5. FDA Review

Under the pilot program, early feasibility study IDE applications will be reviewed according to the approaches outlined in the early feasibility study draft guidance. The essential elements announced in the early feasibility study draft guidance are:

- FDA may approve an IDE application for an early feasibility study, including certain first in human studies, based on less nonclinical data than would be expected for a traditional feasibility or a pivotal study. This is because early feasibility studies are only appropriate where additional nonclinical testing is not available or adequate to provide the information needed to advance the developmental process. Identification of the data necessary to support an early feasibility study should be based on a thorough device evaluation strategy that describes the device and procedure-related attributes and addresses the potential failure modes. Appropriate human subject protection measures and risk mitigation strategies must also be identified. This policy is intended to facilitate initiation of clinical studies in the United States earlier in the device development process than has historically occurred, when appropriate.
- New approaches that facilitate timely device and clinical protocol modifications during an early feasibility study while still requiring compliance with the IDE regulations in 21 CFR part 812.

FDA has provided additional information regarding its expectations for early feasibility study IDE applications in the early feasibility study draft guidance.

D. Duration of the Pilot

FDA intends to accept requests for participation in the pilot program for 180 days from the date of publication of this notice. FDA may decide to terminate the pilot program before the close of the 180-day period or extend the pilot program beyond the 180-day period. The decision to terminate or extend the pilot will be announced in the **Federal Register**. FDA may also decide to modify the pilot program while it is in effect. Any modifications will also be announced in the **Federal Register**. FDA intends to terminate the pilot program when the early feasibility study draft guidance is finalized.

E. Evaluation

FDA intends to use the experience gained from the pilot program to inform the final version of the early feasibility study draft guidance.

Dated: November 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–29116 Filed 11–9–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

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

The meetings 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 Heart, Lung, and Blood Institute Special Emphasis Panel, Life after Linkage: The Future of Family Studies.

Date: December 1–2, 2011.

Time: 8:30 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Garden Inn, 7301 Waverly Street, Bethesda, MD 20814.

Contact Person: YingYing Li-Smerin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892–7924. (301) 435–0277. *lismerin@nhlbi.nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, COPD Case Finding Methodology.

Date: December 1, 2011.

Time: 9 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road NW., Washington, DC 20008.

Contact Person: Stephanie J Webb, Ph.D., Scientific Review Officer, Review Branch/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7196, Bethesda, MD 20892. (301) 435–0291. *stephanie.webb@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel, PPG Review: Endothelium and cardiovascular function.

Date: December 2, 2011.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Crystal City, 2799 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Tony L Creazzo, Ph.D., Scientific Review Officer.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: November 4, 2011.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2011–29142 Filed 11–9–11; 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. App.), 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, Small Grants Program for Cancer Epidemiology.

Date: November 17–18, 2011.

Time: 8:30 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

Contact Person: Jeffrey E. DeClue, Ph.D., Scientific Review Officer, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8059, Bethesda, MD 20892–8329, (301) 496–7904, *decluej@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/sep/sep.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction;