

**SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products" dated August 2001. This guidance document contains comprehensive revised recommendations based upon advisory committee discussions and internal Public Health Service and FDA deliberations. We (FDA) have developed recommendations for donor deferral, and product retrieval, quarantine, and disposition based upon consideration of risk in the donor and product, and the effect that withdrawals and deferrals might have on the supply of life- and health-sustaining blood components and plasma derivatives. The new recommendations are intended to minimize the possible risk of vCJD transmission from blood products while maintaining their availability. When the draft guidance is finalized, the guidance document entitled "Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and New Variant Creutzfeldt-Jakob Disease (nvCJD) by Blood and Blood Products" dated November 1999 (64 FR 65715, November 23, 1999) will be superseded.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

**II. Comments**

This draft document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by September 28, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**III. Electronic Access**

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: August 23, 2001.

**Margaret M. Dotzel,**

*Associate Commissioner for Policy.*

[FR Doc. 01-21920 Filed 8-27-01; 11:39 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Environmental Impact Statement Supplement: Montgomery County, Maryland**

**AGENCY:** National Institutes of Health (NIH), DHHS.

**Authority:** 42 U.S.C. 4321-4347 (National Environmental Policy Act).

**ACTION:** Notice of intent.

**SUMMARY:** The NIH is issuing this notice to advise the public that a supplement to a final environmental impact statement will be prepared for a revision or update of the 1995 Master Plan for the NIH Main Campus in Bethesda in Montgomery County, Maryland.

**FOR FURTHER INFORMATION CONTACT:** Janyce Hedetniemi, Director, Office of Community Liaison, National Institutes of Health, Building 1, Room 259, One Center Drive, Bethesda, Maryland 20892-0172, telephone: (301) 496-3931.

**SUPPLEMENTARY INFORMATION:** The 322-acre NIH Bethesda Campus encompasses the largest biomedical research facility in the world.

Approximately 17,000 people work at the site in 65 buildings with more than seven million square feet of floor space. The Office of the Director, NIH administrative staff, and the researchers and laboratories of individual research Institutes and Centers are located on the campus. The focal point of the campus is the Clinical Center Complex.

A Master Plan provides guidance in coordinating physical development in terms of buildings, utilities, roads, parking, landscaping, and general design guidelines. A Master Plan and Environmental Impact Statement (EIS) were prepared for the campus in 1995 (*1995 Master Plan, NIH Main Campus, Bethesda, Maryland, Final, Environmental Impact Statement for the 1995 NIH Main Campus Master Plan, 2 vol.* The Final Master Plan and Final EIS were published in January 1996 after approval by the National Capital Planning Commission.

The NIH declared its intent in the original documentation to update the Master Plan at approximately five-year intervals. The proposed action is to prepare the updated documentation. Since the development of the 1995 Master Plan included a complete National Environmental Policy Act (NEPA) scoping process and established baseline environmental conditions and potential cumulative impacts, and since the proposed action is an update/revision and not a new alternative, it is the intent of NIH to issue draft and final supplements to the original Final EIS. NIH has kept the surrounding community informed of planning issues on a continuing basis in the interim through the Community Liaison Council.

Alternatives that will be considered include (1) an update or revision of the 1995 master plan, and (2) taking no action.

No formal scoping meeting will be held. Letters describing the proposed action and soliciting comments will be sent to appropriate Federal, State, and local agencies, and to private organizations and citizens who have expressed interest in this proposal. A public hearing will be held, and public notice will be given of the time and place. The Draft EIS supplement will be available for public and agency review and comment. It is anticipated that the Draft will be available in November 2001.

To ensure that the full range of issues related to this proposed action are addressed, comments are invited from all interested parties. Comments and questions should be directed to the NIH at the address listed above.

Dated: August 20, 2001.

**Yvonne T. Maddox,**

*Acting Deputy Director, National Institutes of Health.*

[FR Doc. 01-21778 Filed 8-28-01; 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 agencies 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 contacting Dale D. Berkley, Ph.D., J.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7735 ext. 223; fax: 301/402-0220; e-mail: berkleyd@od.nih.gov. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### Generalized MRI Artifact Reduction Using Array Processing Method

Peter Kellman, Elliott McVeigh (NHLBI)  
DHHS Reference No. E-198-00/0 filed  
03 Apr 2001

The invention is a phased array combining method for reducing artifacts in Magnetic Resonance (MR) imaging. The method uses a constrained optimization that optimizes signal-to-noise subject to the constraint of nulling ghost artifacts at known locations. The method is effective in reducing or canceling artifacts that arise in a wide variety of MR applications, including ghost artifacts from echo planar imaging and Gradient Recalled Echo with Echo Train (FGRE-ET) imaging used in cardiac or other rapid imaging applications. The strategy of using phase encode acquisition orders with distortion that results in ghosts,

followed by applying this phased array ghost cancellation method has a number of benefits, including reduced blur and geometric distortion, reduced acquisition time (eliminating echo shifting), and reduced sensitivity to flow.

#### E-Portals in Commerce (E-PIC)

Diana V. Mukitarian (OD)  
DHHS Reference No. E-147-00/0

The invention is a consolidated database for storing and maintaining vendor contact information and contract services that each can offer. The purpose of the invention is to consolidate vendor sources into one database, enabling vendors to easily add and update their contact information, to provide a variety of search criteria for providing sources for an organization's acquisitions, and to make such a system user friendly and available to the organization administrators. The system serves as a gateway for the business community to gain access to the organization's contracts and allows the organization to follow the acquisition cycle at every step. The database is designed to serve as a center for all communication for any service vendor seeking to do business with the organization. At any time an administrator can visit the repository to look for approved contractors and review their performance on past projects, with the intention of seeking proposals for work via an automated process. For more information, please direct your web browser to <http://sbo.od.nih.gov/epicfactsheet.pdf>.

Dated: August 20, 2001.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.*

[FR Doc. 01-21780 Filed 8-28-01; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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:* National Cancer Institute Special Emphasis Panel, Program Project Application.

*Date:* October 3-5, 2001.

*Time:* 5 p.m. to 12 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn—Georgetown, 2101 Wisconsin Avenue, N.W., Washington, DC 20007.

*Contact Person:* Raymond A. Petryshyn, PhD, Scientific Review Administrator, Grants Review Branch, Division of Extramural Activities, National Cancer Institute, National Institutes of Health, 6116 Executive Blvd., 8th Fl. Room 8133, Bethesda, MD 20892, 301/594-1216.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 21, 2001.

**Laverne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 01-21771 Filed 8-28-01; 8:45 am]

**BILLING CODE 4140-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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