places some restrictions on federal support for research on the transplantation of fetal tissue. Section 498A of the Act provides that the Secretary may conduct or support research on the "transplantation of fetal tissue for therapeutic purposes," only if certain statutory requirements are met. 42 U.S.C. 289g-1. These requirements include obtaining: (1) the informed consent of the woman donating the tissue; (2) a statement by the attending physician regarding the woman's consent and the method of obtaining the tissue; (3) a statement by the researcher regarding his or her understanding of the source of the tissue, that such information has been conveyed to the donee, and that the researcher has not participated in any decision regarding termination of the pregnancy.

Finally, section 498B(b) of the Act provides that it shall be unlawful for any person to solicit or knowingly acquire, receive, or accept a donation of human fetal tissue for the purpose of transplantation into another person if the tissue will be or is obtained pursuant to an induced abortion, and there is a promise to the donor: (1) to transplant the tissue into a person specified by the donor; (2) the tissue will be transplanted into a relative of the donor; or (3) the donee of the tissue has provided valuable consideration for the costs associated with the abortion. 42 U.S.C. 289g-2(b). The Act provides criminal penalties for violation of the prohibition on directed donations.

III. Federal Restrictions on Fetal Research

Federal regulation provides that activities involving cells, tissues, or organs excised from a non-living fetus shall be conducted only in accordance with any applicable state or local law. 45 CFR 46.210, Subpart B. This regulation would apply to certain human pluripotent stem cells, including those derived from the primordial germ cells of non-living fetuses.

IV. Prohibition on Federal Funding for Cloning of Human Beings

In a March 4, 1997, memorandum to the heads of executive departments and agencies, the President directed that no federal funds will be used for the cloning of human beings and that federal funds shall not be allocated for that purpose.[9] There are myriad uses for human pluripotent stem cells that are completely unrelated to cloning. However, to the extent such stem cells were to be used for human cloning, the prohibition on the use of federal funds for that purpose would apply.

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[9] Memorandum from the President of the United States to Heads of Executive Departments and Agencies (March 4, 1997).

ISSCR SAMPLE RESEARCH CONSENT FORM
Egg Procurement for Stem Cell Research
(Eggs Provided Directly and Solely for Stem Cell Research)

Project Title:

Principal Investigator:

Participating Institution(s):

PROJECT INFORMATION

You are being asked to provide eggs for a human embryonic stem cell research project led by **[name of principal investigator]** at **[name(s) of institution(s)]**.

Embryonic stem cells can be found in embryos around the fifth day of development. These stem cells have the unique ability to turn into any kind of specialized human cell, such as liver cells, heart cells, pancreatic cells, or nerve cells. For this reason, embryonic stem cells can be used to study, and possibly one day help treat, diseases or injuries that have caused patients' specialized cells to die or become damaged – diseases and injuries such as Parkinson's disease, heart disease, diabetes, and spinal cord injury.

[Name of principal investigator] wants to collect new human embryonic stem cells from embryos that have been created by **[as applicable: nuclear transfer; parthenogenesis; the union of sperm and egg.]**

[As applicable: "Nuclear transfer" is the process by which researchers place donated adult body cells into unfertilized eggs that have had their DNA removed. If successful, this technique can create embryos that contain stem cells which are genetically matched to the body cell donors.]

[As applicable: "Parthenogenesis" is the process by which an unfertilized egg is stimulated to begin going through the very early stages of human development. Stem cells that arise from parthenogenesis would be genetically matched to the person who provided the unfertilized egg.]

[Insert additional information about this project using very simple language.]

VOLUNTARY CHOICE

Providing your eggs for this research project is completely voluntary. You have the right to agree or to refuse to provide your eggs for this project. The quality of your current or future medical care and your relationship with **[name(s) of institution(s)]** will NOT

change in any way whether you agree or refuse to provide any eggs for this research project.

WHAT IS THE PURPOSE OF THIS CONSENT FORM?

[Name of person obtaining consent] is authorized to give you information and to answer your questions about this research project. It is very important that you have a detailed conversation with this person so that you can make a careful, voluntary decision about whether or not you want to provide your eggs for this research project.

Your signature on the last page of this consent form is meant to show that you have had this conversation and that you freely agree to provide your eggs for this research project. This consent form must not replace actually having this conversation, so be certain you have this conversation.

Please take as much time as you need to ask questions and to talk about this project with your family or friends before you decide whether or not to sign this consent form. You may take this form home with you before you decide what to do. Do not sign this form if you feel pressured in any way by any person to provide your eggs for this project. This must be your own decision, not someone else's.

WHAT WILL HAPPEN TO MY EGGS?

None of the eggs you provide for this research project will be used to produce a baby or a pregnancy. And no embryos created from your eggs will be allowed to develop for more than a total of 14 days after they have been **[as applicable: created through nuclear transfer; created through parthenogenesis]**. If any of the resulting embryos are frozen, then the time that they are frozen is not counted as part of the 14 day limit.

Researchers will only use your eggs to create embryos from which they will attempt to get stem cells before the 14 day limit. The resulting embryos will be destroyed during the stem cell collection process.

There is no guarantee that embryos will be successfully created from your eggs. And there is no guarantee that researchers will be able to get stem cells from any resulting embryos. Researchers will routinely discard as medical waste any eggs which are not used for this research project, as well as any embryos from which they are unable to get stem cells.

WHAT WILL HAPPEN TO THE COLLECTED STEM CELLS?

It is likely that the retrieved stem cells will be stored for many years. Embryonic stem cells have the ability to self-renew indefinitely, and they are likely to be used by researchers at other institutions and for many other research purposes.

One possible research use of these stored stem cells might involve changing some of their genes. Another possible research use might be to study some of the stem cells by placing them into laboratory animals. In addition, the stored stem cells might be used in the future for new research related to human stem cell transplantation. These are just three common examples of what might happen to the stored stem cells. But there are many other future possible research uses that are simply unknown at this time.

You will have no say as to which institutions or researchers may share the stem cells made from the embryos that were created using your eggs. If stem cell transplantation studies are developed in the future, you will have no say as to who may be a transplant recipient of the collected stem cells **[as applicable: except in the case of autologous transplantation after parthenogenesis]**.

Future uses of stored stem cells must be approved by local ethical and scientific review committees to make sure that they are used in scientifically, ethically, and legally appropriate ways. Please contact the individuals listed on the last page of this form if you have any questions or concerns about the future possible uses of the stem cells collected through this research project.

WHAT IS THE EGG RETRIEVAL PROCEDURE?

If you decide to provide your eggs for this research project, you will have to undergo several steps.

First you will meet with fertility physicians and nurses to discuss in detail the medical procedures involved in egg retrieval. These individuals are qualified to discuss with you in much more detail the procedures and the risks of hormonal stimulation and egg retrieval. You will be asked to sign another consent form for these medical procedures specifically.

It is important to emphasize that the consent form you now hold in your hands is not a substitute for these medical consent forms. **[As applicable: The person authorized to give you information about this stem cell research project is not authorized to lead you through an informative conversation about hormonal stimulation and egg retrieval.]**

You will undergo medical testing to screen you for genetic and infectious diseases. **[Specify which tests will be conducted and whether the volunteer will have access to these test results.]**

After your medical tests, you will have to give yourself hormonal injections daily for up to three weeks in order to stimulate your ovaries to produce mature eggs. If you are unwilling to give yourself these shots, you may have another person do this for you.

When your ovaries are ready, doctors will retrieve your eggs by inserting a needle through your vagina and into one or both of your ovaries. Anesthesia and/or sedatives will be used during this process, which will take about thirty minutes.

WHAT ARE THE POTENTIAL RISKS OF PROVIDING EGGS FOR THIS RESEARCH PROJECT?

There are several risks associated with hormonal stimulation and egg retrieval. **[As applicable: A fertility physician who is not a member of the research team will discuss these risks with you in far more detail.]**

Hormonal stimulation poses a possible risk of severe ovarian hyperstimulation syndrome. This is a serious medical condition that, if left untreated, may lead to kidney failure, infertility, and in extremely rare cases, death. These risks can be greatly reduced if doctors use low doses of hormonal stimulation drugs and if your response to these drugs is monitored daily by health professionals. **[As applicable: Therefore, these safety measures will be followed for your care.]**

Other possible risks include bleeding, discomfort, infection, cramping, mood swings, unintended pregnancy, and complications associated with anesthesia.

Hormonal stimulation may also pose some unknown long-term health risks. At this time, scientists do not know for certain what kinds of long-term negative effects, if any, these drugs may have on your fertility or your risk for developing cancer. You should discuss any concerns you may have about these uncertainties with a physician.

The egg retrieval procedure carries some risk that the needle used to retrieve your eggs from your ovaries might accidentally puncture one of your organs or blood vessels.

There are some psychological risks involved in providing your eggs for this project. Some women who provide eggs for stem cell research might experience feelings of anxiety or regret, especially when considering the possibility that their eggs may result in the creation of embryos that will be destroyed during the stem cell collection process. Some may also feel vulnerable and anxious during the consent process.

All egg providers will be asked to undergo medical screening tests for genetic and infectious diseases. While these medical tests involve minimal physical risk, such as from a blood draw, some women may feel anxious about their test results

Due care will be taken to help minimize these psychological risks. **[Specify how this will be done, e.g. whether counseling services will be provided upon request.]**

Providing eggs for this project involves some risk to your privacy. Efforts to protect you against this risk are discussed in the section entitled HOW WILL MY PRIVACY BE PROTECTED?

WHAT WILL HAPPEN IF I GET A RESEARCH RELATED INJURY?

We are obligated to inform you about **[name of institution(s)']** policy in the event that injury occurs resulting from your participation. **[Insert description of the institution's policy addressing provision of healthcare and/or compensation related to injury resulting from participation.]**

WHAT ARE THE POTENTIAL BENEFITS OF PROVIDING EGGS FOR THIS PROJECT?

This research project is not intended to provide any direct medical benefit to you or anyone else. You would be providing your eggs solely for the advancement of this research project and stem cell research in general.

[As applicable: The stem cells that are collected from the resulting embryos may have significant commercial potential in the future. However, by signing this form you understand that there are no plans for you to receive any direct financial benefits from any future commercial development and scientific patents of discoveries made through the use of these stem cells.]

WHAT IF I CHANGE MY MIND?

You may withdraw your consent for whatever reason at any time before or during the egg retrieval process. Similarly, you may also withdraw your consent after your eggs have been retrieved, but before they are used in research.

However, once the resulting embryos are destroyed in the stem cell collection process, you will not be able to change your mind or request that any of the collected stem cells be removed from this research project.

If you decide to withdraw your consent after you have signed this form, please contact any of the individuals listed at the end of this document immediately.

WHAT ARE THE ALTERNATIVES TO PROVIDING MY EGGS FOR THIS PROJECT?

One of your alternatives is to refuse to participate at all in this research project. You may decide to do nothing, or you may decide to undergo hormonal induction specifically to donate your eggs for fertility treatment or another research project. The study staff would be happy to talk with you about other possible alternatives outside of this research project.

In the case that your eggs are retrieved but you decide not to participate any longer in this research project, you may (1) have them discarded according to the routine practice of **[name of institution]**, (2) donate your eggs to another research project, (3) donate your eggs to other individuals for fertility treatment, or (4) use them for your own fertility treatment, if necessary. Please note that your retrieved eggs will no longer be suitable for

reproductive use once they are transferred to Dr. **(principal investigator)**'s laboratory and prepared for research. Also, if you decide to use your eggs for your own or others' fertility treatment, you may have to undergo additional screening tests.

HOW WILL MY PRIVACY BE PROTECTED?

The records of your involvement with this research project will be kept confidential.

Identification codes will be used instead of names, and all records will be kept in a private database that can only be accessed by _____ (person). The results of your medical screen tests will also be confidentially handled through the use of identification codes instead of names. **[Specify how this information will be protected and whether the identification code will be linked to the egg providers and under what circumstances these providers will be identified.]**

[As applicable: If your eggs undergo parthenogenesis, then the resulting stem cells and any new stem cells that they produce will be a complete genetic match to you. To protect your genetic privacy, only your identification code, not your name, will be discoverable to the researchers who collect these stem cells and the researchers who may later work with the resulting stored stem cells.]

[As applicable: Some stem cell researchers working with genetic diseases may want to see genetic information about the egg donors. If you agree to allow these researchers to see this coded information, please check yes. _____ yes _____ no]

[As applicable: Research on the collected stem cells may reveal information that could be important to your health. If you wish to be contacted in the future about any such information, please check yes. _____ yes _____ no]

[As applicable: If you answered "yes" to this question, (name of institution) will, to the extent possible, pass to you any information that it is given from other researchers or other institutions regarding important information received through research on the collected stem cells.]

Local and other regulatory agencies, and project sponsors and funding agencies may review the research project records to ensure that your rights as an egg provider were adequately protected. However, your identity will not be readily discoverable to these individuals.

Any report that the researchers publish will not include any information that will make it possible for readers to identify you as an egg provider.

WILL I RECEIVE PAYMENT?

You will not receive any cash or payment with goods or services for the number or the quality of the eggs you provide for this research project.

[As applicable: Any reimbursements for money you had to spend to participate in the consent process will be decided by local and other relevant review committees.]

[As applicable: You will receive a compensation amount of $_____ in recognition of your time, effort, and inconvenience. This amount has been decided by local and other relevant review committees based on local community standards for paying other healthy research volunteers for their time, effort, and inconvenience.]

DISCLOSURE OF RESEARCHERS' POTENTIAL FINANCIAL INTERESTS

In addition to their scientific interests in this research project, the individuals conducting this stem cell study might profit financially from the research. There may be current or potential financial benefits to the Principal Investigator, **[name]**, the participating institution(s), **[names]**, and other research institutions or researchers arising from discoveries made through this research project and the stem cells collected from your donated embryos. **[Disclose using plain language the researchers' and the institution(s)' financial interests in the research.]** If you have any questions or concerns about these matters, please contact the persons listed below.

[As applicable: If you are undergoing fertility treatment, it is important that your physician inform you of any personal benefits he or she may gain by your agreement to provide eggs for this research project. (Disclose here any potential personal benefits the treating physician may receive through this research protocol.)]

The person who has been authorized to provide you with information may also have a personal vested interest in this research project. **[Disclose here any potential personal benefits this person may have in this research protocol.]**

CONTACT INFORMATION

If you have any questions about this research project, contact:

(Principal Investigator)_____(phone)_____
[List any toll-free or reverse-charge line.]

(Research Administrator) _____(phone)_____
[List any toll-free or reverse-charge line.]

If you have any questions about your rights as an egg provider, contact:

(Review Board Member)_____(phone)_____
[List any toll-free or reverse-charge line.]

If you have any questions about the egg retrieval process, contact:

(Physician)_____(phone)_____
[List any toll-free or reverse-charge line.]

CONSENT AND SIGNATURE

Please read the statements below, think about your choice, and sign if and when you are ready to agree, or take this form home and discuss it with anyone you wish to and then return it to us later if you wish to participate in this research:

[Name of person obtaining consent] has fully explained to me the nature and purpose of this research project in a way that I have understood.

[He/she] has encouraged me to be actively involved during the information interview and has responded to all of my questions and concerns in a satisfactory and respectful way.

[He/she] has offered me opportunities to consult with an independent person whom I trust, including a counselor or a physician, prior to my making my decision and has given me adequate time to decide.

I hereby give my voluntary consent to provide up to _____ (insert number) eggs for the research project entitled **[Project Title]** conducted by **[Principal Investigator]** at **[Participating Institution(s)]**.

_____**Date:**_____ _____
Signature of Egg Provider **Printed Name**

_____**Date:**_____ _____
Signature of Person Obtaining Consent **Printed Name**

Copy given to egg provider:_____Yes

ISSCR SAMPLE RESEARCH CONSENT FORM
Egg Donation for Stem Cell Research
(Eggs Collected During the Course of Fertility Treatment and In Excess of Clinical Need)

Project Title:

Principal Investigator:

Participating Institution(s):

PROJECT INFORMATION

[Name of principal investigator] is conducting a human embryonic stem cell research project at **[name(s) of institution(s)]. He/she** hopes you will donate any eggs you decide not to use in the course of your own or others' fertility treatment. **[Specify whether the eggs to be used are normal or failed-to-fertilize eggs.]**

Embryonic stem cells can be found in embryos around the fifth day of development. These stem cells have the unique ability to turn into any kind of specialized human cell, such as liver cells, heart cells, pancreatic cells, or nerve cells. For this reason, embryonic stem cells can be used to study, and possibly one day help treat, diseases or injuries that have caused patients' specialized cells to die or become damaged – diseases and injuries such as Parkinson's disease, heart disease, diabetes, and spinal cord injury.

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[As applicable: "Nuclear transfer" is the process by which researchers place donated body cells into unfertilized eggs that have had their DNA removed. If successful, this technique can create embryos that contain stem cells which are genetically matched to the body cell donors.]

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[Insert additional information about this project using very simple language.]

VOLUNTARY CHOICE

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future medical care and your relationship with **[name(s) of institution(s)]** will NOT change in any way whether you agree or refuse to donate any eggs for this project.

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[Name of person obtaining consent] is authorized to give you information and to answer your questions about this research project. It is very important that you have a detailed conversation with this person so that you can make a careful, voluntary decision about whether or not you want to donate your eggs for this research project.

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WHAT WILL HAPPEN TO MY EGGS?

None of the eggs you donate for this research project will be used to produce a baby or a pregnancy. And no embryos created from your eggs will be allowed to develop for more than a total of 14 days after they have been **[as applicable: created through nuclear transfer; created through parthenogenesis]**. If any of the resulting embryos are frozen, then the time that they are frozen is not counted as part of the 14 day limit.

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