

Dated: November 2, 2009.

**Marilyn S. Radke,**

*Reports Clearance Officer, Centers for Disease Control and Prevention.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

##### Proposed Projects

*Title:* Tax Refund Offset Program and Administrative Offset Program (TROP/ADOP).

*OMB No.:* 0970-0161.

*Description:* The Tax Refund Offset and Administration Offset Programs collect past-due child support by intercepting certain Federal payments, including Federal tax refunds, of parents who have been ordered to pay

child support and who are behind in paying the debt. The program is a cooperative effort among the Department of the Treasury's Financial Management Service (FMS), the Federal Office of Child Support Enforcement (OCSE), and State Child Support Enforcement (CSE) agencies. The Passport Denial program reports non-custodial parents who owe arrears above a threshold to the Department of State (DOS), which will then deny passports to these individuals. On an ongoing basis, CSE agencies submit to OCSE the names, Social Security numbers (SSNs), and the amount(s) of past-due child support of people who are delinquent in making child support payments.

*Respondents:* State IV-D Agencies

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Input Record .....	54	52	0.30	842.40
Output Record .....	54	52	0.46	1,291.68
Payment File .....	54	52	0.14	379.08
Certification Letter .....	54	1	0.40	21.60

Estimated Total Annual Burden Hours: 2,534.76

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

*The Department specifically requests comments 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) the quality, utility, and clarity of the information to be collected; and (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.

Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 3, 2009.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. E9-26852 Filed 11-6-09; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection; Comment Request; Clinical Trials Reporting Program (CTRP) Database (NCI)

*Summary:* In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Clinical Trials Reporting Program (CTRP) Database. *Type of Information Collection Request:* Revision of currently approved collection [OMB No. 0925-0600, expiration date 01/31/2010]. *Need and Use of Information Collection:*

The NCI is developing an electronic resource, the NCI Clinical Trials Reporting Program (CTRP) Database, to serve as a single, definitive source of information about all NCI-supported clinical research, thereby enabling the NCI to execute its mission to reduce the burden of cancer and to ensure an optimal return on the nation's investment in cancer clinical research. Information will be submitted by clinical research administrators as designees of clinical investigators who conduct NCI-supported clinical research. Deployment and extension of the CTRP Database, which will allow the NCI to consolidate reporting, aggregate information and reduce redundant submissions, is an infrastructure development project that will be enabled by public funds expended pursuant to the American Recovery and Reinvestment Act of 2009, Public Law 111-5 ("Recovery Act"). This information collection adheres to The Public Health Service Act, Section 407(a)(4) (codified at 42 USC 285a-2(a)(2)(D)), which authorizes and requires the NCI to collect, analyze and disseminate all data useful in the prevention, diagnosis, and treatment of cancer, including the establishment of an international cancer research data bank to collect, catalog, store, and disseminate insofar as feasible the results of cancer research undertaken in any country for the use of any person

involved in cancer research in any country. *Frequency of Response:* Once per initial trial registration; four amendments per trial annually; and four accrual updates per trial annually.

*Affected Public:* Individuals, business and other for-profits, and not-for-profit institutions. *Type of Respondents:* Clinical research administrators on behalf of clinical investigators. The

annual reporting burden is estimated at 38,500 hours.

There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

#### A.12-1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (minutes/hours)	Annual burden hours
Clinical Trials .....	Initial Registration .....	5,500	1	120/60	11,000.
	Amendment .....	5,500	4	60/60	22,000.
	Accrual Updates .....	5,500	4	15/60	5,500.
Total .....	.....	16,500			38,500.

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

*For Further Information Contact:* To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact John Speakman, Associate Director for Clinical Trials Products and Programs, Center for Biomedical Informatics and Information Technology, National Cancer Institute, NIH, DHHS, 2115 E. Jefferson Street, Suite 6000, Rockville, MD 20892 or call non-toll-free number 301-451-8786 or e-mail your request, including your address to: [john.speakman@nih.gov](mailto:john.speakman@nih.gov).

*Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: October 30, 2009.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison, National Institutes of Health.*

[FR Doc. E9-26875 Filed 11-6-09; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0233]

#### Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion," dated November 2009. This guidance is intended for establishments that collect Whole Blood and blood components intended for transfusion. The document provides recommendations for testing of donations of Whole Blood and blood components for West Nile Virus (WNV) using an FDA-licensed donor screening assay. FDA believes that the use of a licensed nucleic acid test (NAT) will reduce the risk of transmission of WNV, and therefore recommends use of a licensed NAT to screen donors of Whole Blood and blood components intended for transfusion. The guidance announced in this notice finalizes the recommendations as to Whole Blood and blood components contained in the draft guidance "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion and Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products

(HCT/Ps)," dated April 2008. The recommendations as to HCT/P donor specimens contained in the draft guidance are not being finalized at this time because FDA believes additional public discussion is warranted.

**DATES:** Submit electronic or written comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to <http://www.regulations.gov>. Submit written comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Denise Sánchez, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a document entitled "Guidance for Industry: Use of Nucleic Acid Tests to Reduce the Risk of Transmission of West Nile Virus from Donors of Whole Blood and Blood Components Intended for Transfusion," dated November 2009. The guidance document provides