

260 submissions of 510(k)s for third party review per year.

Proposed revisions to the currently approved information collection:

- Reporting
  - Requests for rerecognition: The Agency anticipates an average annual receipt of four applications for rerecognition for third party 510(k) review. The Agency reached this estimate by reviewing the number of existing recognized firms under the TP Review Program and anticipating the number of firms applying for rerecognition every 3 years.

- Recordkeeping
  - The Agency expects TP Review Organizations to retain and maintain documentation related to recognition and rerecognition.

The respondents for this information collection are private sector, for-profit firms seeking recognition and rerecognition.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; collections of information for the device appeals processes have been approved under OMB control number 0910-0738.

## V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register** but Web sites are subject to change over time.

1. International Medical Device Regulators Forum's Medical Device Single Audit Program documents, available at <http://imdrf.org/documents/documents.asp>.

2. FDA Draft Guidance entitled "Accreditation and Reaccreditation Process for Firms under the Third Party Review Program: Part I," February 15, 2013, available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM339697.pdf>.

Dated: September 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, October 26, 2016, 11:00 a.m. to October 26, 2016, 5:00 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, 4W034, Rockville, MD 20850 which was published in the **Federal Register** on August 25, 2016, 81 FR 58524.

The meeting notice is amended to change the date of the meeting to November 15, 2016 from 11:00 a.m. to 5:00 p.m. The meeting is closed to the public.

Dated: September 6, 2016.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer 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 Cancer Institute Special Emphasis Panel R13 Conference Grant Review.

*Date:* October 11, 2016.

*Time:* 12:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W556, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Bratin K. Saha, Ph.D., Scientific Review Officer, Program Coordination and Referral Branch, Division of Extramural Activities, National Cancer

Institute, 9609 Medical Center Drive, Room 7W556, Rockville, MD 20892-9750, 240-276-6411 [sahab@mail.nih.gov](mailto:sahab@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel Cancer Tissue Engineering Collaborative: Enabling Biomimetic Tissue-Engineered Technologies for Cancer Research (U01).

*Date:* October 14, 2016.

*Time:* 8:00 a.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

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

*Contact Person:* Nadeem Khan, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W260, Rockville, MD 20892-9750 240-276-5856, [nadeem.khan@nih.gov](mailto:nadeem.khan@nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel Cooperative Agreement to Develop Targeted Agents for use with Systemic Agents Plus Radiotherapy (U01).

*Date:* October 21, 2016.

*Time:* 10:00 a.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Thomas A. Winters, Ph.D., Scientific Review Officer, Special Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W412, Rockville, MD 20892-9750, 240-276-6386, [twinters@mail.nih.gov](mailto:twinters@mail.nih.gov).

*Name of Committee:* National Cancer Institute Initial Review Group Subcommittee F—Institutional Training and Education.

*Date:* October 24–25, 2016.

*Time:* 7:30 p.m. to 3:45 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

*Contact Person:* Timothy C. Meeker, Ph.D., Scientific Review Officer, Resources and Training Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W606, Rockville, MD 20892-9750, 240-276-6464, [meekert@mail.nih.gov](mailto:meekert@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel, NCI Clinical and Translational, R21: SEP-7.

*Date:* October 27, 2016.

*Time:* 10:00 a.m. to 1:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Caron A. Lyman, Ph.D., Chief, Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, 9609 Medical Center Drive, Room 7W126, Rockville, MD 20892-9750, 240-276-6348, [lymanc@mail.nih.gov](mailto:lymanc@mail.nih.gov).