

ANNUAL BURDEN ESTIMATES

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Verification of Release (Form R-1)	300	428	0.17	21,828
Discharge Notification (Form R-2)	300	487	0.25	36,525
ORR Release Notification—ORR Notification to ICE Chief Counsel Release of UC to Sponsor and Request to Change Address (Form R-3)	300	440	0.08	10,560
Release Request (Form R-4)—Care Provider	300	430	0.58	74,820
Release Request (Form R-4)—Case Coordinator	170	756	0.50	64,260
Virtual Check-In Questionnaire (R-6)—Sponsor	128,487	3	0.25	96,365
Virtual Check-In Questionnaire (R-6)—Child	128,487	3	0.25	96,365
Virtual Check-In Questionnaire (R-6)—PRS Provider	40	19,273	0.58	447,134
Discharge Plan (Form R-9)	300	11	2.00	6,600

Estimated Annual Burden Hours
Total: 854,457.

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: 6 U.S.C. 279; 8 U.S.C. 1232; *Flores v. Reno* Settlement Agreement, No. CV85-4544-RJK (C.D. Cal. 1996).

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Mental Health Assessment Form and Public Health Investigation Forms, Tuberculosis and Non-Tuberculosis Illness (Office of Management and Budget 0970-0509)

AGENCY: Office of Refugee Resettlement, Administration for Children and Families, United States Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension of the Mental Health Assessment Form (formerly the Health Assessment Form) and Public Health Investigation Forms, Active Tuberculosis (TB) and Non-TB Illness (Office of Management and Budget (OMB) #0970-0509, expiration December 31, 2023). Changes are proposed to the currently approved forms.

DATES: *Comments due within 30 days of publication.* OMB must make a decision about 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 within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function. You can also obtain copies of the proposed collection of information by emailing infocollection@acf.hhs.gov. Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION: The ACF Office of Refugee Resettlement (ORR) places unaccompanied children in their custody in care provider programs until unification with a qualified sponsor. Care provider programs are required to provide children with a range of services including medical, dental, and mental health care. While in ORR care, children meet with onsite mental health counselors on a regular basis. If a child is identified as potentially having a more serious mental health condition, they are referred to a psychiatrist,

psychiatric nurse practitioner or physician's assistant, licensed psychologist, or any other community-based licensed mental health provider (e.g., social worker).

The Mental Health Assessment form is used as a worksheet for mental health specialists to compile information that would otherwise have been collected during the evaluation. Once completed, the form is given to care provider program staff for entry into ORR's secure, electronic data record system. Data is used to monitor the health of unaccompanied children while in ORR care and for case management of any identified conditions.

Children may be exposed to nationally reportable infectious diseases during the journey to the U.S., while in the custody of the Customs and Border Protection after crossing the border, or during their stay in ORR custody. Public health interventions such as quarantine, vaccination or lab testing may be initiated to reduce possible disease transmission. Following an exposure, children are assessed onsite by care provider program staff and if found to be symptomatic, referred to a healthcare provider for evaluation.

The Public Health Investigation Forms are used as worksheets by care provider program staff to record their findings when an exposure has been reported. Once completed, they will enter the data into ORR's secure data record system. Data is used to track disease transmission and health outcomes of children in ORR care.

ORR has repurposed the former Health Assessment Form from a medical and mental health information collection to a mental health collection only, and renamed it, the Mental Health Assessment Form. ORR has incorporated other changes to the forms to streamline the flow of data collection, clarify the intent of certain fields, improve data quality, and ensure alignment with ORR requirements. In

addition, ORR has written an instructional letter for the Mental Health Assessment Form to explain the purpose of the form and provide general

guidance on completion to healthcare providers.

Respondents: Mental health professionals (psychiatrists, psychiatric nurse practitioners or physician's

assistants, licensed psychologist or any other community based licensed mental health provider (*e.g.*, social worker)), care provider program staff.

Annual Burden Estimates

ESTIMATED OPPORTUNITY TIME FOR RESPONDENTS

Instrument	Respondent	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Mental Health Assessment Form	Mental health professionals	500	6.8	0.18	612
Public Health Investigation Form: Active TB.	Care provider program staff	500	1	0.08	400
Public Health Investigation Form: Non-TB Illness.		500	200	0.08	8,000

Estimated Total Annual Burden Hours: 9,012.

ESTIMATED RECORDKEEPING TIME

Instrument	Respondent	Annual number of respondents	Total number of responses per respondent	Average burden hours per response	Annual burden hours
Mental Health Assessment Form	Care provider program staff	500	6.8	0.21	714
Public Health Investigation Form: Active TB		500	1	0.08	400
Public Health Investigation Form: Non-TB Illness		500	200	0.08	8,000

Estimated Total Annual Burden Hours: 9,114.

Authority: 6 U.S.C. 279; Exhibit 1, part A.2 of the Flores Settlement Agreement (*Jenny Lisette Flores, et al., v. Janet Reno, Attorney General of the United States, et al.*, Case No. CV 85–4544–RJK [C.D. Cal. 1996])

Mary B. Jones,

ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 060

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a publication containing

modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled “Modifications to the List of Recognized Standards, Recognition List Number: 060” (Recognition List Number: 060), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable August 7, 2023.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards 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