

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships.

DATES: The meeting will be held on Thursday, November 15, 2018, from 8:30 a.m. to 2:45 p.m.

ADDRESSES: The meeting will be held at AHRQ, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: Jaime Zimmerman, Designated Management Official, at the Agency for Healthcare Research and Quality, 5600 Fishers Lane, Mail Stop 06E37A, Rockville, Maryland 20857, (301) 427-1456. For press-related information, please contact Karen Migdail at (301) 427-1855 or Karen.Migdail@ahrq.hhs.gov.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than Thursday, November 1, 2018. The agenda, roster, and minutes will be available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 5600 Fishers Lane, Rockville, Maryland 20857. Ms. Campbell's phone number is (301) 427-1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality. The National Advisory Council

for Healthcare Research and Quality is authorized by Section 941 of the Public Health Service Act, 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director of AHRQ on matters related to AHRQ's conduct of its mission including providing guidance on (A) priorities for health care research, (B) the field of health care research including training needs and information dissemination on health care quality and (C) the role of the Agency in light of private sector activity and opportunities for public private partnerships. The Council is composed of members of the public, appointed by the Secretary, and Federal ex-officio members specified in the authorizing legislation.

II. Agenda

On Thursday, November 15, 2018, the Council meeting will convene at 8:30 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The meeting is open to the public and will be available via webcast at www.webconferences.com/ahrq. The meeting will begin with an update on AHRQ's budget, programs and initiatives. The agenda will also include updates on AHRQ Data, Analytics, and Insights and AHRQ's Support of Secretary Priorities including, opioids, value, and drug pricing. The final agenda will be available on the AHRQ website at www.AHRQ.gov no later than Thursday, November 8, 2018.

Francis D. Chesley, Jr.,
Acting Deputy Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Information Collection for HHS Certification of Foreign Adult Victims of Human Trafficking.

OMB No.: 0970-0454.

Description: The Trafficking Victims Protection Act, Public Law 106-386 (TVPA) requires the Department of Health and Human Services (HHS) to certify adult alien ("foreign") victims of severe forms of trafficking in persons ("human trafficking") who are willing to assist law enforcement in the investigation and prosecution of human

trafficking, unless unable to cooperate due to physical or psychological trauma, and who have either made a bona fide application for T nonimmigrant status that has not been denied or been granted Continued Presence (CP) from the U.S. Department of Homeland Security (DHS). The Office on Trafficking in Persons (OTIP) within the HHS Administration for Children and Families issues HHS Adult Certification Letters that grant adult foreign victims of human trafficking eligibility for federal and state benefits and services to the same extent as refugees.

In general, OTIP initiates the certification process when it receives a notice from DHS that DHS has granted a foreign victim of trafficking CP or T nonimmigrant status, or has determined an application for T nonimmigrant status is bona fide. To issue HHS Adult Certification Letters, it is necessary for OTIP to collect information from a victim, or a victim's representative, such as an attorney, case manager, or law enforcement victim specialist, including an address to send the HHS Certification Letter.

OTIP will ask if the victim is in need of a case management services and the current location (city, state) of the victim, and refer the victim to an appropriate service provider in his or her area, if requested. OTIP will also ask about the victim's primary language and urgent concerns, such as medical care or housing, and transmit this information to the service provider with the victim's consent.

Finally, OTIP reports information on victim certification to provide to Congress in an annual report on U.S. Government activities to combat trafficking that is prepared by the U.S. Department of Justice. Congress requires HHS and other appropriate Federal agencies to report information on the number of persons who received benefits or other services under subsections (b) and (f) of section 7105 of Title 22 of the U.S. Code in connection with programs or activities funded or administered by HHS. HHS may include in these annual reports additional aggregate information that it collects about the victims when assisting each victim to obtain HHS Certification.

OTIP developed the form to facilitate the submission of consistent information and improve program reporting. The trafficking victim or his or her representative may submit the completed form, which we recommend be done via password-protected email or encryption, to OTIP for the purpose of issuing a Certification Letter. OTIP will store this information in OTIP's secure database for no longer than 10 years, at

which time it will be destroyed, unless required for business use by HHS. Other details maintained in the victim's file may include OTIP staff actions, referrals, and notes regarding the victim's interest in receiving services. Maintaining victim records within

OTIP's database will ensure efficient service delivery for victims, allow OTIP staff to track victims' progress toward certification, verify eligibility for benefits, and organize information for reporting aggregate data to Congress. *Respondents:* Nongovernmental entities providing social or legal

services, or victim/survivors of trafficking may use this form to submit a request for certification. The use of this form is optional; the victim or his/her representative has the option to make a request for certification via telephone or email.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
HHS Certification Instrument	800	1	.5	400

Estimated Total Annual Burden Hours: 400.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201. Attention Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: infocollection@acf.hhs.gov.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tropical Disease Priority Review Vouchers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 Tropical Disease Priority Review Vouchers.

DATES: Submit either electronic or written comments on the collection of information by January 7, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before January 7, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of January 7, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://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 Submissions" 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-2008-D-0530 for the "Tropical Disease Priority Review Vouchers." 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