based models, (3) costs of home visiting programs, and (4) family and child outcomes (via a review of grantee analysis reports). A process study will focus on the broader grant initiative to understand how programs plan and develop the infrastructure needed to support home visitation services and how they ensure service quality.

Information will be collected through biennial site visits, web-based data entry, a data quality progress table, a relationship questionnaire completed by participants and home visitors, and a grantee-partner network survey. In particular, site visits will include interviews with key grantee staff and stakeholders involved in the execution of the grant and in the efforts to make system changes. Grantees will complete systems web-based data entry on goals and operations every six months while agencies implementing home visiting programs associated with the grantee will utilize the fidelity/cost web-based data entry to provide EBHV program, provider, and participant characteristics along with yearly data on costs of home visiting programs.

Respondents: EBHV grantee and key staff (evaluators, home visitors and supervisors), partners, implementing agencies, home visiting participants, and home visitors.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hour per response	Estimated annual burden hours
EBHV grantee and key staff-partner interview guide	249	2	1.60	797
EBHV grantee systems web-based data entry	17	2	1.00	34
EBHV agency fidelity/cost web-based data entry	50	12	9.00	5,400
EBHV grantee data quality progress table	17	4	4.25	289
Participant-home visitor relationship questionnaire	4,716	2	0.25	2,358
Home visitor-participant relationship questionnaire	4,716	2	0.25	2,358
EBHV grantee-partner network survey	142	2	0.42	119
Estimated Total Burden Hours				11,355

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *OPREinfocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: October 14, 2009.

Seth F. Chamberlain,

OPRE Reports Clearance Officer.

[FR Doc. E9–25259 Filed 10–23–09; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0307 (formerly Docket No. 2007–D–0173)]

Guidance for Industry on Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects.'' This guidance is intended to assist investigators in meeting their responsibilities with respect to protecting human subjects and ensuring the integrity of data in the conduct of clinical investigations. The guidance also clarifies FDA's expectations concerning the investigator's responsibility for supervising a clinical study in which some study tasks are delegated to employees of the investigator or to outside parties.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Joseph Griffin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 4204, Silver Spring, MD 20993, 301–796–2270, *Joseph.Griffin@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Investigator Responsibilities—Protecting the Rights, Safety, and Welfare of Study Subjects.'' Under the regulations in part 312 (21 CFR part 312) (Investigational New Drug Application) and part 812 (21 CFR part 812) (Investigational Device Exemptions), an investigator is responsible for ensuring that a clinical investigation is conducted according to the signed investigator statement, the

investigational plan, and applicable regulations; for protecting the rights, safety, and welfare of subjects under the investigator's care; and for the control of drugs, biological products, and devices under investigation (§§ 312.60 and 812.100). This guidance clarifies the responsibilities of investigators in the conduct of clinical investigations conducted under parts 312 and 812, particularly the responsibilities to supervise the conduct of the clinical investigation, and to protect the rights, safety, and welfare of study participants in drug, biologic, and medical device clinical trials. The guidance also provides recommendations on how investigators should supervise the study-related actions of persons not in the direct employ of the investigator, including certain study staff and parties conducting associated testing and assessments.

On May 10, 2007 (72 FR 26639), FDA issued a draft of this guidance with the goal of received input from the public. During the finalization of this guidance, FDA carefully considered all substantive comments concerning the content of the guidance. During finalization, FDA's major emphasis was on clarifying issues that were identified as confusing and correcting apparent errors. These efforts resulted in relatively minor changes throughout the guidance. FDA also removed a significant amount of content from the background section because it was duplicative of content in the guidance appendices. FDA also reordered section III.A.3 of the guidance concerning adequate supervision of the conduct of a clinical trial to make the sequence more logical. We reversed the order of presentation so that the section begins with the factors that may predispose to inadequate supervision, and ends with the steps that could be taken to mitigate the potential for inadequate supervision.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on investigator responsibilities. 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 requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 312 have been approved under OMB control number 0910–0014; and the collections of information in part 812 have been approved under OMB control number 0910–0078. The information requested for general investigator responsibilities is covered by the collection of information in FDA's regulations for investigational new drug applications (part 312) and investigational device exemptions (part 812) and FDA Form 1572. The guidance also refers to FDA's requirements in 21 CFR parts 11, 50, 54, and 56 for the conduct of clinical trials of drugs, biologics, and medical devices. The collections of information in 21 CFR part 11 have been approved under OMB control number 0910–0303; the collections of information in 21 CFR part 54 have been approved under OMB control number 0910–0396; and the collections of information in 21 CFR part 56 (including information required under 21 CFR part 50) have been approved under OMB control number 0910–0130. The collection of information for form FDA 3674 has been approved under OMB control number 0910–0616.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm*, *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*, or *http://www.regulations.gov*.

Dated: October 20, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25629 Filed 10–23–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences; Special Emphasis Panel Trauma and Burn.

Date: November 19, 2009.

Time: 1 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, Room 3AN34, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Brian R. Pike, PhD, Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN18, Bethesda, MD 20892, 301–594–3907, *pikbr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.375, Minority Biomedical Research Support; 93.821, Cell Biology and Biophysics Research; 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.862, Genetics and Developmental Biology Research; 93.88, Minority Access to Research Careers; 93.96, Special Minority Initiatives, National Institutes of Health, HHS)

Dated: October 16, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–25513 Filed 10–23–09; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as