

necessary information to improve program processes and operations in order to improve the quality of STD prevention and treatment.

The 4,500 respondents (who will engage in a total of 11,769 respondent instances) represent an average of the number of health professionals trained by PTC grantees during 2015. The evaluation instruments collect data on the impact of the training by the NNPTC. This data collection is necessary to assess and evaluate the performance of the grantees in delivering training, and to standardize training registration processes across the PTCs. The NNPTC Abbreviated HPAT allows CDC grantees to use a single instrument when collecting demographic data from its training and capacity building participants, regarding

their: (1) Occupations, professions, and functional roles; (2) principal employment settings; (3) location of their work settings; and (4) programmatic and population foci of their work. The NNPTC Abbreviated HPAT takes approximately three minutes to complete. This data collection provides CDC with information to determine whether the training grantees are reaching their target audiences in terms of provider type, the types of organizations in which participants work, the focus of their work and the population groups and geographic areas served.

The evaluation instruments are used to assess training and capacity-building outcomes (knowledge, confidence, intention to use information, actual changes made as a result of training)

immediately after and again 90 days after training events. The evaluation instruments vary based on the type of training offered and take between approximately 16 minutes to complete (for intensive multi-day trainings) to two minutes to complete (for short didactic or webinar sessions).

The CDC's Funding Opportunity Announcement PS 14-1407, National Network of Sexually Transmitted Diseases Clinical Prevention Training Centers (NNPTC) requires the collection of national demographic information on grantees' trainees and national evaluation outcomes. There are no costs to respondents other than their time. The estimated annualized burden hours for this data collection are 502 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)
Healthcare Professionals .....	NNPTC Abbreviated Health Professional Application for Training (HPAT).	4,500	1	3/60
Healthcare Professionals .....	Intensive Complete Post-Course Evaluation .....	116	1	16/60
	Intensive Complete Long-Term Evaluation .....	36	1	10/60
Healthcare Professionals .....	Intensive-Didactic Post-Course Evaluation .....	166	1	10/60
	Intensive-Didactic Long-Term Evaluation .....	58	1	7/60
Healthcare Professionals .....	Practicum Post-Course Evaluation .....	70	1	4/60
	Practicum Long-Term Evaluation .....	20	1	3/60
Healthcare Professionals .....	Wet Mount Post-Course Evaluation .....	40	1	3/60
	Wet Mount Long-Term Evaluation .....	15	1	2/60
Healthcare Professionals .....	STD Tx Guidelines Complete Post-Course Evaluation .....	548	1	6/60
	STD Tx Guidelines Complete Long-Term Evaluation .....	180	1	5/60
Healthcare Professionals .....	Short Guidelines Post-Course Evaluation .....	500	1	3/60
	Short Guidelines Long-Term Evaluation .....	160	1	3/60
Healthcare Professionals .....	Basic Post-Course Evaluation .....	150	1	2/60
	Basic Long-Term Evaluation .....	50	1	2/60
Healthcare Professionals .....	Immediate Post-Course email invitation .....	4,500	1	1/60
Healthcare Professionals .....	3 Month Long-Term email invitation .....	660	1	1/60

Jeffrey M. Zirger,

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-5971]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Recommendations To Reduce the Risk of Transfusion-Transmitted of Infection in Whole Blood and Blood Components; Agency Guidance**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of

information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Submit written comments (including recommendations) on the collection of information by May 4, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0681. Also include the FDA docket number found in

brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Recommendations To Reduce the Risk of Transfusion-Transmitted Infection in Whole Blood and Blood Components; Agency Guidance**

*OMB Control Number 0910–0681—Extension*

Under § 630.3(h) (21 CFR 630.3(h)), a list is set forth of relevant transfusion-transmitted infections (RTTIs) (§ 630.3(h)(1)) and the conditions under which a transfusion-transmitted infection (TTI) would meet the definition of an RTTI (§ 630.3(h)(2)). The list of RTTIs under § 630.3(h)(1) includes, among other things, the following: *Trypanosoma cruzi* (Chagas), Creutzfeldt Jacob Disease (CJD)/variant Creutzfeldt Jacob Disease (vCJD), *plasmodium* species (malaria), and West Nile virus. The RTTIs FDA has identified thus far under § 630.3(h)(2) include Zika virus and babesiosis. In addition, FDA has determined Ebola virus to be a TTI identified under § 630.3(l). FDA has issued several guidance documents with recommendations regarding the RTTIs or TTIs including Chagas, babesiosis, Zika virus, West Nile virus, Ebola virus, malaria, CJD and vCJD, human immunodeficiency virus (HIV) and human T-lymphotropic virus, types I and II (HTLV).

The Chagas, babesiosis, Zika virus, West Nile virus, and HTLV guidance documents provide recommendations for consignee and physician notification relating to donors that tested reactive for these infections.

In addition, a blood establishment may receive information from a donor following collection that reveals the donor had a risk factor for an RTTI or TTI at the time of collection and should have been deferred for the risk factor. FDA has recommended, in the following guidance documents, that such a blood collection establishment notify the consignee regarding the distributed blood components that are potentially at-risk for an RTTI or TTI. In some cases, we recommend that if the blood

was transfused, the consignee notify the transfusion recipient's physician of record regarding the potential risk. This recommendation is included in Ebola virus, malaria, CJD and vCJD, and HIV guidance documents. These guidance documents are available from our website at <https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances>.

In the *Federal Register* of January 7, 2020 (85 FR 716), we published a 60-day notice requesting public comment on the proposed collection of information. For purposes of estimating burden under the PRA, we provided an estimate of one response and one burden hour annually. As we discussed in our 60-day notice, although such notifications are rare, we believe that these notification practices would be part of the usual and customary business practice for blood establishments and consignees in addressing the RTTIs or TTIs under the regulations. In addition, we believe respondents would have already developed standard operating procedures for notifying consignees and the recipient's physician of record regarding distributed blood components potentially at risk for a TTI. No comments were received in response to our 60-day notice, and we therefore retain this estimate. As other relevant transfusion-transmitted infections are determined under § 630.3, we may continue to issue guidance accordingly, and, if approved, intend the information collections to be included under this OMB control number.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. These guidance documents, as applicable, also refer to previously approved FDA collections of information. The collections of information in 21 CFR parts 601 and 640, and Form FDA 356h have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

Dated: March 24, 2020.

**Lowell J. Schiller,**

*Principal Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2016–N–2066]

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by May 4, 2020.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review—Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910–0832. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Certification of Identity; Form FDA 3975**

*OMB Control Number 0910–0832—Extension*

This information collection supports Form FDA 3975 entitled “Certification of Identity,” which is used by FDA to identify an individual requesting a particular record under the Freedom of Information Act (FOIA) and the Privacy Act. The form is available from our website at: <https://www.fda.gov/>