Experience Reporting is approved under OMB Control No. 0910–0230 through April 30, 2009; and IND regulations are approved under OMB Control No. 0910–0014 through May 31, 2009) and any additional burden imposed by this proposed collection would be minimal. Thus, FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Consideration; Pending Application on File	1	1	1	15	15
Request for Consideration; No Application Pending	1	1	1	50	50
Pre-Emergency Submissions; Pending Application on File	10	1	10	20	200
Pre-Emergency Submissions; No Application Pending	3	1	3	75	225
Manufacturers of an Unapproved EUA Product	3	4	12	2	24
State and Local Public Health Officials; Unapproved EUA Product	30	4	120	2	240
Total					754

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

TABLE 2.—ESTIMATED RECORDKEEPING ANNUAL BURDEN[1]

	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Manufacturers of an Unapproved EUA Product	3	4	12	25	300
State and Local Public Health Officials; Unapproved EUA Product	30	4	120	3	360
Total					660

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

The annual burden estimate for this information collection is 1,414 hours. The estimated reporting burden for this collection is 754 hours and the estimated recordkeeping burden is 660 hours.

Dated: April 10, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–8922 Filed 4–17–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Evaluation of Networking Suicide Prevention Hotlines (OMB No. 0930–0274)—Revision

This project revision includes the continuation of two previously approved data collection activities [Evaluation of Networking Suicide Prevention Hotlines Follow-Up Assessment (OMB No. 0930–0274) and Call Monitoring of National Suicide Prevention Lifeline Form (OMB No. 0930–0275)], and a revision to expand the scope of the ongoing evaluation in an effort to advance the understanding of crisis hotline utilization and its impact. The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) funds a National Suicide Prevention Lifeline Network (NSPL), consisting of two toll-free telephone numbers, that route calls from anywhere in the United States to a network of local crisis centers. In turn, the local centers link callers to local emergency, mental health, and social service resources.

The overarching purpose of the proposed Evaluation of the Networking Suicide Prevention Hotlines—Revision is to (1) continue to monitor and ensure quality of calls and gather follow-up information from the callers themselves, (2) expand the number of centers participating in order to assess whether the two national suicide prevention hotline numbers (*i.e.,* 1–800–273–TALK and 1–800–SUICIDE) reach similar or complimentary populations of at risk callers, and, (3) to evaluate additional but related activities (*e.g.,* motivational interviewing and safety planning) recently funded through a new cooperative agreement between

SAMHSA and crisis hotline centers in the NSPL. In total this effort's proposed evaluation includes six data collection activities.

Clearance is being requested to continue the following two previously approved data collection activities to continue call quality monitoring and caller follow-up assessment activities. The number of centers proposed to participate in these continuing activities is sufficient to address the additional question related to use of the two existing hotline numbers.

(1) To ensure quality, the vast majority of crisis centers conduct on-site monitoring of selected calls by supervisors or trainers using unobtrusive listening devices. To monitor the quality of calls and to inform the development of training for networked crisis centers, the national Suicide Prevention Lifeline proposes to remotely monitor calls routed to sixteen crisis centers during the shifts of consenting staff. The procedures are anonymous in that neither staff nor callers will be identified on the *Call Monitoring Form.* The monitor, a trained crisis worker, will code the type of problem presented by the caller, the elements of a suicide risk assessment that are completed by the crisis worker as well as what action plan is developed with and/or what referral(s) are provided to the caller. No centers will be identified in the reports.

During the shifts of consenting crisis staff, a recording will inform callers that some calls may be monitored for quality assurance purposes. Previous comparisons of matched centers that did and did not play the recordings found no difference in hang-up rates before the calls were answered or within the first 15 seconds of the calls.

The 18 centers to be monitored are selected based on the geographic region(s) they serve and center call volume. A total of 1,320 calls will be monitored during year 1 of the proposed three year clearance period.

(2) With input from multiple experts in the field of suicide prevention, a telephone interview survey was created to collect data on follow-up assessments from consenting individuals calling the Lifeline network.

During year 1 of the proposed three year clearance period, a total of 1,095 callers will be recruited from 18 of the approximately 100 crisis hotline centers that participate in the Lifeline network. Trained crisis workers will conduct the follow-up assessment (''*Crisis Hotline Telephone Follow-Up Assessment''*) within one month of the initial call. Assessments will be conducted only one time for each client. Strict measures to ensure privacy will be followed.

Telephone scripts provide potential participants with standardized information to inform their consent decision. Using the *Crisis Hotline Telephone Initial Script,* trained crisis counselors will ask for permission to have the evaluation staff re-contact the caller. The *Crisis Hotline Telephone Consent Script,* used at the time of re-contact, incorporates the required elements of a written consent form,

The resulting data will measure (a) suicide risk status at the time and since the call, (b) depressive symptoms at follow-up, (c) service utilization since the call, (d) barriers to service access, and (e) the client's perception of the efficacy of the hotline intervention.

Clearance is also being requested for *four new activities* are being proposed to evaluate the process and impact of motivational training and safety planning (MI/SP) with callers who have expressed suicidal desire. Five centers will train counselors to implement an intervention with callers during the initial call to a center, which incorporates aspects of motivational interviewing and safety planning (MI/SP) and utilizes an evidence-based practice model to provide follow-up to callers who have expressed a suicidal desire. An assessment of MI/SP fidelity and process measures will be incorporated into the design through the observation of calls via silent monitoring and the administration of two self-administered questionnaires to crisis center counselors. The impact assessment of MI/SP counselor training will include silent monitoring of calls and follow-up telephone interviews with callers to assess their emotions and behaviors following their interaction with the MI/SP trained counselor.

(1) Research monitors, trained crisis counselors not affiliated with the centers in the project, will access a remote ''real-time'' monitoring system through the Internet to conduct silent monitoring. Monitors will complete the ''MI/SP Silent Monitoring Form,'' to gather: (a) Call specifics for each call such as date, time, and length; (b) suicide risk status of the caller; (c) information on elements of safety planning, such as making the environment safe and identifying triggers that led to the caller's suicidality; (d) types of referrals the counselor gave and to what services; (e) ratings of counselor behaviors and caller behavioral changes that occurred; and (f) re-contact permission status. At the end of the call and once the counselor deems the intervention to be complete, counselors will ask all appropriate callers, using the MI/SP Caller Initial Script, for permission to be re-contacted by research staff for a follow-up interview. Only a caller whose call has been silently monitored is eligible to be followed by the research team; thus, counselors will state that the caller *may* be contacted by the research team if randomly selected for a follow-up call. A total of 1110 calls will be monitored across the 3-year data collection period. Prior to monitoring and collecting of the data, crisis counselors must have read and signed a *MI/SP Counselor Consent.* This form explains the purpose of the research, privacy, risks and benefits, what the study entails, and participant rights.

(2) The ''*MI/SP Counselor Attitude Questionnaire''* attitude questionnaire will be administered to counselors at the conclusion of their MI/SP training and be used as a possible predictor of fidelity of the MI//SP intervention. Information to be gathered includes (a) counselors' views of the applicability of the MI/SP for preparing them to conduct safety planning and follow up with callers; (b) possible anticipated challenges (*i.e.,* impeding factors) to applying the MI/SP training in their centers; (c) the relationship of the MI/SP model to their centers; (d) the extent to which trainees are provided with or obtain adequate resources to enable them to use MI/SP on the job; (h) impeding and facilitating factors; and (9) attitudes about counselors' self-efficacy to use MI/SP and views on its utility. It is expected that a total of 225 counselors will be trained over the course of 3 years in an effort to maintain 175 counselors at any given time. Thus, a total of 225 counselors are expected to complete this questionnaire during the 3-year data collection period.

(3) Counselors will be asked to complete the ''*MI/SP Counselor Follow-up Questionnaire''* for each call that is monitored. The questionnaire will incorporate an assessment of the outreach, telephonic follow up and/or other strategies that the center has proposed to implement, and whether the counselor was able to implement the center's site plan as originally conceived. The questionnaire will also include items on the demographic characteristics of the caller, whether contact was successfully made with the caller, whether the caller followed through with the safety plan and/or referral given by the counselor, whether MI/SP was re-implemented during the follow-up contact, whether another follow-up is scheduled, the educational and crisis experience of the person attempting re-contact with the caller, and that person's prior experience with

follow-up. Barriers to implementing the follow-up, as well as types of deviation from the site's follow-up plan will also be assessed. Open-ended questions about what led to deviations from the site's follow-up plan will also be included. In total, it is expected that counselors will complete the questionnaire for each of the calls that were monitored.

(4) Researchers will begin conducting follow-up interviews with callers approximately 6 weeks after the initial call to the center. This follow-up telephone interview (''*MI/SP Caller Follow-up Interview''*) will be conducted to collect information on demographic characteristics, gather caller feedback on the initial call made to the center, suicide risk status at the time of and since the call, current depressive symptomatology, follow through with the safety plan and referrals made by the crisis counselor, and barriers to service. Taking into account attrition and the number of callers who do not give consent, it is expected that the total number of follow-up interviews conducted by the research team will not exceed 885. The *MI/SP Caller Initial Script* protects the privacy of callers by asking the caller how and when they want to be contacted, and what type of message (if any) can be left on an answering machine or with the person picking up the telephone. The caller also has the option of not providing contact information to the crisis center if he/she prefers to call the evaluation team back directly. The telephone script used when the evaluation team contacts the participant for their follow-up interview (*MI/SP Caller Follow-up Consent Script,* see Attachment H) includes (1) the fact that the information collection is sponsored by an agency of the Federal Government, (2) the purpose of the information collection and the uses which will be made of the results, (3) the voluntary nature of participation, and (4) the extent to which responses will be held confidential.

The estimated response burden to collect this information is as follows annualized over the requested three year clearance period is presented below:

TOTAL AND ANNUALIZED AVERAGES: RESPONDENTS, RESPONSES AND HOURS

Instrument	Number of respondents	Number of responses per respondent*	Hours/ response	Response burden*
National Suicide Prevention Lifeline—Call Monitoring Form	10	44	.58	249
Crisis Hotline Telephone Initial Script	365	1	.08	29
Crisis Hotline Telephone Consent Script	365	1	.17	62
Crisis Hotline Telephone Follow-up Assessment	365	1	.67	245
MI/SP Silent Monitoring Form	10	37	.58	214
MI/SP Caller Initial Script	368	1	.08	29
MI/SP Caller Follow-up Consent Script	368	1	.17	63
MI/SP Caller Follow-up Interview	295	1	.67	198
MI/SP Counselor Consent	75	1	.08	6
MI/SP Counselor Attitudes Questionnaire	75	1	.25	19
MI/SP Counselor Follow-up Questionnaire	175	2	.17	89
Total	2,471			1,181

* Rounded to the nearest whole number.

Written comments and recommendations concerning the proposed information collection should be sent by May 20, 2009 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–6974.

Dated: April 13, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–8974 Filed 4–17–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Criteria for Vaccination Requirements for U.S. Immigration Purposes [Correction]

A notice ''Criteria for Vaccination Requirements for U.S. Immigration Purposes'' was published in the **Federal Register** on April 8, 2009 (74 FR 15986). This notice is corrected as follows: On page 15986 second column, under **DATES**, second sentence should read: Comments received after May 8, 2009, will be considered to the extent possible.

Dated: April 13, 2009.

James D. Seligman,

Chief Information Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–8981 Filed 4–17–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Interagency Autism Coordinating Committee.

The meeting will be open to the public, with attendance limited to space availability, and will be accessible by videocast. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should inform the Contact Person listed below at least 5 business days in advance of the meeting.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Date: May 4, 2009.

Time: 9 a.m. to 4 p.m.