laboratories. Research nurses will collect blood and urine samples and return them to the study's laboratories. *Affected Public:* Individuals from participating communities. *Type of Respondents:* Men aged 18+ years and women aged 18–40 years. *Estimated Number of Respondents:* Approximately 500 couples enrolling (minimum of 400 completing the study). *Estimated Number of Response Sets Per Respondent:* 7 per woman and 4 per man over approximately two years. *Average Burden Hours Per Response:* (1) 0.17 hours for completing the screening instrument; (2) 0.42 hours for baseline interviews with men and women; (3) 2.5 hours for daily journal while attempting pregnancy for men and women; (4) 0.38 and 0.7 hours for biospecimen collection for women and men, respectively; (5) 2.6 hours for fertility monitors; (6) 0.27 hours for pregnancy testing for women; and (7) 0.29 hours for pregnancy journals for women. *Estimated Total Annual Burden Hours Requested:* 1,640 to 4,950 hours for female participants and 1,050 to 2,740 hours for male participants depending upon the length of time required for pregnancy. There is no cost to respondents. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov,* or by fax to 202–395–6974, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Dr. Germaine M. Buck Louis, Epidemiology Branch, Division of Epidemiology, Statistics & Prevention Research, NICHD, 6100 Executive Blvd., Room 7B03, Rockville, MD 20852, 301–496–6155. You may also e-mail your request to *louisg@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: March 12, 2008.

Paul L. Johnson,

Project Clearance Liaison, The Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health.

[FR Doc. E8–5700 Filed 3–20–08; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Emergency Review; Comment Request; Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank

Summary: In accordance with Section 3507(j) of the Paperwork Reduction Act of 1995, the National Institutes of Health hereby publishes notification of an Emergency Clearance for the expansion of the information related to the ''Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank.'' The expanded program will include information on certain clinical trials of drugs, biologics, and devices, whether or not they relate to serious and life-threatening diseases.

The information collection is essential to the mission of the FDA and National Institutes of Health [42 U.S.C. 282(j)(2)(A)(ii)] and is critical to meeting their roles in the Clinical Trial Registry that was expanded by Public Law 110–85, which was enacted on September 27, 2007.

NIH cannot reasonably comply with the normal clearance procedures for information collection, because the use of normal procedures will delay the collection and hinder the agency in accomplishing its mission and meeting new statutory requirements, to the detriment of the public good. Compelling reason exists for the collection of required information for successful planning and implementation of the expansion of the Clinical Trial Registry, as described in Public Law 110–85.

This information collection is essential to the effective stewardship of Federal Funds. After consultation with other agencies and NIH components, NIH has determined that the information is not currently available in any single, reliable, accessible source.

Proposed Collection: Title: Information Program on Clinical Trials for Serious and Life-Threatening Diseases: Maintaining a Databank; Type of Information Collection Request: New; Form Number: NA; Need and Use of Information Collection: In compliance with provisions of Title VIII of Public Law 110–85 (Food and Drug Administration Amendments Act of 2007) the National Institutes of Health is modifying the clinical trial registry established under previous law [ClinicalTrials.gov, established in response to FDAMA, Section 113]. The registry collects specified 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 registry 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 to include certain defined clinical trials of drugs, biologics, and devices subject to FDA regulation, regardless of whether they are related to serious or life-threatening diseases. It also increases the clinical trial information (*i.e.*, number of data elements) that must be submitted as part of each registration.

Frequency of Response: Responsible parties for applicable clinical trials must submit the required information shortly after the initiation of a trial [by the later of 21 days after the first patient is enrolled or December 26, 2007]. Updates to registration records are thereafter 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. Records for trials that were ongoing (as defined in the Law) as of December 26, 2007 are also required to be updated to comply with the new registration data elements, even if they were previously registered.

Description of Respondents: Respondents are referred to in the law as ''responsible parties.'' The statute defines the responsible party 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: Under the clearance to date (OMB No. 0910–0459), the FDA total hours burden was 200,839. The current annual reporting burden is shown in Table 1. It is estimated that approximately 3,500 applicable clinical trials of drugs and biologics and 445 applicable trials of devices will be registered annually in accordance with Public Law 110–85, Section 801. This estimate is based on FDA reports that in 2005 some 5,332 new clinical trial protocols were submitted to its Center for Drug Evaluation and Research and 474 new protocols were submitted to the Center for Biologics Evaluation and Research. FDA projects that rates of submission will remain at or near this level in the near future. An estimated 50% of the drug and biological protocols received in 2005, or approximately 2,900 protocols, were for trials involving assessments of effectiveness, which would be subject to the provisions of Title VIII of Public Law 110–85. This figure was raised to 3,500 drug and biological trials per year to account for IND-exempt trials that are required to register in the expanded registration data bank, but for which a protocol might not be sent to FDA. The estimated 445 new applicable device clinical trials per year includes trials related to pre-market applications (approximately 50 applications to FDA containing 75 clinical trial protocols in 2005), 510(k) submissions (approximately 360 submissions to FDA containing clinical trial protocols in 2005), and humanitarian device exemptions (9 in 2005). The estimates of drug, biologic, and device trials computed using this approach are consistent with the numbers of relevant trials that were registered with the ClinicalTrials.gov registry in calendar year 2007.

The hour burden accounts for time required to register trials and provide necessary updating over the course of the study. Based on previous experience, it is estimated that each new registration record will be updated an average of 8 times during the course of the study (*e.g.*, to reflect protocol changes, additions of investigational sites, updates of recruitment status, trial completion). The time to complete an initial (new) registration (for trials of drugs, biologics, or devices) is estimated to be 7 hours (including time to extract, reformat and submit information which has already been produced for other purposes), an increase of 50% above the 4.6 hours that was estimated by FDA for the smaller set of information collected under previous law. The time required for subsequent updates of this information is expected to be significantly less than for the original registration (as less information must be provided), and is estimated at 2 hours per update. Applying these figures to the anticipated numbers of trials produces a burden estimate for mandatory, new trial registrations of 90,735 hours.

TABLE 1.—ESTIMATED BURDEN FOR MANDATORY NEW TRIAL REGISTRATIONS

Type of respondents	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Drugs and Biologics	3,500	1 New	7	24,500
		8 Subsequent Updates	2	56,000
Devices	445	1 New	7	3,115
		8 Subsequent Updates	2	7,120
Total	3,945			90,735

In addition to mandatory registrations, the registration databank will also receive a large number of voluntary submissions of information from registrants who wish to make their information public for purposes of recruitment or compliance with other policies (*e.g.*, International Committee of Medical Journal Editors). Voluntary registration is explicitly authorized in Public Law 110–85 [*Pub. L. 110–85, Section 801(a), adding new 42 U.S.C. 282(j)(4)(A)*] and information is collected in accordance with the same specifications established for mandatory registrations. The number of voluntary registrations is estimated by subtracting the anticipated annual number of mandatory registrations from the total number of trial registrations that is expected. In calendar year 2007, there were approximately 13,300 new trials registered in the ClinicalTrial.gov registry databank, of which some 8,000 were trials with drugs or biologics as an intervention, 900 were trials with a device as an intervention, and 4,400 were other types of trials (*e.g.*, observational studies, procedural interventions, behavioral interventions). These figures are consistent with the numbers of trials registered during calendar year 2005. Subtracting the anticipated number of mandatory trial registrations (from Table 1) from the anticipated number of total registrations (2007 statistics) produces estimated numbers of voluntary registrations of 4,500 trials of drugs and biologics, 455 trials of devices, and 4,400 trials of other intervention types. To account for a possible increase in voluntary submissions resulting from the heightened level of attention being devoted to clinical trials information, these estimates were raised by 20 percent to 5,400 trials of drugs and biologics, 545 trials of devices, and 5,280 trials of other intervention types. Assuming the same average time per response as for mandatory trials, the annual burden is estimated to be 258,175 hours (Table 2).

TABLE 2.—ESTIMATED BURDEN FOR VOLUNTARY REPORTING

Type of respondents	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Drugs and Biologics	5,400	1 New	7	37,800
		8 Updates	2	86,400
Devices	545	1 New	7	3,815
		8 Updates	2	8,720
Other	5,280	1 New	7	36,960
		8 Updates	2	84,480
Total Voluntary	11,225			258,175

The combined, recurring burden for mandatory and voluntary reporting would be the sum of the totals in Tables 1 and 2, or 348,910 hours. This figure would be expected to decline over time as registrants become more familiar with the registration processes and refine their data submission systems.

During the first year of implementation, there will be an additional mandatory reporting burden associated with the collection of information for applicable trials of drugs, biologics, and devices that were ongoing as of December 26, 2007, but had been previously registered with ClinicalTrials.gov. These respondents have already provided information collected under the previous OMB clearance and will provide only the additional elements subject to this clearance. The number of trials subject to this requirement is estimated by searching the existing ClinicalTrials registry for ongoing, interventional Phase 2–4 studies of drugs, biologics, and devices. Doing so produces an estimate of 7,650 trials: 7,000 previously registered trials of drugs and biologics and 650 previously registered trials of devices. It is anticipated that information collection required to bring these trials into compliance with the new information collection requirements will be significantly less than for a new trial registration and is estimated as 3 hours. Information for these trials will need to be updated to reflect the continued progress of the trial. The number of updates is estimated to be 4, which is half of the updates estimated for new registrations. Each update is estimated to require 2 hours, consistent with the updates for newly registered trials. The total burden associated with the updating of information for ongoing trials is 84,150 hours, as shown in Table 3.

TABLE 3.—ESTIMATED BURDEN FOR MANDATORY UPDATING OF INFORMATION FOR ONGOING TRIALS

Type of respondents	Number of respondents	Frequency of response	Average time per response (hours)	Annual hour burden
Drugs and Biologics	7,000	1 Compliance Update	3	21,000
		4 Subsequent Updates	2	56,000
Devices	650	1 Compliance Update	3	1,950
		4 Subsequent Updates	2	5,200
Total	7,650			84,150

There are no Capital Costs, Operating Costs or Maintenance 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.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Office of Management and Budget, Office of Regulatory Affairs. All comments should be sent via e-mail to *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH. 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 15 days of the date of this publication.

Dated: March 14, 2008.

Betsy L. Humphreys,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.