EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
POC Questionnaire	3	2,100	2/60	210
Focus Groups	4	8	1	32
Total	7	na	na	242

Exhibit 2 shows the annualized cost burden for the respondent's time to participate in this project. The total cost burden is estimated to be $21,775.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate* ($)	Total cost burden ($)
POC Questionnaire	3	210	92.03	19,326
Focus Groups	4	32	76.53	2,449
Total	7	242	na	21,775

*Based upon the weighted average of the ''registered nurse'' mean and the ''surgeon'' mean of the average wages, May 2007 National Occupational Employment and Wage Estimates, United States, U.S. Department of Labor, Bureau of Labor Statistics. *http://www.bls.gov/oes/current/oes_nat.htm#b29–0000* (accessed Nov. 1, 2008). The ''surgeon'' mean salary was used for the 3 ED respondents and the ''registered nurse'' mean salary was used for the 1 Call Center.

Estimated Annual Costs to the Federal Government

Exhibit 3 shows the total and annualized cost of this two-year project to the federal government. The total cost is $34,730 and includes $7,500 for project development, $8,400 for data collection activities, $6,580 for data processing and analysis, $1,000 for the publication of results and $11,250 for project management.

EXHIBIT 3—ESTIMATED COST

Cost component	Total cost ($)	Annualized cost ($)
Project Development	7,500	3,750
Data Collection Activities	8,400	4,200
Data Processing and Analysis	6,580	3,290
Publication of Results	1,000	500
Project Management	11,250	5,625
Overhead	0	0
Total	34,730	17,365

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research, quality improvement and information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: November 14, 2008.

Carolyn M. Clancy,

Director.

[FR Doc. E8–28033 Filed 11–28–08; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State Council on Developmental Disabilities Program Performance Report.

OMB No.: 0980–0172.

Description: A Developmental Disabilities Council Program Performance Report is required by federal statute. Each State Developmental Disabilities Council must submit an annual report for the preceding fiscal year of activities and accomplishments. Information provided

in the Program Performance Report will be used (1) in the preparation of the biennial Report to the President, the Congress, and the National Council on Disabilities and (2) to provide a national perspective on program accomplishments and continuing challenges. This information will also be used to comply with requirements in the Government Performance and Results Act of 1993.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Council on Developmental Disabilities Program Performance Report ..	55	1	138	7,590
Estimated Total Annual Burden Hours:	.....	.....	.....	7,590

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@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: November 24, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–28249 Filed 11–28–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0576]

Guidance for Sponsors, Clinical Investigators, and IRBs; Data Retention When Subjects Withdraw From FDA-Regulated Clinical Trials; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials.'' This guidance clarifies FDA's position that it is critical that data be retained from trial participants who decide to discontinue participation in a clinical study of an investigational product, who are withdrawn by their legally authorized representative, as applicable, or who were discontinued from participation by the clinical investigator. The guidance will be of interest especially to sponsors, clinical investigators, and members of investigational review boards (IRBs).

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

ADDRESSES: 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: Sara F. Goldkind, Office of Science and Health Coordination/Good Clinical Practice Program (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for sponsors, clinical investigators, and IRBs entitled ''Data Retention When Subjects Withdraw from FDA-Regulated Clinical Trials.'' This guidance clarifies FDA's long-standing position that it is critical that data be retained from individuals who decide to discontinue participation in a clinical study of an investigational product, or who were discontinued from participation by the clinical investigator.

FDA developed this guidance in response to questions from sponsors, clinical investigators, and members of IRBs about previously collected data from subjects who withdraw or are withdrawn from clinical investigations. This guidance describes the regulatory and statutory basis for FDA's position, as well as the supporting ethical and quality standards, and outlines key points regarding the withdrawal of subjects from a clinical investigation. Because data resulting from these clinical investigations is used to support research applications and new product approvals, it is critical that FDA have a complete and accurate data set. If data were to be removed from the study database, the scientific validity of the data and thus FDA's analysis of it could be jeopardized potentially compromising the agency's ability to safeguard the public health.

This Level 1 guidance is being issued for immediate implementation to prevent the potential loss of important clinical trial data. This approach is consistent with FDA's good guidance practices regulation (21 CFR 10.115). If comments are received on this Level 1 guidance, FDA will review the comments and revise the guidance if appropriate. This guidance represents the agency's long-standing policy and current thinking on the retention of data when subjects withdraw from FDA-regulated clinical trials. 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. Interested persons may submit written comments on the guidance to the Division of Dockets Management (see **ADDRESSES**).

Elsewhere in this issue of the **Federal Register**, the Office of Human Research Protections (OHRP) is announcing the availability of a draft guidance document entitled ''Guidance on Important Considerations for When