

## ANNUAL BURDEN ESTIMATES

| Instrument     | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|----------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| OCSE-157 ..... | 54                    | 1                                  | 7                                 | 378                |

*Estimated Total Annual Burden Hours: 378.*

**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](mailto: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](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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**BILLING CODE 4184-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Strengthening Relationship Education and Marriage Services (STREAMS) Evaluation (OMB#0970-0481)

**AGENCY:** Office of Planning, Research, and Evaluation, Administration for Children and Families, HHS.

**ACTION:** Request for Public Comment.

**SUMMARY:** The Office of Family Assistance (OFA) within the Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services has issued grants to organizations to provide healthy marriage and relationship education (HMRE) services. Under a previously approved data collection activity (OMB#0970-0481), the Office of Planning, Research, and Evaluation (OPRE) within ACF is conducting the Strengthening Relationship Education and Marriage Services (STREAMS) evaluation with five HMRE grantees. The purpose of STREAMS is to measure the effectiveness and quality of HMRE programs designed to strengthen intimate relationships. This data collection request is for an extension of previously approved data collection instruments and for two additional data collection instruments.

**DATES:** *Comments due within 60 days of publication.* In compliance with the requirements of Section 3506(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.

**ADDRESSES:** 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 Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

#### SUPPLEMENTARY INFORMATION:

**Description:** The STREAMS evaluation includes two components, an impact study and a process study. The evaluation will examine HMRE programs for youth in high school, adult couples, and adult individuals.

1. **Impact Study.** The goal of the impact study is to provide rigorous estimates of the effectiveness of program services and interventions to improve program implementation. The impact study uses an experimental design. Eligible program applicants are randomly assigned to either a program group that is offered program services or a control group that is not. STREAMS collects baseline information from eligible program applicants prior to random assignment and administers a follow-up survey to participants 12 months after random assignment.

2. **Process study.** The goal of the process study is to support the interpretation of impact findings and document program operations to support future replication. STREAMS conducts semi-structured interviews with program staff and selected community stakeholders, conducts focus groups with program participants, administers a survey to program staff, and collects data on adherence to program curricula through an add on to an existing program MIS (nFORM, OMB no. 0970-0460).

This data collection request is for an extension of previously approved data collection instruments for the impact study and for two additional data collection instruments associated with the impact study. The two additional instruments will allow for longer-term follow-up in two of the five evaluation sites. (1) The second follow-up survey for youth will be administered approximately 24 to 36 months after random assignment to study participants in the STREAMS site serving youth. (2) The second follow-up survey for adults will be administered approximately 30 months after random assignment to study participants in one of the STREAMS evaluation sites serving adults.

**Respondents:** Study participants.

## ANNUAL BURDEN ESTIMATES

| Instrument   | Total number of respondents | Annual number of respondents | Number of responses per respondent | Average burden hours per response | Annual burden hours |
|--|-----------------------------|------------------------------|------------------------------------|-----------------------------------|---------------------|
| Previously Approved Burden that Remains            |                             |                              |                                    |                                   |                     |
| Introductory script, grantee staff .....           | 8                           | 8                            | 25                                 | 0.08                              | 16                  |
| Introductory script, program applicants .....      | 600                         | 200                          | 1                                  | 0.08                              | 16                  |
| Add-on to nFORM to conduct random assignment ..... | 8                           | 8                            | 25                                 | 0.08                              | 16                  |
| Follow-up survey for youth .....                   | 690                         | 230                          | 1                                  | 0.5                               | 115                 |
| Baseline survey for adults .....                   | 600                         | 200                          | 1                                  | 0.5                               | 100                 |
| Follow-up survey for adults .....                  | 2,300                       | 767                          | 1                                  | 0.75                              | 575                 |
| Current Request for Approval                       |                             |                              |                                    |                                   |                     |
| Second follow-up survey for youth .....            | 1,500                       | 500                          | 1                                  | 0.5                               | 250                 |
| Second follow-up survey for adults .....           | 800                         | 267                          | 1                                  | 0.75                              | 200                 |
| Estimated Total Annual Burden Hours: .....         |                             |                              |                                    |                                   | 1,288               |

*Comments:* 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.

**Authority:** 42 U.S.C. 603; Sec. 811 (b) Healthy Marriage Promotion and Promoting Responsible Fatherhood Grants of the Claims Resolution Act of 2010, Pub. L. No. 111–291, 124 Stat. 3064

**Mary B. Jones,**

*ACF/OPRE Certifying Officer.*

[FR Doc. 2018–26450 Filed 12–4–18; 8:45 am]

**BILLING CODE 4184–73–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2014–D–1814]

#### **Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services To Enhance the Safety and Availability of Platelets for Transfusion; Draft 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 draft document entitled “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Draft Guidance for Industry.” The draft guidance document provides blood collection establishments and transfusion services with recommendations to control the risk of bacterial contamination of room temperature stored platelets intended for transfusion. The guidance provides recommendations for all platelet products, including platelets manufactured by automated methods (apheresis platelets), whole blood derived (WBD) platelets, pooled platelets (pre-storage and post-storage) and platelets stored in additive solutions. The draft guidance replaces the draft guidance of the same title dated March 2016.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 4, 2019. Submit either electronic or written comments on the draft guidance by February 4, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

**ADDRESSES:** You may submit comments on any guidance at any time as follows:

#### *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–2014–D–1814 for “Bacterial Risk Control Strategies for Blood Collection