

8. Healthy People 2010

PHS is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting priority areas. This FOA is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at <http://www.health.gov/healthypeople>.

9. Smoke-Free Workplace

PHS strongly encourages all grant recipients to provide a smoke-free workplace and discourage the use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

10. Authority and Regulation

This program is not subject to the intergovernmental review requirements of Executive Order 12372. FDA's research program is described in the Catalog of Federal Domestic Assistance (CFDA), No. 93.103 <http://www.cfda.gov/>.

FDA will support the clinical studies covered by this notice under the authority of section 301 of the PHS Act as amended (42 U.S.C. 241) and under applicable regulations at 42 CFR part 52 and 45 CFR parts 74 and 92. All grant awards are subject to applicable requirements for clinical investigations imposed by sections 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act or safety, purity, and potency for licensing under section 351 of the PHS Act, including regulations issued under any of these sections.

All human subject research regulated by FDA is also subject to FDA's regulations regarding the protection of human subjects (21 CFR parts 50 and 56). Applicants are encouraged to review the regulations, guidance, and information sheets on human subject protection and Good Clinical Practice available on the Internet at <http://www.fda.gov/oc/gcp/>.

The applicant is referred to HHS regulations at 45 CFR 46.116 and 21 CFR 50.25 for details regarding the required elements of informed consent.

All awards will be subject to all policies and requirements that govern the research grant programs of the PHS as incorporated in the HHS Grants Policy Statement, dated January 1, 2007,

(<http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>).

11. Human Subjects Protection

Federal regulations (45 CFR part 46) require that applications and proposals involving human subjects must be evaluated with reference to: (1) The risks to the subjects, (2) the adequacy of protection against these risks, (3) the potential benefits of the research to the subjects and others, and (4) the importance of the knowledge gained or to be gained (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>).

12. Human Embryonic Stem Cell Research and Cloning

Section 498 of the PHS Act places certain restrictions on human fetal research. In addition, under currently applicable executive orders, HHS funds may not be used to support human embryo research under any extramural award instrument. HHS funds may not be used for the creation of a human embryo for research purposes or for research in which a human embryo is destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under 45 CFR 46.204 and 46.207 and subsection 498(b) of the PHS Act (42 U.S.C. 289g(b)). The term "human embryo" includes any organism not protected as a human subject under 45 CFR part 46, as of the date of enactment of the governing appropriations act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

In addition, HHS is prohibited, by a March 4, 1997, Presidential memorandum, from using Federal funds for cloning human beings. In implementing this program, FDA will comply with all applicable statutes, regulations, presidential memoranda and Executive orders.

Criteria for Federal funding of research on hESCs can be found at: <http://www.hhs.gov/faq/research/stemcell/r-0006.html> and <http://stemcells.nih.gov/research/registry/eligibilityCriteria.asp>.

Dated: December 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meeting**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Behavior and Health.

Date: December 19, 2008.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Gayle M. Boyd, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, MSC 7808, Bethesda, MD 20892, 301-451-9956, gboyd@mail.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: December 9, 2008.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Center for Scientific Review; Notice of Closed Meetings**

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice