

(Ebola). Ebola is a type of viral hemorrhagic fever that is often fatal in humans and nonhuman primates. Ebola can spread through human-to-human transmission, with infection resulting from direct contact (through broken skin or mucous membranes) with the blood, secretions, droplets, or other body fluids of infected people, and indirectly from contact with surfaces or items (such as needles) contaminated with such fluids.

With respect to viral hemorrhagic fevers, placement on the DNB list and associated Lookout record is requested for people known or suspected to have a viral hemorrhagic fever. Placement may also be requested for people without symptoms who have been exposed to a viral hemorrhagic fever, particularly if these individuals intend to travel against public health recommendations. Even though people without symptoms are not infectious, these restrictions are requested because of the possibility that symptoms could develop during travel, particularly long international flights. Exposure is determined through a CDC risk factor assessment using information available from a variety of public health, medical and other official sources. Examples of types of potential exposure to viral hemorrhagic fevers contained within the CDC risk factor assessment include the following. It should be noted that not all of these exposures may result in travel restrictions.

- Having been in a country with widespread Ebola virus transmission within the past 21 days and, although having had no known exposures, is showing symptoms
- Percutaneous (e.g., needle stick) or mucous membrane exposure to blood or body fluids of a person with Ebola while the person was showing symptoms
- Exposure to the blood or body fluids (including but not limited to feces, saliva, sweat, urine, vomit, and semen) of a person with Ebola while the person was showing symptoms without appropriate personal protective equipment (PPE) (see <http://www.cdc.gov/vhf/ebola/hcp/procedures-for-ppe.html>)
- Laboratory processing of blood or body fluids of a person with Ebola while the person was showing symptoms without appropriate PPE or standard biosafety protections
- Direct contact with a dead body without appropriate PPE in a country with widespread Ebola virus transmission (see <http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/distribution-map.html>)
- Having lived in the immediate household and provided direct care to

a person with Ebola while the person was showing symptoms

- In countries with widespread Ebola virus transmission: Direct contact while using appropriate PPE with a person with Ebola while the person was showing symptoms, or with the person's body fluids, or any direct patient care in other healthcare settings
- Close contact in households, healthcare facilities, or community settings with a person with Ebola while the person was showing symptoms
- Close contact is defined as not wearing appropriate PPE within approximately 3 feet (1 meter) of a person with Ebola while the person was showing symptoms
- Having brief direct contact (e.g., shaking hands), while not wearing appropriate PPE, with a person with Ebola while the person was in the early stage of disease
- In countries without widespread Ebola virus transmission: Direct contact while using appropriate PPE with a person with Ebola while the person was showing symptoms
- Traveled on an aircraft with a person with Ebola while the person was showing symptoms

Exposure risk factors, such as those just described, will be considered by HHS/CDC in their totality when determining whether an individual meets the first criteria for placement on the DNB List, as described in Section I of this notice. HHS/CDC would also consider other facts and information it may have to make a decision with respect to the other criteria, as described in Section I of this notice. It should be noted that all facts are considered when applying the criteria. Again, with the exception of the first criteria, not all of the other criteria need to be present for HHS/CDC to make a request to DHS to have an individual placed on DNB and Lookout.

HHS/CDC would also consider these risk factors when assessing an individual who has been in a country where outbreaks of viral hemorrhagic fevers were occurring and refuses to comply with a public health assessment, and otherwise meets the travel restriction criteria. Refusing to comply with a public health risk assessment in this situation could include refusing to provide relevant information that would allow public health officials to assess the exposure risk.

V. Provisions of This Notice

HHS/CDC will make requests of DHS based on the criteria in this notice effective immediately. Individuals who have had their travel temporarily

restricted as a result of placement on the DNB list and associated Lookout records may submit a written response to the Director, Division of Global Migration and Quarantine, if they believe that HHS/CDC has erred in its public health request to DHS. The response should be addressed to: Director, Division of Global Migration and Quarantine, ATTN: Travel Restriction and Intervention Activity, Centers for Disease Control and Prevention, 1600 Clifton Road, MS E-03, Atlanta, GA 30329. Responses may also be faxed to CDC at (404) 718-2158 or emailed to travelrestrictions@cdc.gov.

As part of the response, individuals should include the reference number listed in the notification letter they received and any facts or other evidence indicating why they believe that HHS/CDC's public health request was made in error.

The policy and program operations described above will become effective on March 27, 2015.

Dated: March 24, 2015.

Sylvia M. Burwell,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0908]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees

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, including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information concerning the establishment and operation of clinical trial data monitoring committees.

DATES: Submit either electronic or written comments on the collection of information by May 26, 2015.

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: 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: 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, including each proposed extension of an existing 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.

Guidance for Clinical Trial Sponsors: Establishment and Operation of Clinical Trial Data Monitoring Committees—(OMB Control Number 0910-0581)—Extension

Sponsors are required to monitor studies evaluating new drugs, biologics, and devices (21 CFR 312.50 and 312.56 for drugs and biologics, and 21 CFR 812.40 and 812.46 for devices). Various individuals and groups play different roles in clinical trial monitoring. One such group is a data monitoring committee (DMC), appointed by a sponsor to evaluate the accumulating outcome data in some trials. A clinical trial DMC is a group of individuals with pertinent expertise that reviews on a regular basis accumulating data from one or more ongoing clinical trials. The DMC advises the sponsor regarding the continuing safety of current trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

The guidance document referenced in this document is intended to assist sponsors of clinical trials in determining when a DMC is needed for monitoring a study, and how such committees should operate. The guidance addresses the roles, responsibilities, and operating procedures of DMCs, describes certain reporting and recordkeeping responsibilities, including the following: (1) Sponsor reporting to FDA on DMC recommendations related to safety; (2) standard operating procedures (SOPs) for DMCs; (3) DMC meeting records; (4) sponsor notification to the DMC regarding waivers; and (5) DMC reports based on meeting minutes to the sponsor.

1. Sponsor Reporting to FDA on DMC Recommendations Related to Safety

The requirement of the sponsor to report DMC recommendations related to serious adverse events in an expedited manner in clinical trials of new drugs (section 312.32(c)(21 CFR 312.32(c))) would not apply when the DMC recommendation is related to an excess of events not classifiable as serious. Nevertheless, the Agency recommends in the guidance that sponsors inform FDA about all recommendations related to the safety of the investigational product whether or not the adverse event in question meets the definition of "serious."

2. SOPs for DMCs

In the guidance, FDA recommends that sponsors establish procedures to do the following things:

- Assess potential conflicts of interest of proposed DMC members;

- Ensure that those with serious conflicts of interest are not included in the DMC;

- Provide disclosure to all DMC members of any potential conflicts that are not thought to impede objectivity and, thus, would not preclude service on the DMC;

- Identify and disclose any concurrent service of any DMC member on other DMCs of the same, related, or competing products;

- Ensure separation, and designate a different statistician to advise on the management of the trial, if the primary trial statistician takes on the responsibility for interim analysis and reporting to the DMC; and

- Minimize the risks of bias that are associated with an arrangement under which the primary trial statistician takes on the responsibility for interim analysis and reporting to the DMC, if it appears infeasible or highly impractical for any other statistician to take over responsibilities related to trial management.

3. DMC Meeting Records

The Agency recommends in the guidance that the DMC or the group preparing the interim reports to the DMC maintain all meeting records. This information should be submitted to FDA with the clinical study report (section 314.50(d)(5)(ii) (21 CFR 314.50(d)(5)(ii))).

4. Sponsor Notification to the DMC Regarding Waivers

The sponsor must report to FDA certain serious and unexpected adverse events in drugs and biologics trials (section 312.32) and unanticipated adverse device effects in the case of device trials (section 812.150(b)(1) (21 CFR 812.150(b)(1))). The Agency recommends in the guidance that sponsors notify DMCs about any waivers granted by FDA for expedited reporting of certain serious events.

5. DMC Reports of Meeting Minutes to the Sponsor

The Agency recommends in the guidance that DMCs should issue a written report to the sponsor based on the DMC meeting minutes. Reports to the sponsor should include only those data generally available to the sponsor. The sponsor may convey the relevant information in this report to other interested parties, such as study investigators. Meeting minutes or other information that include discussion of confidential data would not be provided to the sponsor.

Description of Respondents: The submission and data collection

recommendations described in this document affect sponsors of clinical trials and DMCs.

Burden Estimate: Table 1 of this document provides the burden estimate of the annual reporting burden for the information to be submitted in accordance with the guidance. Table 2 of this document provides the burden estimate of the annual recordkeeping burden for the information to be maintained in accordance with the guidance. Table 3 of this document provides the burden estimate of the annual third-party disclosure burden for the information to be submitted in accordance with the guidance.

Reporting, Recordkeeping, and Third-Party Disclosure Burdens: Based on information from FDA review divisions, FDA estimates there are approximately 740 clinical trials with DMCs regulated by the Center for Biologics Evaluation and Research, the Center for Drug Evaluation and Research, and the Center for Devices and Radiological Health. FDA estimates that the average length of a clinical trial is 2 years, resulting in an annual estimate of 370 clinical trials. Because FDA has no information on which to project a change in the use of

DMCs, FDA estimates that the number of clinical trials with DMCs will not change significantly. For purposes of this information collection, FDA estimates that each sponsor is responsible for approximately 10 trials, resulting in an estimated 37 sponsors that are affected by the guidance annually.

Based on information provided to FDA by sponsors that have typically used DMCs for the kinds of studies for which this guidance recommends them, FDA estimates that the majority of sponsors have already prepared SOPs for DMCs, and only a minimum amount of time is necessary to revise or update them for use for other clinical studies. FDA receives very few requests for waivers regarding expedited reporting of certain serious events; therefore, FDA has estimated one respondent per year to account for the rare instance a request may be made. Based on FDA's experience with clinical trials using DMCs, FDA estimates that the sponsor on average would issue two interim reports per clinical trial to the DMC. FDA estimates that the DMCs would hold two meetings per year per clinical trial resulting in the issuance of two

DMC reports of meeting minutes to the sponsor. One set of both of the meeting records should be maintained per clinical trial.

The "Average Burden per Response" and "Average Burden per Recordkeeping" are based on FDA's experience with comparable recordkeeping and reporting provisions applicable to FDA regulated industry. The "Average Burden per Response" includes the time the respondent would spend reviewing, gathering, and preparing the information to be submitted to the DMC, FDA, or the sponsor. The "Average Burden per Recordkeeping" includes the time to record, gather, and maintain the information.

The information collection provisions in the guidance for 21 CFR 312.30, 312.32, 312.38, 312.55, and 312.56 have been approved under OMB Control No. 0910-0014; 21 CFR 314.50 has been approved under OMB Control No. 0910-0001; and 21 CFR 812.35 and 812.150 have been approved under OMB Control No. 0910-0078.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Section of guidance/reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
5. Sponsor reporting to FDA on DMC recommendations related to safety	37	1	37	0.50 (30 min.)	18.5

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

Section of guidance/recordkeeping activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
4.1. and 6.4 SOPs for DMCs	37	1	37	8	296
4.4.3.2. DMC meeting records	370	1	370	2	740
Total					1,036

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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

Section of guidance/disclosure activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
4.4.1.2. Sponsor notification to the DMC regarding waivers	1	1	1	0.25 (15 minutes)	0.25
4.4.3.2. DMC reports of meeting minutes to the sponsor	370	2	740	1	740
Total					740.25

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

Dated: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-15-15UX: Docket No. CDC-2015-0011]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing efforts to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. This notice invites comment on “Continuing and New International and U.S. Data Collections from the 2014 CDC Ebola Virus Disease Emergency Response”. Under the current 60-day **Federal Register** Notice, the CDC is announcing its intention to seek three-year OMB approval to continue several Ebola-related information collections beyond their current emergency expiration dates and to conduct newly proposed information collections within international borders of Ebola-affected West African countries and within the domestic borders of State, Territorial and Local (STL) public health authorities in the U.S. These existing “source” information collections and new information collection requests (ICRs) will be submitted under four “destination” ICRs for Office of Management and Budget (OMB) approval.

DATES: Written comments must be received on or before May 26, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0011, by any of the following methods:

- *Federal eRulemaking Portal:* Regulation.gov. Follow the instructions for submitting comments.
- *Mail:* Leroy A. Richardson, Information Collection Review Office, Centers for Disease Control and

Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to Regulations.gov, including any personal information provided. For access to the docket to read background documents or comments received, go to Regulations.gov.

Please note: All public comment should be submitted through the Federal eRulemaking portal (Regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact the Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS-D74, Atlanta, Georgia 30329; phone: 404-639-7570; Email: omb@cdc.gov.

SUPPLEMENTARY INFORMATION: 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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or

provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information.

Proposed Project

Continuing and New International and U.S. Data Collections from the 2014 CDC Ebola Virus Disease Emergency Response—New—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The international outbreak of Ebola virus disease (EVD) in West Africa began March 10, 2014. The initial cases were from southern Guinea, near its rural border with Liberia and Sierra Leone. Highly mobile populations contributed to increasing waves of person-to-person transmission of EVD that occurred in multiple countries in West Africa. The Centers for Disease Control and Prevention (CDC) Emergency Operations Center (EOC) was activated on July 9, 2014, to help coordinate technical assistance and control activities with international partners and to deploy teams of public health experts to the affected countries.

The operations turned to the United States (U.S.) when the first imported case of EVD was diagnosed in Texas on September 30, 2014. In response, on October 11, 2014, the CDC Quarantine Stations and the Department of Homeland Security (DHS) Customs and Border Patrol (CBP) mobilized to screen, detect, and refer arriving travelers who were potential persons at risk for EVD to appropriate state, territorial, and local (STL) authorities. The CDC also increased its commitment to support STL public health authorities to combat and control the spread of EVD within their jurisdictions.

Thus in 2014, the CDC used OMB emergency clearance procedures to initiate and expedite multiple urgently needed information collections in West Africa, at U.S. ports of entry, and within STL jurisdictions. These procedures allowed the agency to accomplish its primary mission on many fronts to quickly prevent public harm, illness,