TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of Guidance/Reporting Activity	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
4.4.1.2. Sponsor notification to the DMC regarding waivers	1	1	1	.25	.25
4.4.3.2. DMC reports of meeting minutes to the sponsor	370	2	740	1	740
5. Sponsor reporting to FDA on DMC recommendations related to safety	37	1	37	.5	18.5
Total					758.75

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Recordkeeping Activity	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Record	Total Hours
4.1. and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2. DMC meeting records	370	1	370	2	740
Total					1,036

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

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: September 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–23833 Filed 10–7–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Information Program on Clinical Trials: Maintaining a Registry and Results Databank

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Information Program on Clinical Trials: Maintaining a Registry and Results Databank; *Type of Information Collection Request:* Revision of currently approved collection [OMB No. 0925–0586, expiration date 01/31/2009], *Form Number:* NA; *Need and Use of Information Collection:* The National Institutes of Health is modifying the clinical trial registry databank established under previous law [FDAMA, Section 113] to comply with provisions of Title VIII of Public Law 110–85 (Food and Drug Administration Amendments Act of 2007). The databank collects specified registration and results information on certain clinical trials identified in the law, with the objective of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical trials, to the benefit of public health. The databank is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research studies. Public Law 110–85 expands the scope of clinical trials that must be registered in ClinicalTrials.gov, increases the clinical trial information that must be submitted as part of each registration, and requires the submission of basic results information for registered trials of approved drugs, biologics and devices. *Frequency of Response:* Responsible parties must submit the required registration information not later than 21 days after enrolling the first subject. Results information is to be reported not later than 12 months after the completion date (as defined in the law), but can be delayed under certain circumstances. Updates to submitted information are required at least once a year, unless there are no changes to report. Changes in recruitment status and completion of a trial must be reported not later than 30 days after such events. *Description of Respondents:* Respondents are referred to in the law as ''responsible parties,'' and are defined as: (1) The sponsor of the clinical trial (as defined in 21 CFR 50.3) or (2) the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, provided that ''the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements'' for submitting information under the law. *Estimate of Burden:* The burden associated with this information collection consists of two parts: the burden associated with registration of clinical trials; and the burden associated with the reporting of results information. In both cases, the burden includes the time necessary to extract information from the study protocol or results record, reformat it, enter it into the databank, and provide necessary updating over the course of the study. It is estimated that registration information will be required

for 3,000 trials of drugs and biologics and 445 trials of medical devices each year. Each initial registration is estimated to take 7 hours and each of the subsequent 8 updates to the record are estimated to take 2 hours, resulting in an annual burden of 79,235 hours. It is estimated that there will be voluntary submissions of registration information for 6,000 trials of drugs and biologics, 545 trials of devices, and 5,280 trials of other types of medical interventions. Using the same hour estimates as for mandatory registration, the burden associated with voluntary registrations is estimated at 271,975 hours, bringing the total registration burden to 351,210 hours. In the first year of operation, it is estimated that there will be an additional burden of 84,150 hours associated with the updating of information for 7,000 trials of drugs and biologics and 650 trials of medical devices that were previously registered in the databank and ongoing as of December 26, 2007 (90 days after enactment). It is estimated that such trials will require one update of 3 hours to bring them into compliance with the new law (FDAAA) and 4 subsequent updates of 2 hrs each. Results reporting is required only for those applicable clinical trials of drugs, biologics, and devices that are subject to the mandatory registration requirements of FDAAA and for which the product(s) under study have been approved or cleared by the FDA. It is estimated that results reporting will be required for 1,645 trials of drugs and biologics and 375 trials of medical devices each year. Initial submission of results information is estimated to require 10 hours, and each result submission is expected to require two updates that take 5 hours each. The total burden for results reporting is therefore estimated at 40,400 hours per year. There are no capital costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: David Sharlip, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll free number 301–402–9680 or E-mail your request to *sharlipd@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: September 30, 2008.

Betsy L. Humphreys,

Deputy Director, National Library of Medicine, National Institutes of Health.

[FR Doc. E8–23790 Filed 10–7–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Office of Refugee Resettlement

Replacement Grant Award

CFDA#: 93.576.

AGENCY: Office of Refugee Resettlement, ACF, DHHS.

ACTION: Notice to award a replacement grant to Catholic Charities of Tennessee, Inc.

SUMMARY: In Fiscal Year 2005, in an effort to assist local school systems that were being strained by the arrivals of large numbers of refugee children, The Office of Refugee Resettlement (ORR) awarded, through competition, a Refugee School Impact grant to the Tennessee Department of Human Services, Nashville, TN, for a project period of August 15, 2005 through August 14, 2010. The Tennessee Department of Human Services served as the fiscal sponsor and legal entity for the project. As of June 30, 2008, the Tennessee Department of Human Services relinquished the grant. Catholic Charities of Tennessee, Inc., Nashville, TN, is now awarded a non-competitive replacement grant to continue to provide services under the Refugee School Impact project. Services provided under the grant to Catholic Charities of Tennessee, Inc., are within the scope and operation of the original award. Under the award, Catholic Charities of Tennessee, Inc., is eligible apply for a non-competitive continuation award for the period of August 15, 2009 through August 14, 2010.

FOR FURTHER INFORMATION CONTACT: Pamela Green-Smith, Director, Division of Refugee Assistance, Office of Refugee Resettlement, 370 L'Enfant Promenade, SW., Washington, DC 20447. Telephone: 202–401–4531. E-mail: *Pamela.Greensmith@acf.hhs.gov*

SUPPLEMENTARY INFORMATION:

Legislative Authority: This program is authorized by Section 412 (c)(1)(A)(iii), as amended of the Immigration and Nationality Act (8 U.S.C. 1522 (c)(1)(A)(iii)) and covers the following Services: (1) English as a Second Language instruction (2) After-school tutorials focused on helping students understand and complete programs that encourage high school completion and full participation in school activities (3) After-school summer programs that support remedial work or promote school readiness (4) Parental involvement programs (5) Interpreter services for parent/teacher meetings and conferences and (6) Bi-lingual/bi-cultural counselors and aides.

Amount of Award: $224,834.76.

Project Period: August 15, 2008—August 14, 2010.

Dated: October 1, 2008.

Pamela Green-Smith,

Director, Division of Refugee Assistance, Office of Refugee Resettlement.

[FR Doc. E8–23774 Filed 10–7–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2008–1006]

National Offshore Safety Advisory Committee; Meeting

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The National Offshore Safety Advisory Committee (NOSAC) will meet, in New Orleans, LA, to discuss various issues relating to offshore safety and security. The meeting will be open to the public.

DATES: NOSAC will meet on Thursday, November 13, 2008, from 9 a.m. to 3 p.m. The meeting may close early if all business is finished. Written material and requests to make oral presentations should reach the Coast Guard on or before October 30, 2008. Requests to