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.

DATES: Comments on the ICR must be received on or before June 18, 2018.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–New–30D and project title for reference., to *Sherrette.funn@hhs.gov,* or call the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: 0990–0260–Extension Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation.

Abstract: Assistant secretary for Health, Office for Human Research Protections is requesting an extension on a currently approved information collection by the Office of Management and Budget, on the Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/ Consent Documentation. The purpose of the Federal Policy for the Protection of Human Subjects (also known as the Common Rule) is to provide a uniform government-wide standard for institutions engaged in research conducted or supported by the Department of Health and Human Services (HHS) to apply regarding the protection of human subjects involved in research. The HHS codification of the Common Rule is at 45 CFR part 46 subpart A. The respondents for this collection are institutions engaged in such research. Institutional adherence to the Common Rule also is required by other federal departments and agencies that have codified or follow the Common Rule which is identical to 45 CFR part 46, subpart A.

Likely Respondents: Institutions engaged in nonexempt human subjects research.

ESTIMATE ANNUALIZED BURDEN IN HOURS TABLE

Title	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
.103(b)(4), .109(d)IRB Actions, .116 and .117 Informed Consent	6,000	39.33	1	235,980
.115(a) IRB Recordkeeping	6,000	15	10	900,000
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting	6,000	0.5	45/60	2,250
Total				1,138,230

Terry Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2018–10511 Filed 5–16–18; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2018–0011; FXIA16710900000–178–FF09A30000]

June 18, 2018 Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities. The ESA also requires that we invite public comment before issuing these permits.

DATES: We must receive comments by June 18, 2018.

ADDRESSES:

Document availability: The applications, as well as any comments and other materials that we receive, will be available for public inspection online in Docket No. FWS–HQ–IA–2018–0011 at *http://www.regulations.gov.*

Submitting Comments: You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2018–0011.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2018–0011 U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

When submitting comments, please indicate the name of the applicant and the PRT# at the beginning of your comment. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see **SUPPLEMENTARY INFORMATION** for more information).

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

You may submit your comments and materials by one of the methods listed above under *Submitting Comments* in **ADDRESSES**. We will not consider comments sent by email or fax, or to an address not in **ADDRESSES**.

Please make your requests or comments as specific as possible, confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we