

activities relevant to CER/PCOR training and whether those activities are increasing CER/PCOR capacity. Two surveys, each tailored for four respective PCORTF-TP respondent groups as well as key informant interviews will yield data on training activities, trainees' career plans, trainees' research and clinical activities relevant to CER/PCOR, and primary mentor experiences. The

surveys are designed to capture primarily quantitative data with some qualitative data. The interview guide is designed to collect qualitative data.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in this evaluation. The survey will be completed by approximately 288

awardees, scholars, principal investigators (PI), and mentors. The surveys will each require approximately 30 minutes to complete. The key informant interview will be conducted with approximately 13 PIs. These interviews are expected to take one hour each. The total hour burden is expected to be 150.5 hours for this participant data collection effort.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
K Awardee/K12 Scholar * Survey	147	1	0.5	73.5
K Awardee/K12 Primary Mentor Survey	128	1	0.5	64
Key Informant Interview Guide for K12 Program Directors	13	1	1	13
Total	288			150.5

* K Awardee/K12 Scholar survey = K01/K08/K99/K18 Awardees and K12 Scholars.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to participate in this

project. The total cost burden is estimated to be \$11,134.34.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
K Awardee/K12 Scholar Survey	147	73.5	*\$74.43	\$5,434.59
K Awardee/K12 Primary Mentor Survey	128	64	*74.43	4,732.16
Key Informant Interview Guide for K12 Program Directors	13	13	*74.43	967.59
	288	150.5		11,134.34

* Average hourly wage (\$73.94) based on the average annual salary for three categories of Health Specialties Teachers, Postsecondary (25-1071; Scientific Research and Development Services—\$178,090; General Medical and Surgical Hospitals—\$153,790; and Colleges, Universities, and Professional Schools—\$126,890). *Data Source:* National Occupational Employment and Wage Estimates in the United States, May 2018, "U.S. Department of Labor, Bureau of Labor Statistics" (available at http://www.bls.gov/oes/current/naics4_621400.htm).

Request for Comments

In accordance with the Paperwork Reduction Act, 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's 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: January 21, 2020.
Virginia L. Mackay-Smith,
Associate Director.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Domestic Victims of Human Trafficking Program Data (New Collection)

AGENCY: Office on Trafficking in Persons, Administration for Children and Families, HHS.

ACTION: Request for public comment.

SUMMARY: The Office on Trafficking in Persons (OTIP), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS) is proposing to collect data for the Domestic Victims of Human Trafficking Program (DVHT). The DVHT Program is inclusive of three distinct programs: The Domestic Victims of Human Trafficking and Services Outreach Program, Demonstration Grants to Strengthen the Response to Victims of Human Trafficking in Native Communities Program, and the Strengthen the Health Care Response for Victims of Human Trafficking Program grants. The data collection instruments are intended to collect information for all three DVHT programs.

DATES: *Comments due within 30 days of publication.* 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.

ADDRESSES: 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.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov*. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Trafficking Victims Protection Act of 2000, as amended, authorizes the Secretary of Health and Human Services to establish a program

to assist United States citizens and lawful permanent residents who are victims of severe forms of trafficking (22 U.S.C. 7105(f)). OTIP will award cooperative agreements to implement the DVHT program, which will include: (1) The Domestic Victims of Human Trafficking and Services Outreach Program, (2) Demonstration Grants to Strengthen the Response to Victims of Human Trafficking in Native Communities Program, and (3) the Strengthen the Health Care Response for Victims of Human Trafficking Program. Through the DVHT program, grantees will provide comprehensive case management to domestic survivors of severe forms of human trafficking in a traditional case management, Native community, or health care setting. The intent of the program is to connect survivors with the services they need to improve their lives and health outcomes.

OTIP proposes to collect information to measure grant project performance, provide technical assistance to grantees, assess program outcomes, improve

program evaluation, respond to congressional inquiries and mandated reports, and inform policy and program development that is responsive to the needs of victims.

The information collection captures information on participant demographics (e.g., age, sex, and country of origin); types of trafficking experienced (e.g., sex, labor, or both); types of enrollment; types of services requested and provided, along with their cost; barriers to service delivery; subrecipients enrolled into the grantee's network; victim outreach activities; and the types of training provided to subrecipient organizations or other partners.

Respondents: Domestic Victims of Human Trafficking and Services Outreach Program grantees, Demonstration Grants to Strengthen the Response to Victims of Human Trafficking in Native Communities Program grantees, and the Strengthen the Health Care Response for Victims of Human Trafficking Program grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Client Characteristics and Enrollment Form	1,908	1	1	1,908	636
Client Service Use and Delivery Form	1,908	3	.25	1,431	477
Client Case Closure Form	1,908	1	.167	319	106
Barriers to Service Delivery and Monitoring Form	36	15	.167	90	30
DVHT Spending Form	36	3	.75	81	27
Partnership Development and Expansion: Enrollment Form	25	1	.25	6	3
Partnership Development and Expansion: Exit Form	25	1	.083	2	1
Training Form	36	15	.5	270	90
Victim Outreach Reporting Form	36	15	.3	162	54

Estimated Total Annual Burden Hours: 1,424.

Authority: 22 U.S.C. 7105(f).

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-3090]

Hematologic Malignancies: Regulatory Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled "Hematologic Malignancies: Regulatory

Considerations for Use of Minimal Residual Disease in Development of Drug and Biological Products for Treatment." This guidance is intended to help sponsors planning to use minimal residual disease (MRD) as a biomarker in clinical trials conducted under an investigational new drug application (IND) or to support marketing approval of drugs and biological products for treating specific hematologic malignancies. An analysis of marketing applications showed inconsistent quality of MRD data. Based on this analysis and discussion at various public workshops on MRD, FDA identified a need to provide guidance on the use of MRD as a biomarker in regulatory submissions. This guidance finalizes the draft guidance of the same title issued on October 16, 2018.