Dated: September 17, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24228 Filed 9–23–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1939]

Use of Investigational Tobacco Products; Draft Guidance for Industry and Investigators; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and investigators entitled ''Use of Investigational Tobacco Products.'' The draft guidance, when finalized, will describe FDA's current thinking regarding the definition of ''investigational tobacco product'' and will discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations governing the use of investigational tobacco products become effective or FDA provides written notice of its intent to change its enforcement policy.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft by November 23, 2015. Submit either electronic or written comments on the proposed collection of information by November 23, 2015.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance, including comments on the proposed collection of information, to *http://www.regulations.gov.* Submit written comments on the draft guidance, including comments on the proposed collection of information, to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers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:

With regard to the draft guidance: Laura Rich or Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373, *CTPRegulations@fda.hhs.gov*, *laura.rich@fda.hhs.gov*, or *Deirdre.Jurand@fda.hhs.gov.*

With regard to the proposed collection of information: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and investigators entitled ''Use of Investigational Tobacco Products.'' This draft guidance, when finalized, will describe FDA's current thinking regarding the definition of ''investigational tobacco product'' and will discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations governing the use of investigational tobacco products become effective or FDA provides written notice of its intent to change its enforcement policy. It is intended to provide guidance not only to persons who currently intend to submit study information to FDA, but to all persons who conduct ''nonclinical laboratory studies,'' as that term is used in the draft guidance, and ''clinical investigations,'' as that term is used in the draft guidance, using investigational tobacco products.

The draft guidance also discusses that for clinical investigations, a sponsor (as defined in the guidance) may submit information regarding a proposed use of an investigational tobacco product to FDA for review prior to enrolling subjects. As discussed in the guidance, FDA encourages this type of voluntary submission because it will allow FDA to work with a sponsor to help ensure that the factors FDA considers in making enforcement decisions are appropriately accounted for. FDA has created a form to assist sponsors in submitting information. While use of the form is voluntary, it will help ensure that complete information is provided for FDA's consideration and will facilitate FDA's processing and review. A copy of the form is attached as Appendix A to this guidance.

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31) (Tobacco Control Act) into law. The Tobacco Control Act amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and grants FDA authority to regulate the manufacture, marketing, and distribution of tobacco products to protect public health generally and to reduce tobacco use by minors.

To introduce or deliver for introduction into interstate commerce a new tobacco product, there must be in effect a marketing authorization order issued by FDA for the tobacco product under section 910(c)(1)(A)(i) of the FD&C Act (21 U.S.C. 387j(c)(1)(A)(i)) unless, in brief:

- A substantial equivalence order under section 910(a)(2)(A)(i) of the FD&C Act is in effect for the tobacco product;
- FDA has granted a request for an exemption of the tobacco product from the requirement to obtain a substantial equivalence order and the manufacturer has made the required submission under section 905(j)(1)(A)(ii) of the FD&C Act and waited 90 days before introducing its product to the market; or
- The manufacturer has submitted a substantial equivalence report in accordance with section 910(a)(2)(B) of the FD&C Act and there is no order finding that the tobacco product is not substantially equivalent.

To introduce or deliver for introduction into interstate commerce a modified risk tobacco product, there must be in effect an order under section 911(g) of the FD&C Act (21 U.S.C. 387k(g)) and the applicant must satisfy any applicable premarket review requirements under section 910 of the FD&C Act.

Further, a tobacco product must conform in all respects with applicable tobacco product standards established under section 907 of the FD&C Act (21 U.S.C. 387g).

Persons intending to file submissions with FDA to demonstrate that a tobacco product meets the criteria for marketing set forth in section 910 or 911 of the FD&C Act, and other researchers seeking to study tobacco products, may need to conduct or sponsor studies involving tobacco products that do not have marketing authorization or that do not comply with an applicable tobacco product standard.

Section 910(g) of the FD&C Act gives FDA the authority to issue regulations to exempt tobacco products intended for investigational use from the provisions of chapter IX of the FD&C Act, including premarket submission requirements. FDA intends to propose regulations establishing conditions for exempting investigational tobacco products from certain FD&C Act requirements. Until then, investigational tobacco products are not exempt from applicable FD&C Act requirements, including premarket submission requirements and tobacco product standards. This draft guidance discusses the factors FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products in both nonclinical laboratory studies and clinical investigations until regulations become effective or FDA provides written notice of its intent to change its enforcement policy.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Use of Investigational Tobacco Products.'' 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 statute and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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.

Use of Investigational Tobacco Products (OMB Control Number 0910—NEW)

FDA is announcing the availability of the draft guidance entitled ''Use of Investigational Tobacco Products.'' This guidance, when finalized, will describe FDA's current thinking regarding the definition of ''investigational tobacco product'' and discuss the kind of information FDA intends to consider in making enforcement decisions regarding the use of investigational tobacco products until regulations become effective or FDA provides written notice of its intent to change its enforcement policy. When finalized, it is intended to provide guidance, not only to persons who currently intend to submit study information to FDA, but to all persons who conduct nonclinical laboratory studies and clinical investigations using investigational tobacco products. Such persons may include sponsors, investigators, sponsor-investigators, contract research organizations (CROs),[1] and committees or groups formally designated to oversee research involving human subjects (*e.g.*, institutional review boards (IRBs)) involved in investigations using investigational tobacco products.

We have identified the following recommendations in the draft guidance as collections of information.

In the draft guidance, FDA provides examples of information that may help FDA to evaluate specific proposed uses of investigational tobacco products, and encourages persons who intend to study investigational tobacco products to meet with FDA to discuss certain topics in connection with nonclinical laboratory studies and clinical investigations.

For clinical investigations, FDA encourages sponsors to submit information regarding a proposed use of an investigational tobacco product to FDA for review prior to enrolling subjects in the planned investigation. FDA has created a form to assist sponsors in submitting information. While use of this form is voluntary, its use will likely reduce the burden hours and will help ensure that sponsors provide complete information for FDA's consideration, processing, and review.

Furthermore, to ensure that studies are conducted in a manner that protects human subjects, the draft guidance contains recommendations as to how sponsors should put procedures in place to keep FDA and the committee or group formally designated to oversee research involving human subjects informed about any changes relating to the conduct of, and issues that arise during, the study. In the draft guidance, FDA further recommends that sponsors, CROs, sponsor-investigators, and clinical investigators maintain documentation to permit evaluation of the conduct of a clinical investigation, including assessing the quality and integrity of the study data and protection of human subjects.

In the draft guidance, FDA also recommends that sponsors consult with the Agency, clinical investigators, and any committee or group formally designated to oversee research involving human subjects when certain events occur during the conduct of a clinical investigation, including adverse experiences. In addition, FDA recommends that sponsors notify FDA if they choose to terminate a study (or withdraw or inactivate a protocol or want to withdraw all studies of a product) before completion and in the notification include certain information. Moreover, in the draft guidance, FDA recommends that under certain circumstances, sponsors also should inform any clinical investigators who participated in the discontinued investigation of the reason(s) for discontinuing the clinical investigation.

FDA also makes recommendations related to nonclinical laboratory studies and clinical investigations of using investigational tobacco products conducted outside of the United States (U.S.), but intended for submission to FDA, and refers to section 801(e) of the FD&C Act with respect to exported tobacco products intended for investigational use. The guidance also recommends that sponsors should prepare and maintain certain records and reports, for studies conducted outside of the U.S. but intended for submission to FDA to permit FDA to evaluate the conduct of a clinical investigation, including assessing the quality and integrity of the study data and protection of human subjects.

[1] The term ''contract research organization'' (CRO) as used in this draft guidance means a person that assumes, as an independent contractor with the sponsor, one or more of the obligations of the sponsor (*e.g.*, design of a protocol).

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/FDA form 3934	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Capital and operating and maintenance costs
Initial Submission	30	1	30	40	1,200	
Protocol Submission	10	1	10	20	200	
Protocol Amendments	5	1	5	0.50 (30 minutes)	2.5	
Information Amendments	4	1	4	15	60	
Administrative Amendments	1	1.5	1.5	0.50 (30 minutes)	0.75	
Other Information	3	1	3	0.50 (30 minutes)	1.5	
Serious or Unexpected Adverse Experience Reports.	4	3	12	2	24	
First year, electronic set-up safety reporting portal.	4	1	4	0.33 (20 minutes)	1.3	
First year, Electronic Gateway setup and verification certificate (One time burden).	30	1	30	42 [1]	1,260	37,800
Electronic Gateway Submission (recurring).	30	1	30	3	90	2,700
Total Reporting Burden Hours.					2,840	40,500

[1] Respondent may already have a valid WebTrader account established for other FDA electronic submissions.

Table 1 describes the annual reporting burden as a result of respondents submitting information regarding the use of investigational tobacco products in certain clinical investigations. FDA estimates that 30 respondents will submit study information to FDA annually. FDA estimates that it will take each respondent approximately 40 hours to prepare the study information necessary for FDA to issue a response to the proposed use of an investigational tobacco product in these clinical investigations. FDA's estimate includes the anticipated burden for completing the form for the initial submission, which will include the initial protocol, time for intra-company edits and approvals, as well as the burden for assembling additional information, as described in the draft guidance.

The initial submission should include an initial study protocol, which should in turn include certain information and call for recordkeeping or other steps that may involve the submission of information to others. In addition, sponsors may wish to provide protocol amendments to reflect certain changes to a protocol. FDA estimates that 10 respondents will submit a new protocol. The estimated time for submitting a new protocol is 20 hours per response. Only 4 respondents are estimated to submit information amendments. Since this may take a little less than half the time of an initial submission, FDA estimates information amendments taking around 15 hours.

FDA estimates that it could take respondents 30 minutes to prepare protocol amendments and that about 5 respondents submitting study information will submit protocol amendments.

FDA estimates that respondents will infrequently need to report administrative amendments. The total number of respondents of this type of information is estimated to be 1. FDA estimates that this submission is estimated to take 30 minutes per respondent.

FDA estimates that approximately 3 respondents will report other types of submissions. This submission is estimated to take 30 minutes per response.

FDA estimates that 4 respondents will report serious or unexpected adverse experiences. This submission will take an average of 2 hours per respondent. FDA estimates that setting up an account in safety reporting portal for submission of serious or unexpected experiences will take 20 minutes per response.

As referenced in the guidance, FDA allows for three ways of submission but strongly encourages the use of electronic format for submission. The submitter should first set up an account with WebTrader to go through the Electronic Submissions Gateway (ESG). FDA estimates from past experience with the ESG system, WebTrader, that the first year to set up the account and to receive the verification certificate takes approximately 40 hours. This burden may be minimized if the respondent already has an established account in WebTrader for other electronic submissions to FDA, but FDA is assuming that all respondents for these products will be setting up a WebTrader account for the first time in the first year. In subsequent years, the burden hours are estimated at 1 hour to renew the yearly required Verification Certification.

FDA further estimates that the gathering, scanning, and submission of information and related correspondence would take approximately 2 hours utilizing the eSubmitter system.

Therefore, the first year will include 40 hours for the WebTrader system plus 2 hours for the eSubmitter submission process, resulting in 42 hours per response for the first year. For subsequent years, it is estimated that only 1 hour will be necessary for the WebTrader system plus the 2 hours for the eSubmitter submission process, resulting in 3 hours per response each year thereafter.

Additionally, there are capital and operating or maintenance costs associated with this information collection. The costs are $30 per year to establish and maintain the ESG verification certificate. The total cost may be lower if the respondents already have a verification certificate for that year for other electronic submissions to FDA. However, for purposes of this estimate, FDA is assuming that all respondents for these products will be

incurring this cost. The total costs are estimated to be $40,500.

The total reporting burden for this collection of information is estimated to be 2,840 hours. These burden estimates were computed using FDA staff expertise and by reviewing comments received from recent FDA information collections for other tobacco-related initiatives.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity records maintained	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records by Sponsors	50	1	50	10	500
Records By Sponsor-Investigators	20	1	20	20	400
Records by Investigators and CROs	50	1	50	15	750
Total Recordkeeping Burden Hours					1,650

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

Table 2 describes the annual recordkeeping burden of maintaining records relating to the investigational use of tobacco products. FDA anticipates that 50 sponsors will maintain records relating to the use of investigational tobacco products in clinical investigations. FDA estimates that it will take each of them approximately 10 hours annually to maintain these records. FDA anticipates that there will generally be one investigator per investigation. FDA anticipates there will be a total of 120 sponsors, sponsor-investigators, investigators, and CROs who will maintain records relating to the use of investigational tobacco products in clinical investigations. FDA estimates that it will take each sponsor approximately 10 hours annually to maintain these records. FDA estimates that it will take each sponsor-investigator approximately 20 hours annually to maintain these records. FDA estimates that it will take each of these investigators and CROs approximately 15 hours annually to maintain these records. The total reporting burden for recordkeeping is estimated to be 1,650 hours (500 hours for sponsors + 400 hours for sponsor-investigators + 750 for investigators and CROs.)

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Disclosures to Investigators	30	1	30	1	30
Disclosures to any Committee or Group	30	1	30	0.17 (10 minutes)	5
Disclosure to Study Subjects	30	2	60	0.50 (30 minutes)	30
Total					65

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

Table 3 describes the annual third party disclosure burden.

FDA estimates that disclosing information to investigators will take 1 hour per disclosure. FDA estimates that disclosing information to any committee or group formally designated to oversee research involving human subjects will average 10 minutes per disclosure.

The guidance also references examples of disclosing information to study subjects such as informed consent. On average, two disclosures per respondent will be provided to study subjects. FDA estimates this will take 30 minutes per disclosure.

The total burden for the collection of information under this draft guidance is estimated to be 4,455 hours.

This draft guidance also refers to previously approved collections of information. The draft guidance includes a recommendation that persons who intend to study tobacco products meet with FDA to discuss research plans. Additional information about how to request meetings with FDA's Center for Tobacco Products can be found in FDA's guidance: ''Meetings with Industry and Investigators on the Research and Development of Tobacco Products.'' The collections of information in the guidance referenced have been approved under OMB control number 0910–0731. The collections of information in section 801(e) of the FD&C Act and 21 CFR 1.101(b) have been approved under OMB control number 0910–0482; the collections of information for the Safety Reporting Portal have been approved under OMB control number 0910–0645; the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910–0673.

III. Request for Comments

A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on *http://www.regulations.gov.* This is

determined by information indicating that the submission is written by an individual, for example, the comment is identified with the category ''Individual Consumer'' under the field titled ''Category (Required),'' on the ''Your Information'' page on *www.regulations.gov.* For this docket, however, FDA will not be following this general practice. Instead, FDA will post on *http://www.regulations.gov* comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on *http://www.regulations.gov* if you include that information in the body of your comments. For electronic comments submitted to *http://www.regulations.gov,* FDA will post the body of your comment on *http://www.regulations.gov* along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (*e.g.,* individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on *http://www.regulations.gov,* but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

IV. Electronic Access

Persons with access to the Internet may obtain an electronic version of this guidance document at *http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm281147.htm* or *http://www.regulations.gov.*

Dated: September 16, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–24218 Filed 9–23–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: *http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html.*

DATES: The meeting will be held on Wednesday, October 21, 2015, from 8:30 a.m. until 5:00 p.m. and Thursday, October 22, 2015, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., on Wednesday, October 21, followed by opening remarks from Dr. Jerry Menikoff, Executive Secretary of SACHRP and OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair. The Committee will hear the Subpart A Subcommittee (SAS) and Subcommittee on Harmonization (SOH) reports on the recent Notice of Proposed Rulemaking (NPRM) titled Federal Policy for the Protection of Human Subjects (80 FR 53933, Sep. 8, 2015). Both days will be devoted to the discussion of the NPRM.

SAS was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

SOH was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The meeting will adjourn at 4:30 p.m. October 22, 2015. Time for public comment sessions will be allotted both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. Pre-registration is required for participation in the on-site public comment session; individuals may pre-register the day of the meeting. Individuals who would like to submit written statements should email or fax their comments to SACHRP at *SACHRP@hhs.gov* at least five business days prior to the meeting.

Dated: September 18, 2015.

Jerry Menikoff,

Executive Secretary, Secretary's Advisory Committee on Human Research Protections, Director, Office for Human Research Protections.

[FR Doc. 2015–24264 Filed 9–23–15; 8:45 am]

BILLING CODE 4150–36–P

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: Hospital Data Abstraction Form, Formerly Entitled Evaluation of Emergency Department Crisis Center Follow-Up—(OMB No. 0930–0337)—Revision

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) will conduct an evaluation to assess the impact of crisis center follow-up with patients admitted to emergency departments following a suicide attempt.