public health outcomes such as mortality, suicide, substance abuse, hospitalization, and use of services; rates of incarceration by patients; rates of homelessness among patients; and patient and family satisfaction with program participation. The data collected under this submission will help ASPE address the evaluation questions listed above and inform the required reports to Congress.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS TO RESPONDENTS

Forms	Respondents	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total annual burden (hours)
Client Interview Instrument	Program Participant	520	3	1.00	1560.00
	Comparison Subjects	520	3	1.00	1560.00
Family Satisfaction Survey	Program Participant's Family Member.	173	1	15/60	43.25
Cost Questionnaire	Program Administrator	6	1	1.25	7.50
	Other Site Representatives	12	1	1.25	15.00
Docket Case Monitoring Form	AOT Local Evaluator	6	390	6/60	234.00
AOT Characteristics Form	AOT Local Evaluator	6	12	30/60	36.00
Total		1,243	411	0.76	3,455.75

Terry Clark,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

[FR Doc. 2018–10512 Filed 5–16–18; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. FDA–2016–D–1605]

Institutional Review Board Written Procedures: Guidance for Institutions and Institutional Review Boards; Availability

AGENCY: The Office for Human Research Protections, Office of the Assistant Secretary for Health, Office of the Secretary, and the Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health, and the Food and Drug Administration (FDA) are announcing the availability of a guidance entitled ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' The guidance is intended for institutions and IRBs responsible for review and oversight of human subject research under the Department of Health and Human Services (HHS) and FDA regulations. The purpose of this guidance is to assist staff at institutions and IRBs who are responsible for preparing and maintaining written procedures. The guidance announced in this notice finalizes the draft guidance of the same title dated August 2016.

DATES: The announcement of the guidance is published in the **Federal Register** on May 17, 2018.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–2016–D–1605 for ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' 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.

- 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.gpo.gov/fdsys/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.

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 guidance to the Office of Good Clinical Practice (OGCP), Office of Special Medical Programs, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993; or Division of Policy and Assurances, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling OGCP at 301–796–8340 or OHRP at 240–453–6900 or 866–447–4777. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Janet Donnelly, Office of Good Clinical Practice, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5167, Silver Spring, MD 20993, 301–796–4187; or Irene Stith-Coleman, Office for Human Research Protections, 1101 Wootton Pkwy., Suite 200, Rockville, MD 20852, 240–453–6900.

SUPPLEMENTARY INFORMATION:

I. Background

OHRP and FDA are announcing the availability of a guidance document entitled ''Institutional Review Board (IRB) Written Procedures: Guidance for Institutions and IRBs.'' OHRP and FDA frequently receive questions about the scope and content of written procedures. We created a Written Procedures Checklist (also referred to as the Checklist) to assist institutions and IRBs in preparing and maintaining written procedures. The Checklist is designed to prompt a thorough evaluation of written procedures that help to ensure the protection of human research subjects. The Checklist incorporates the HHS and FDA regulatory requirements in 45 CFR 46.103(b)(4) and (5) and 21 CFR 56.108(a) and (b) for written procedures for the IRB and recommendations about operational details to include to support each of these requirements. In addition, the Checklist identifies some additional topics the institution/IRB may consider when developing comprehensive procedures. This guidance supersedes OHRP's July 1, 2011, ''Guidance on Written IRB Procedures'' and FDA's 1998 ''Appendix H: A Self-Evaluation Checklist for IRBs'' (formerly part of FDA's Information Sheet Guidance for IRBs, Clinical Investigators, and Sponsors).

This document is a final guidance document, based on the Agencies' review of submitted comments. The Agencies are always open to additional comments on this and other Agency guidance.

To enhance human subject protection and reduce regulatory burden, OHRP and FDA have been actively working to harmonize the Agencies' regulatory requirements and guidance for human subject research. This guidance document was developed as a part of these efforts. In addition, on December 13, 2016, the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) was signed into law. Title III, section 3023 of the Cures Act requires the Secretary of HHS to harmonize differences between the HHS human subject regulations and FDA's human subject regulations. This guidance document is consistent with the goals of section 3023 of the Cures Act.

In the **Federal Register** of August 2, 2016 (81 FR 50711), OHRP and FDA announced the availability of a draft guidance of the same title dated August 2016. OHRP and FDA received several comments on the draft guidance, and considered all comments in finalizing this guidance. OHRP and FDA revised the guidance to clarify which written procedures are specifically required, and which are recommended. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated August 2016.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of OHRP and FDA on written procedures for institutions and IRBs. It does not establish any rights for any person and is not binding on OHRP, FDA, or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 21 CFR 56.115, including the information collection activities in the provisions in 21 CFR 56.108(a) and (b), have been approved under OMB control numbers 0910–0755 and 0910–0130. The collections of information referenced in this guidance that are related to IRB recordkeeping requirements under 45 CFR 46.115, including the information collection activities in the provisions in 45 CFR 46.103(b)(4) and (5) have been approved under OMB control number 0990–0260.

III. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/alphabetical-list/index.html,* or *https://www.regulations.gov.*

Dated: April 27, 2018.

Brett P. Giroir,

ADM, USPHS, Assistant Secretary for Health.

Dated: May 9, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–10441 Filed 5–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0260]

Agency Information Collection Request. 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.