

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: September 25, 2019.

Virginia L. Mackay-Smith,

Associate Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-19-19AXA]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Annual Reporting of the Rape Prevention and Education (RPE) Program: CE19-1902 Cooperative Agreement" to the Office of Management and Budget (OMB) for review and approval. CDC previously

published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on June 5, 2019 to obtain comments from the public and affected agencies. One public comment public comment was received. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570 or send an email to omb@cdc.gov. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Annual Reporting of the Rape Prevention and Education (RPE) Program: CE19-1902 Cooperative Agreement—New—National Center for

Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC's Division of Violence Prevention (DVP) provides national leadership in prevention of sexual violence (SV) perpetration and victimization before it begins (*i.e.*, primary prevention). DVP administers the RPE Program, which provides funding to health departments in all 50 states, the District of Columbia (DC), Puerto Rico, Guam, the U.S. Virgin Islands, and the Commonwealth of Northern Mariana Islands. The CDC seeks OMB approval for three years to collect information related to implementation and outcomes annually from recipients funded under the Rape Prevention and Education (RPE): Using The Best Available Evidence for Sexual Violence Prevention cooperative agreement.

RPE Program recipients or designated delegates will submit data annually into the online data system, DVP Partners Portal. Recipients will monitor and report progress on their goals, objectives, and activities, as well as relevant information on the implementation of their prevention strategies, outcomes, evaluation, and state action plan.

Information to be collected will provide crucial data for program performance monitoring. Information collected will allow CDC to help ensure consistency in documenting, enhancing accountability of the use of federal funds, providing timely program reports and responses to information requests, such as Congressional requests mandated by the authorizing legislation, improve real-time communications between CDC and RPE recipients, and strengthening CDC's capacity to provide responsive data-driven technical assistance and to monitor and evaluate recipients' progress and performance.

Submission of the Annual Progress Report is required for cooperative agreement grantees. The total estimated annualized burden hours are 440. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
RPE-funded Health Departments (State, DC, and Territories) and their Designated Delegates.	Annual Reporting—Initial Population Annual Reporting—Subsequent Reporting	55 55	1 2	4 2

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3767]

Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Immunology Devices Panel of the Medical Devices Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on scientific issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 13 and 14, 2019, from 8 a.m. to 6 p.m.

ADDRESSES: Doubletree by Hilton DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. The hotel's website is at: <https://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-washington-dc-north-gaithersburg-GAIGWDT/index.html>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comments on this meeting. The docket number is FDA-2019-N-3767. The docket will close on December 16, 2019. Submit either electronic or written comments on this public meeting to the docket by December 16,

2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 16, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submission) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before October 28, 2019, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submission" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-3767 for "Immunology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.