Financial Disclosure by Clinical Investigators

(OMB Control Number 0910–0396)—Extension

Respondents to this collection are sponsors of marketing applications that contain clinical data from studies covered by the regulations. These sponsors represent pharmaceutical, biologic, and medical device firms. Respondents are also clinical investigators who provide financial information to the sponsors of marketing applications.

Under § 54.4(a) (21 CFR 54.4(a)), applicants submitting an application that relies on clinical studies must submit a complete list of clinical investigators who participated in a covered clinical study, and must either certify to the absence of certain financial arrangements with clinical investigators (Form FDA 3454) or, under § 54.4(a)(3), disclose to FDA the nature of those arrangements and the steps taken by the applicant or sponsor to minimize the potential for bias (Form FDA 3455).

Under § 54.6, the sponsors of covered studies must maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. Sponsors of covered studies maintain many records with regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to the clinical investigators' file.

Under § 54.4(b), clinical investigators supply to the sponsor of a covered study financial information sufficient to allow the sponsor to submit complete and accurate certification or disclosure statements. Clinical investigators are accustomed to supplying such information when applying for research grants. Also, most people know the financial holdings of their immediate family and records of such interests are generally accessible because they are needed for preparing tax records. For these reasons, FDA estimates that it will take clinical investigators 15 minutes to submit such records to the sponsor.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Certification—54.4(a)(1) and (a)(2)—Form FDA 3454	1,000	1	1,000	1	1,000
Disclosure—54.4(a)(3)—Form FDA 3455	100	1	100	5	500
Total					1,500

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Recordkeeping—54.6	1,000	1	1,000	0.25 (15 minutes)	250

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
54.4(b)—Clinical Investigators	7,106	1	7,106	0.17 (10 minutes)	1,208

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 23, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–09908 Filed 4–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Institute of Neurological Disorders and Stroke Special Emphasis Panel, April 22, 2015, 08:00 a.m. to April 23, 2015, 06:00 p.m., Lorien Hotel & Spa, 1600 King Street, Alexandria, VA, 22314 which was published in the **Federal Register** on April 3, 2015, 80FRN18241.

The meeting notice is amended to change the location of the meeting from the Lorien Hotel & Spa to the Hotel Monaco Alexandria. The date and time remain the same. The meeting is closed to the public.

Dated: April 23, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–09877 Filed 4–28–15; 8:45 am]

BILLING CODE 4140–01–P

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/contract proposals 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/contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Prevent ToxPharm.

Date: May 19, 2015.

Time: 10:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2W914, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Thomas M. Vollberg, Ph.D., Chief, Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20850, 240–276–6341, *vollbert@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.

Name of Committee: National Cancer Institute Special Emphasis Panel; Novel Imaging Agents to Expand the Clinical Toolkit for Cancer Diagnosis, Staging and Treatment.

Date: May 20, 2015.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 1E030, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Kenneth L. Bielat, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W244, Rockville, MD 20850, 240–276–6373, *bielatk@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.

Name of Committee: National Cancer Institute Special Emphasis Panel; Prevent Bioefficacy/Intermediate Endpoints.

Date: May 28, 2015.

Time: 10:30 a.m. to 4:30 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 2W914, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Thomas M. Vollberg, Ph.D., Chief, Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W102, Rockville, MD 20850, 240–276–6341, *vollbert@mail.nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Tumor Tissue Culture Systems.

Date: June 23, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposal.

Place: National Cancer Institute, Shady Grove, 9609 Medical Center Drive, Room 6W030, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Nicholas J. Kenney, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W246, Rockville, MD 20850, 240–276–6374, *nicholas.kenney@nih.gov*.

Name of Committee: National Cancer Institute Special Emphasis Panel; Omnibus SEP–16.

Date: July 15, 2015.

Time: 8:00 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 6W032, Rockville, MD 20850 (Telephone Conference Call).

Contact Person: Majed M. Hamawy, Ph.D., MBA, Scientific Review Officer, Research Program Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W120, Rockville, MD 20850, 240–276–6457, *mh101v@nih.gov*.

(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: April 23, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–09875 Filed 4–28–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; 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 Institute of Neurological Disorders and Stroke Special Emphasis Panel; Contract Grant Review.

Date: May 5, 2015.

Time: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Ernest Lyons, Ph.D., Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892–9529, 301–496–4056,*lyonse@ninds.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. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: April 23, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–09876 Filed 4–28–15; 8:45 am]

BILLING CODE 4140–01–P