Institutions Not Engaged in Human Subjects Research

Release of Identifiable Private Information or Biological Specimens

In the **Federal Register** of December 8, 2006 (71 FR 71169), OHRP noted that the office was particularly interested in the public's comments on the proposal that institutions whose employees or agents release to investigators at another institution identifiable private information or identifiable biological specimens pertaining to the subjects of the research, not be considered engaged in human subjects research.

The public comments supported this proposed scenario. OHRP retained this scenario in the final guidance document, with only minor clarifying changes (see scenario B.(6) in the final guidance).

Administration of Clinical Trial-Related Medical Services

In the **Federal Register** of December 8, 2006 (71 FR 71169), OHRP also noted that the office was particularly interested in the public's comments on the proposal that institutions (including private practices) not selected as research sites whose employees or agents administer clinical trial-related medical services, not be considered engaged in human subjects research provided that specified conditions were met. One of the proposed conditions was that the institution's employees or agents do not administer the primary study interventions being tested under the protocol.

The public comments on this proposed scenario were generally supportive, but several commenters sought clarifications on some of the proposed conditions. In addition, a few of the commenters recommended that OHRP expand the scenario to permit the employees or agents of an institution not selected as a research site to administer the study intervention being tested or evaluated under the protocol, and still not consider such an institution to be engaged in human subjects research.

In the final guidance, OHRP retained the proposed scenario, with minor changes in response to the public comments (see scenario B.(2) in the final guidance). However, OHRP also has included another scenario in the final guidance that would allow employees or agents of an institution not initially selected as a research site to administer the study interventions being tested or evaluated under the protocol, provided that this occurs on a one-time or short-term basis, and specified conditions are met (see scenario B.(3) in the final guidance). OHRP believes this is responsive to the concern raised in a public comment that research subjects are sometimes unexpectedly hospitalized or otherwise unexpectedly unable to receive a study intervention being tested or evaluated in a protocol from an institution that had previously been designated as a research site.

III. Comments

Interested persons may submit comments regarding this guidance document to OHRP at any time. Please see the **ADDRESSES** section for information on where to submit written comments.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance document on OHRP's Web site at *http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.htm.*

Dated: October 16, 2008.

Ivor A. Pritchard,

Acting Director, Office for Human Research Protections.

[FR Doc. E8–25177 Filed 10–22–08; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Community-Based Abstinence Education Performance Progress Report.

OMB No.: 0970–0272.

Description: The discretionary funding Community-Based Abstinence Education Program (CBAE) is authorized by Title XI, Section 1110, of the Social Security Act (using the definitions contained in Title V, Section 510(b)(2) of the Social Security Act).

Performance Progress Report/Program Narrative

The CBAE Performance Progress Report/Program Narrative is a semiannual report form through which grantees report performance information used by the Administration for Children and Families (ACF) to evaluate each grantee's compliance with Federal law and progress toward achieving its goals. Performance information includes:

Description of major activities and accomplishments during the reporting period;

Description of deviations or departures from the original project;

Description of significant findings and events;

Description of dissemination activities;

Description of other activities; and

Description of activities planned for the next reporting period, including goals and objectives.

Program-Specific Performance Measure

The CBAE program is developing a program-specific performance measure in response to the PART review (a process by which the Office of Management and Budget analyzes and rates a Federal program's procedures and strategies for evaluating its effectiveness), for which the program received a rating of Adequate. In an effort to gather program-specific data on rates of abstinence pre- and post-program participation, ACF and the Office of Management and Budget determined that a program-specific performance measure should be developed to assess key outcomes among program participants. The CBAE office convened a panel of abstinence education experts to gather input on the measure, and, based on the input provided, the CBAE office is developing the measure. CBAE grantees will be required to ask ten to fifteen questions of the youth served in a pre- and post-survey, as well as a representative sample of the youth served in a post-post-survey.

The questions are being carefully constructed by an experienced evaluator to measure initiation and discontinuation of sexual intercourse as well as two key predictors of initiation: Sexual values and behavioral intentions.

The program office will collect and compile data to establish baselines and ambitious targets for the program-specific performance measure. The data will be aggregated and results will be shared with the public as they become available.

Respondents: Performance Progress Report/Program Narrative—Non-profit community-based organizations, faith-based organizations, schools/school districts, universities/colleges, hospitals, public health agencies, local governments, Tribal councils, small businesses/for-profit entities, housing authorities, etc. Program-Specific Performance Measure—Youth Participants.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Community-Based Abstinence Education Program Announcement Performance Progress Report/Program Narrative	60	2	50	6,000
Community-Based Abstinence Education Program—Program-Specific Performance Measure	1,000,000	3	0.17	510,000

Estimated Total Annual Burden Hours: 516,000

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: October 20, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8–25285 Filed 10–22–08; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0546]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on the use of MedWatch^{Plus} Portal and Rational Questionnaire to collect electronically all adverse event, consumer complaint/product problem and medication use error data submitted to FDA.

DATES: Submit written or electronic comments on the collection of information by December 22, 2008.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, 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: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

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 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.

Electronic Data Collection Using MedWatch^{Plus} Portal and Rational Questionnaire—21 CFR 310.305, 314.80, 314.98, 514.80, 600.80, 1271.350 and Part 803

FDA is implementing electronic data collection to improve adverse event reporting across the agency. FDA's current processes and systems for adverse event reporting vary across its centers and are not optimal for the efficient collection of voluntary and mandatory adverse event reports, product problems/consumer complaints, or errors associated with the use of FDA-regulated products. Current FDA reporting forms (Forms FDA 3500, 3500A, 1932, and 1932a) are an outgrowth of a paper process era and frequently result in the submission of inconsistent and poor quality information. In addition, the agency is limited in its ability to modify its paper forms to keep pace with changes in the types of regulated products and the information necessary to meet evolving standards to ensure post market safety. Further, the existing supporting business processes are not able to efficiently manage the information being provided on the paper forms. For example, the upfront data integrity