burden to be 25 hours per response, for a total burden of 250 hours.

As noted, FDA estimates that all of the future Forms FDA 3479, 3480, and 3480A submissions will be made electronically through the ESG. While FDA does not charge for the use of the ESG, FDA requires respondents to obtain a public key infrastructure certificate in order to set up the account. This can be obtained in-house or outsourced by purchasing a public key certificate that is valid for 1 year to 3 years. The certificate typically costs from $20 to $30.

Dated: June 7, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14227 Filed 6–11–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0835]

Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another Institutional Review Board; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Considerations When Transferring Clinical Investigation Oversight to Another IRB.'' The draft guidance discusses regulatory responsibilities of institutional review boards (IRBs), clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. The draft guidance also addresses questions that have been previously raised concerning procedures and processes that are required and/or recommended by FDA when such oversight is transferred.

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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either written or electronic comments on the draft guidance by August 13, 2012.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002 (1–888–463–6332 or 301–796–3400); or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448 (1–800–835–4709 or 301–827–1800); or the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4622, Silver Spring, MD 20993 (1–800–638–2041 or 301–796–7100). Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Bridget Foltz, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg, 32, Rm. 5174, Silver Spring, MD 20993–0002, 301–796–8340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled ''Considerations When Transferring Clinical Investigation Oversight to Another IRB.'' The draft guidance discusses the regulatory responsibilities of IRBs, clinical investigators, and sponsors when oversight of a previously approved clinical investigation under FDA's jurisdiction is transferred from one IRB to another IRB. In particular, the draft guidance discusses eight steps to be considered when transferring oversight of a previously approved clinical investigation between two IRBs. These include: Identifying those studies for which IRB oversight is being transferred; ensuring availability and retention of pertinent records; establishing an effective date for the transfer; conducting a review of research by the receiving IRB, where appropriate; confirming or establishing the date for the next continuing review; determining whether the consent form needs to be revised; notifying the key parties; and updating IRB registration information. This list is not meant to be exhaustive as the circumstances involved in the transfer may vary.

To enhance human subject protections and reduce regulatory burden, FDA and the Office for Human Research Protections (OHRP) have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subjects research. This draft guidance document was developed as a part of these efforts. OHRP has simultaneously published in this same issue of the **Federal Register** a draft guidance document entitled ''Considerations in Transferring a Previously Approved Research Project to a New IRB or Research Institution'' that is similar to FDA's draft document.

FDA and OHRP recognize that the two documents may appear somewhat different as there are minor variations in formatting and some necessary variations due to differences in the regulated entities under FDA's and OHRP's jurisdiction. The Agencies wish to stress, however, that our intent was to provide harmonized guidance to IRBs, sponsors, institutions, investigators, and other entities involved in the study oversight transfer process. FDA and OHRP will continue to work closely in the development of final guidance and appreciate comments from interested parties.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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.

II. The Paperwork Reduction Act of 1995

This draft guidance includes information collections provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this draft guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, which include the requirements for records related to informed consent, have been approved under OMB control number 0910–0130; the collection of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; and the collections of information in 21 CFR part 812 have been approved under

OMB control number 0910–0078. In accordance with the PRA, prior to publication of any final guidance document, FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this draft guidance that are new or that would represent material modifications to these previously approved collections of information found in FDA regulations.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ProposedRegulationsandDraftGuidances/default.htm* or *http://www.regulations.gov.*

Dated: June 6, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–14295 Filed 6–11–12; 8:45 am]

BILLING CODE 4160–01–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: 2013 National Survey on Drug Use and Health—(OMB No. 0930–0110)—Revision

The National Survey on Drug Use and Health (NSDUH) is a survey of the civilian, non-institutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

Data from clinical interviews completed in 2008 were combined with the main interview short scale data to develop a predictive model that was applied to the full main sample to estimate SMI. Follow-up clinical interviews continued to be conducted with NSDUH respondents from 2009 to 2012. Data from these interviews were analyzed annually to update the calibration of the screening measure. To maximize trend validity, this model has been applied to 2009–2011 data. With the completion of 1500 clinical interviews in 2012, SAMHSA will have accumulated a large enough sample (4,500) to update and improve the models. Therefore, the MHSS clinical interviewing will be discontinued in 2013.

For the 2013 NSDUH, a few questionnaire changes are proposed. The instrument has been updated to include new questions on military service, medical marijuana, physician substance use screening, and respondent characteristics.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2013 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. The total annual burden estimate is shown below:

ESTIMATED BURDEN FOR 2013 NSDUH

Instrument	Number of respondents	Responses per respondent	Hours per response	Total burden hours	Hourly wage rate	Annualized costs
Household Screening	145,474	1	0.083	12,074	$14.45	$174,469
Interview	67,500	1	1.000	67,500	14.45	975,375
Screening Verification	5,400	1	0.067	362	14.45	5,231
Interview Verification	10,125	1	0.067	678	14.45	9,797
Total	145,474			80,614		1,164,872

Written comments and recommendations concerning the proposed information collection should be sent by July 12, 2012 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2012–14197 Filed 6–11–12; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health