Instrument	Total number of respondents	Total annual number of responses per respondent	Average burden hours per response	Total burden hours
Annex I: Transmittal form under Article 12(2)	54	37	1	1,998
Annex II: Acknowledgment form under Article 12(3)	54	74	0.5	1,998
Annex A: Application for Recognition and Enforcement, including restricted information on the applicant	54	15	0.5	405
Annex A: Abstract of Decision	54	4	1	216
Annex A: Statement of Enforceability of Decision	54	15	0.17	138
Annex A: Statement of Proper Notice	54	4	0.5	108
Annex A: Status of Application Report—Article 12	54	30	0.33	535
Annex B: Application for Enforcement of a Decision Made or Recognized in the Requested State, including restricted information on the applicant	54	15	0.5	405
Annex B: Status of Application Report—Article 12	54	30	0.33	535
Annex C: Application for Establishment of a Decision, including restricted information on the Applicant	54	4	0.5	108
Annex C: Status of Application Report—Article 12	54	7	0.33	125
Annex D: Application for Modification of a Decision, including Restricted Information on the Applicant	54	4	0.5	108
Annex D: Status of Application Report—Article 12	54	7	0.33	125
Annex E: Financial Circumstances Form	54	37	2	3,996
Annex F: Request for Specific Measures—Article 7(1)	54	2	0.17	18
Annex F: Request for Specific Measures—Response—Article 7(1)	54	7	0.17	64
Estimated Total Annual Burden Hours:				10,882

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. 654(20) and 666(f)

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–19045 Filed 9–29–25; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB #: 0970–0554]

Expedited Office of Management and Budget Review and Public Comment: Placement and Transfer of Unaccompanied [Alien] Children Into ORR Care Provider Facilities

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

ACTION: Request for public comments.

SUMMARY: The Office of Refugee Resettlement (ORR), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is requesting expedited review of an information collection request from the Office of Management and Budget (OMB) and inviting public comments on the proposed collection. This request will ensure that ORR can continue to properly enact its mandates and comply with all applicable authorities related to the placement of unaccompanied alien children into a restrictive placement.

DATES: *Comments due December 1, 2025.*

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: ACF is requesting that OMB grant a 180-day approval for this request under procedures for expedited processing (*see* 5 CFR 1320.13). In compliance with the PRA, ACF will request review under normal procedures within 180 days of the approval for this request. Any edits resulting from public comment will be incorporated into the submission under normal procedures.

ORR is proposing the below-listed changes to the *Notice of Placement in a Restrictive Setting (Form P–4) and Unaccompanied [Alien] Child Referral (aka Intakes Placement Checklist) (Form P–7).* The proposed changes are related to current administration priorities, to align the placement criteria in forms with the criteria found in 45 CFR 410.1105 and UAC Policy Guide sections 1.2.4 and 1.4.6 and to meet requirements in the *Lucas R.* Disabilities Settlement Agreement (Case No. 2:18–CV–05741 DMG PLA), and *Flores* litigation (Case No. CV85–4544–RJK (C.D. Cal. 1996)). Some of these are nonsubstantive in nature but are being submitted with the items that warrant emergency approval to ensure all updates are reviewed and approved and ready for use as soon as possible.

Global Terminology Updates

Update terminology to align with ORR regulations and to comply with Executive Order 14168 *Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,* as well as other guidance from the current Administration.

Notice of Placement in a Restrictive Setting (Form P–4)

- Reorganize where some information/fields appear in the form for clarity.
- Add a ''Disability Considerations'' subsection in ''Section B: Placement Information'' to meet requirements found in the *Lucas R.* Disabilities Settlement Agreement.
- Remove ''Section B: ORR's Determination Related to Safety'' to align the form with ORR's regulation and policy guide.
- Update ''Section C: Reasons for Restrictive Placement'' to align the placement criteria in the form with ORR's regulation and policy guide and to comply with *Flores* litigation requirements.
- Add ''Translation'' subsection to ''Section E: Acknowledgement and Certification'' to help ORR monitor form compliance with translation requirements in its regulation.

Unaccompanied [Alien] Child Referral (aka Intakes Placement Checklist) (Form P–7)

ORR has two versions of Form P–7 approved under this information collection. The first version, titled Unaccompanied [Alien] Child Referral, was created for the UAC Path system, which was never implemented. The second version, titled Intakes Placement Checklist, is a PDF version that is currently in use. ORR is only proposing revisions to the PDF version of this form.

- Change form title from ''Intakes Placement Checklist'' to ''Intakes Restrictive Placement Checklist'' to better align the form's title with its purpose.
- Reorganize ''Section B: Heightened Supervision Facility Criteria'' and ''Section C: Secure Facility Criteria'' for clarity.
- Update criteria and supporting factors in Sections B and C to align with ORR's regulation and policy guide.
- Add follow-up questions in Sections B and C to document what information was relied on the make the placement determination and clarify whether each placement criterion was met.
- Reword field labels and add a field to document the reason for the recommended level of care in ''Section D: Placement Determination''

Respondents: ORR grantee and contractor staff; unaccompanied alien children; and other federal agencies.

Annual Burden Estimates: These burden estimates include burden related to the revisions described above and currently approved forms for which we are not proposing any changes. ORR updated the burden hours for all forms to reflect a decrease in the number of children referred to ORR and a decrease in the number of care provider facilities. In the materials for submission to OMB, ORR also updated the estimated costs for all forms to reflect more recent wage data from the Bureau of Labor Statistics. Finally, ORR updated the average burden hours per response for the Notice of Placement in a Restrictive Setting (Form P–4) from 0.33 hours to 0.5 hours.

Information collection title	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual total burden hours
Placement Authorization (Form P–1)	220	446	0.08	7,850
Authorization for Medical, Dental, and Mental Health Care (Form P–2)	220	446	0.08	7,850
Notice of Placement in a Restrictive Setting (Form P–4)	6	83	0.50	249
Long Term Foster Care Placement Memo (Form P–5)	115	7	0.25	201
Unaccompanied [Alien] Child Referral (aka Intakes Restrictive Placement Checklist) (Form P–7)	40	2,394	1.00	95,760
Care Provider Checklist for Transfers to Influx Care Facilities (Form P–8)	220	2	0.25	110
Medical Checklist for Non-Influx Transfers (Form P–9A)	220	8	0.08	141
Medical Checklist for Transfers to Influx Care Facilities (Form P–9B)	220	5	0.17	187
Transfer Request (Form P–10A)—Grantee Case Manager	220	11	0.25	605
Transfer Request (Form P–10A)—Contractor Case Coordinator	275	11	0.17	514
Placement Confirmation (Form P–10B)—Grantee Case Manager	220	11	0.17	411
Placement Confirmation (Form P–10B)—Contractor Case Coordinator	275	11	0.17	514
Transfer Summary and Tracking (Form P–11)	220	11	0.17	411
Bed Configuration Module (Form P–12A)	220	12	0.17	449
Bed Assignment and Capacity Overview Module (Form P–12B)	220	435	0.17	16,269
Program Entity (Form P–12C)	220	12	0.50	1,320
Unaccompanied [Alien] Child Profile (Form P–13)	220	435	0.75	71,775
ORR Transfer Notification—ORR Notification to Immigration and Customs Enforcement Chief Counsel of Transfer of UC and Request to Change Address/Venue (Form P–14)	220	11	0.17	411
Family Group Entity (Form P–15)	40	75	0.08	240
Influx Transfer Manifest (Form P–16)	3	12	0.33	12
Influx Transfer Manual and Prescreen Criteria Review (Form P–17)	220	52,232	0.50	5,745,520
Notice of Administrative Review (Form P–18)	200	1	0.83	166
Estimated Annual Burden Hours Total				5,950,965

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; 45 CFR part 410; *Flores* v. *Reno* Settlement Agreement (No. CV85–4544–RJK (C.D. Cal. 1996)); *Lucas R. et al.* v. *Becerra et al.* Disabilities Settlement Agreement (Case No. CV 18–5741–DMG (PLAx))

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–18927 Filed 9–29–25; 8:45 am]

BILLING CODE 4184–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–3023]

E20 Adaptive Designs for Clinical Trials; International Council for Harmonisation; 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 guidance for industry entitled ''E20 Adaptive Designs for Clinical Trials.'' The draft guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The draft guidance is intended to provide a transparent and harmonized set of recommendations for clinical trials with an adaptive design. The draft guidance focuses on principles for the planning, conduct, analysis, and interpretation of clinical trials with an adaptive design that aim to confirm the efficacy and support the benefit-risk assessment of a treatment. The draft guidance emphasizes principles that are critical for ensuring clinical trials produce reliable and interpretable results and that involve specific considerations with use of an adaptive design.

DATES: Submit either electronic or written comments on the draft guidance by December 1, 2025 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–2025–D–3023 for ''E20 Adaptive Designs for Clinical Trials.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. The guidance may also be obtained by mail by calling Center for Biologics Evaluation and Research at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: *Regarding the guidance:* Gregory Levin, Center for Drug Evaluation and Research, Food and Drug Administration, 301–796–4228, *Greg.Levin@fda.hhs.gov;* or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–7911.

Regarding the ICH: Brooke Dal Santo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6304, Silver Spring,