

Instrument	Respondent	Number of respondents (total over request period)	Number of responses per respondent (total over request period)	Average burden per response (in hours)	Total burden (in hours)	Annual burden (in hours)
1: Applicant Characteristics .....	Program applicants .....	150,000	1	0.25	37,500	12,500
	Program staff .....	330	455	0.10	15,015	5,005
2: Program Operations .....	Program staff .....	110	12	0.32	422	141
3: Service Delivery Data .....	Program staff .....	1,650	86	0.50	70,950	23,650
4: Entrance and Exit Surveys .....	Program clients (entrance) .....	141,498	1	0.42	59,429	19,810
	Program clients (exit) .....	94,734	1	0.42	39,788	13,263
	Program staff (entrance and exit on paper) .....	220	351	0.10	7,722	2,574
5: Semi-annual Performance Progress Report (PPR) .....	Program staff .....	110	6	3	1,980	660
6: Quarterly Performance Report (QPR) .....	Program staff .....	110	6	1	660	220
7: CQI Plan .....	Program staff .....	110	3	4	1,320	440

*Estimated Total Annual Burden*

*Hours: 78,263.*

*Authority: Sec. 403. [42 U.S.C. 603].*

**Mary C. 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; Administration for Children and Families Generic for Engagement Efforts (New Umbrella Generic)

**AGENCY:** Administration for Children and Families, Department of Health and Human Services.

**ACTION:** Request for public comments.

**SUMMARY:** The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) intends to request approval from the Office of Management and Budget (OMB) to establish a new umbrella generic clearance to request information while engaging individuals and groups who could provide valuable information to inform ACF programs and work, including but not limited to those who are served or have been served by ACF, those with expertise in ACF program areas, and individuals invested in the outcomes of ACF research and evaluation. These engagement activities often need to be conducted quickly, to allow for sufficient time to inform project direction and decision-making. Additionally, planning for engagement activities is most often on a quick timeline and the standard timeline to comply with a full request under the Paperwork Reduction Act (PRA) often inhibits the ability to collect

information to inform these activities.

Therefore, an umbrella generic is necessary to allow for quick turnaround requests for similar information collections related to these activities.

**DATES:** *Comments due within 30 days of publication.* OMB must decide 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](http://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 [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). Identify all requests by the title of the information collection.

#### SUPPLEMENTARY INFORMATION:

**Description:** The Executive Order (E.O.), Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (E.O. 13985) <sup>1</sup> emphasizes consulting with communities that have been historically underserved by Federal policies and programs and those with lived experience <sup>2</sup> in ACF programs. The E.O. on Further Advancing Racial Equity and Support for Underserved Communities

<sup>1</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

<sup>2</sup> Assistant Secretary for Planning and Evaluation. (2021, December). *Methods and Emerging Strategies to Engage People with Lived Experience*. (Contract Number HHSP2332015000711). U.S. Department of Health and Human Services. <https://aspe.hhs.gov/sites/default/files/documents/47f62cae96710d1fa13b0f590f2d1b03/lived-experience-brief.pdf>.

Through the Federal Government <sup>3</sup> followed in 2023 and built on E.O. 13985, calling upon agencies to increase engagement with underserved communities and to “collaborate with OMB, as appropriate, to identify and develop tools and methods” to meet this goal. This generic mechanism is a tool that could directly address these E.O.s. Particularly many requirements outlined in section 3 and section 5 of the 2023 E.O.

Additionally, the Presidential Memorandum on Restoring Trust in Government through Scientific Integrity and Evidence-Based Policy Making, <sup>4</sup> the HHS Strategic Plan fiscal year (FY) 2022–2026, <sup>5</sup> ACF’s Strategic Plan, <sup>6</sup> and the ACF Evaluation Policy <sup>7</sup> discuss community engagement and inclusion in research. Consistent with these guidance documents, and to ensure meaningful involvement with a variety of individuals with diverse experiences and perspectives, ACF often conducts active engagement activities to inform various efforts, including research and evaluation.

Hearing the perspective of those affected by, experienced in, interested in, or potentially interested in ACF programs and similar programs is vital to ensure ACF is responsive to the needs of those it serves and that resources are, and programming is appropriate, useful, and relevant for audiences. Information collections under this generic would gather information from individuals

<sup>3</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/02/16/executive-order-on-further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

<sup>4</sup> <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/27/memorandum-on-restoring-trust-in-government-through-scientific-integrity-and-evidence-based-policy-making/>.

<sup>5</sup> <https://www.hhs.gov/about/strategic-plan/2022-2026/index.html>.

<sup>6</sup> <https://www.acf.hhs.gov/about/acf-strategic-plan-2022>.

<sup>7</sup> <https://www.acf.hhs.gov/opre/report/acf-evaluation-policy>.

with diverse experiences and perspectives to inform ACF policies and programs. The information collected would allow for ongoing, two-way collaborative and actionable communications between ACF and its State, local and/or Tribal partners, program participants, communities served or affected by ACF programs, and or others experienced with or interested in ACF programs or similar programs.

ACF envisions using information collected to inform a variety of efforts and activities such as the improvement, planning, and implementation of research studies, program changes, development and dissemination of resources and products developed under ACF studies, regulatory activities, guidance, outreach and/or training activities. The specific types of information gathering methods included under the umbrella of this clearance will vary, but will use well-established methodologies, including but not limited to:

- Semi-structured discussions or conference calls
- Focus groups
- Telephone or in-person interviews
- Questionnaires/Surveys
- Roundtable and/or Breakout Sessions
- Open-ended requests
- Contextualizing Existing Data

Data collection will take place through a variety of activities—both in-person and virtual—dependent on the specific project. ACF will submit individual requests under this clearance. ACF requests OMB provide a response on individual generic information collections within 10 business days.

**Respondents:** Respondents could include current or prospective service providers, training and technical assistance providers, grant recipients, contractors, current and potential participants in ACF programs or other comparable groups and other individuals with lived experience with ACF or similar programs, experts in

fields pertaining to ACF programs, other key groups involved in ACF projects and programs, individuals engaged in program re-design or demonstration development for evaluation, State or local government officials, those in broader fields of study related to human services, or others involved in or prospectively involved in ACF programs.

**Burden Estimates:** The burden table below is illustrative. Estimates for the number of respondents and time per response have been made based on discussion with ACF program offices, but as this is a new umbrella generic, it may be possible that we will need to adjust estimates throughout the three-year approval period. If needed, ACF will submit a change request for these updates. While we will not exceed the total burden cap for this generic without requesting a change for updates, we may use more or less burden within each instrument type.

Example types of information collections	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours
Semi-Structured Discussions and Focus Groups .....	10,000	1	2	20,000
Interviews .....	4,500	1	1	4,500
Questionnaires/Surveys .....	8,000	1.5	.5	6,000
Templates and Open-ended requests .....	1,000	1	10	10,000
Estimated Totals .....	23,500	.....	.....	40,500

**Mary C. Jones,**

*ACF/OPRE Certifying Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2023-D-5259]

#### Master Protocols for Drug and Biological Product Development; Draft Guidance for Industry; Extension of Comment Period

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

**ACTION:** Notice of availability; extension of comment period.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that published in the **Federal Register** of December 22, 2023. In that notice, FDA requested comments on the draft guidance for industry entitled, “Master Protocols for

Drug and Biological Product Development.” The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

**DATES:** FDA is extending the comment period on the draft guidance published December 22, 2023 (88 FR 88623). Submit either electronic or written comments by March 21, 2024, to ensure that the Agency considers your comments 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