

basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRB's deliberations, and any employment relationship between each member and the IRB's institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and

clinical investigators are providing adequate protections to human subjects participating in clinical research.

In the **Federal Register** of March 17, 2004 (69 FR 12700), the agency requested comments on the proposed collection of information. FDA received one comment. The comment strongly disagreed with the estimate of the time required to transcribe and type the minutes of IRB meetings, to maintain records of continuing review activities, and to make copies of all correspondence between the IRB and investigative member records and of written IRB procedures. The comment explained that the burden estimate should include the time required to

keep membership lists current, distribute educational materials to members, orient new members, instruct researchers and their staffs about IRB requirements, provide information to institutions, attend IRB meetings, transcribe discussions, incorporate all revisions into typed minutes and into the official IRB correspondence that is issued to investigators, collate materials, stamp, file, keypunch database entry, and other responsibilities. FDA has considered the comment and has revised the burden estimate to 100 hours.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	5,000	14.6	73,000	100	7,300,000
Total					7,300,000

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

The recordkeeping requirement burden is based on the following: The burden for each of the paragraphs under 21 CFR 56.115 has been considered as one estimated burden. FDA estimates that there are approximately 5,000 IRBs. The IRBs meet on an average of 14.6 times annually. The agency estimates that approximately 100 hours of person-time per meeting are required to meet requirements of the regulation.

Dated: July 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-16628 Filed 7-21-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0296]

Agency Information Collection Activities; Proposed Collection; Comment Request; Good Laboratory Practice Regulations for Nonclinical Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the

Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the good laboratory practice (GLP) for nonclinical laboratory studies regulations.

DATES: Submit written or electronic comments on the collection of information by September 20, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs, (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

“Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Good Laboratory Practice (GLP) Regulations for Nonclinical Studies—21 CFR Part 58 (OMB Control Number 0910-0119)—Extension

Sections 409, 505, 512, and 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348, 355, 360(b), 360(e)) and related statutes require manufacturers of food additives, human drugs and biological products, animal drugs, and medical devices to demonstrate the safety and utility of their product by submitting applications to FDA for research or marketing permits. Such applications contain, among other important items, full reports of all studies done to demonstrate product safety in man and/or other animals. In order to ensure adequate quality control for these studies and to provide an adequate degree of consumer protection, the agency issued the GLP regulations. The regulations specify minimum standards for the proper conduct of safety testing and contain sections on facilities, personnel, equipment, standard operating procedures (SOPs), test and control articles, quality assurance, protocol and conduct of a

safety study, records and reports, and laboratory disqualification.

The GLP regulations contain requirements for the reporting of the results of quality assurance unit inspections, test and control article characterization, testing of mixtures of test and control articles with carriers, and an overall interpretation of nonclinical laboratory studies. The GLP regulations also contain recordkeeping requirements relating to the conduct of safety studies. Such records include: (1) Personnel job descriptions and summaries of training and experience; (2) master schedules, protocols and amendments thereto, inspection reports, and SOPs; (3) equipment inspection, maintenance, calibration, and testing records; (4) documentation of feed and water analyses and animal treatments; (5) test article accountability records; and (6) study documentation and raw data.

The information collected under GLP regulations is generally gathered by testing facilities routinely engaged in conducting toxicological studies and is used as part of an application for a research or marketing permit that is voluntarily submitted to FDA by

persons desiring to market new products. The facilities that collect this information are typically operated by large entities, e.g., contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies. Failure to include the information in a filing to FDA would mean that agency scientific experts could not make a valid determination of product safety. FDA receives, reviews, and approves hundreds of new product applications each year based on information received. The recordkeeping requirements are necessary to document the proper conduct of a safety study, to assure the quality and integrity of the resulting final report, and to provide adequate proof of the safety of regulated products. FDA conducts onsite audits of records and reports, during its inspections of testing laboratories, to verify reliability of results submitted in applications.

The likely respondents collecting this information are contract laboratories, sponsors of FDA-regulated products, universities, or Government agencies.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
58.35(b)(7)	300	60.25	18,075	1	18,075
58.185	300	60.25	18,075	27.65	499,774
Total					517,849

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
58.29(b)	300	20	6,000	.21	1,260
58.35(b)(1) through (b)(6) and (c)	300	270.76	81,228	3.36	279,926
58.63(b) and (c)	300	60	18,000	.09	1,620
58.81(a), (b), and (c)	300	301.8	90,540	.14	12,676
58.90(c) and (g)	300	62.7	18,810	.13	2,445
58.105(a) and (b)	300	5	1,500	11.8	17,700
58.107(d)	300	1	300	4.25	1,275
58.113(a)	300	15.33	4,599	6.8	31,273
58.120	300	15.38	4,614	32.7	150,878

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
58.195	300	251.5	75,450	3.9	294,255
Total					793,308

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

Dated: July 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–16629 Filed 7–21–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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 Human Genome Research Institute Special Emphasis Panel HapMap Genotyping Review.

Date: August 6, 2004.

Time: 3 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 5635 Fishers Lane, Suite 4076, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Rudy O. Pozzatti, PhD, Scientific Review Administrator, Office of Scientific Review, National Human Genome Research Institute, National Institutes of Health, Bethesda, MD 20892, 301–401–0838.

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. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 15, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–16620 Filed 7–21–04; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of 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 a meeting of the National Advisory Council for Human Genome Research.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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/or contract proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with grant applications and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.

Date: September 13–14, 2004.

Open: September 13, 2004, 8:30 a.m. to 1 p.m.

Agenda: To discuss matters of program relevance.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

Closed: September 13, 2004, 1 p.m. to adjournment on Tuesday, September 14, 2004.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Mark S. Guyer, Director for Extramural Research, Assistant Director for Scientific Coordination, National Human Genome Research Institute, 31 Center Drive, MSC 2033, Building 31, Room B2B07, Bethesda, MD 20892, 301–435–5536, guyerm@mail.nih.gov.

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.

Information is also available on the Institute's/Center's home page: <http://www.genome.gov/11509849>, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 15, 2004.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 04–16621 Filed 7–21–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research 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 552(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