ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total
Patients	Case questionnaire	161	1	25/60	67
Controls	Control questionnaire	483	1	25/60	201
					268

LeRoy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2014–08014 Filed 4–9–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: ACF Program Instruction: Children's Justice Act.

OMB No.: 0970–0425.

Description: The Program Instruction, prepared in response to the enactment of the Childrens Justice Act (CJA), Title II of Public Law 111–320, Child Abuse Prevention and Treatment Act Reauthorization of 2010, provides direction to the States and Territories to accomplish the purposes of assisting States in developing, establishing and operating programs designed to improve: (1) The assessment and investigation of suspected child abuse and neglect cases, including cases of suspected child sexual abuse and exploitation, in a manner that limits additional trauma to the child and the child's family; (2) the assessment and investigation of cases of suspected child abuse-related fatalities and suspected child neglect-related fatalities; (3) the investigation and prosecution of cases of child abuse and neglect, including child sexual abuse and exploitation; and (4) the assessment and investigation of cases involving children with disabilities or serious health-related problems who are suspected victims of child abuse or neglect. This Program Instruction contains information collection requirements that are found in Public Law 111–320 at Sections 107(b) and 107(d), and pursuant to receiving a grant award. The information being collected is required by statute to be submitted pursuant to receiving a grant award. The information submitted will be used by the agency to ensure compliance with the statute; to monitor, evaluate and measure grantee achievements in addressing the investigation and prosecution of child abuse and neglect; and to report to Congress.

Respondents: State Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Application and Annual Report	52	1	60	3,120

Estimated Total Annual Burden Hours: 3,120.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment

OMB is required to make a decision concerning 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. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2014–08065 Filed 4–9–14; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0062]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exception From General Requirements for Informed Consent

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of

information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information related to the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances.

DATES: Submit either electronic or written comments on the collection of information by June 9, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Exception From General Requirements for Informed Consent—21 CFR 50.23 (OMB Control Number 0910–0586)—Extension

In the **Federal Register** of June 7, 2006 (71 FR 32827), FDA issued an interim final rule to amend its regulations to establish a new exception from the general requirements for informed consent, to permit the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents without informed consent in certain circumstances. The Agency took this action because it was concerned that, during a potential terrorism event or other potential public health emergency, delaying the testing of specimens to obtain informed consent may threaten the life of the subject. In many instances, there may also be others who have been exposed to, or who may be at risk of exposure to, a dangerous chemical, biological, radiological, or nuclear agent, thus necessitating identification of the agent as soon as possible. FDA created this exception to help ensure that individuals who may have been exposed to a chemical, biological, radiological, or nuclear agent are able to benefit from the timely use of the most appropriate diagnostic devices, including those that are investigational.

Section 50.23(e)(1) (21 CFR 50.23(e)(1)) provides an exception to the general rule that informed consent is required for the use of an investigational in vitro diagnostic device. This exception applies to those situations in which the in vitro investigational diagnostic device is used to prepare for, and respond to, a chemical, biological, radiological, or nuclear terrorism event or other public health emergency, if the investigator and an independent licensed physician make the determination and later certify in writing that: (1) There is a life-threatening situation necessitating the use of the investigational device, (2) obtaining informed consent from the subject is not feasible because there was no way to predict the need to use the investigational device when the specimen was collected and there is not sufficient time to obtain consent from the subject or the subject's legally authorized representative, and (3) no satisfactory alternative device is available. Under the rule, these determinations are made before the device is used, and the written certifications are made within 5 working days after the use of the device. If use of the device is necessary to preserve the life of the subject and there is not sufficient time to obtain the determination of the independent licensed physician in advance of using the investigational device, § 50.23(e)(2) provides that the certifications must be made within 5 working days of use of the device. In either case, the certifications are submitted to the Institutional Review Board (IRB) and, under § 50.23(e)(3) (76 FR 36989, June 24, 2011), to FDA within 5 working days of the use of the device.

Section 50.23(e)(4) provides that an investigator must disclose the investigational status of the device and what is known about the performance characteristics of the device at the time test results are reported to the subject's health care provider and public health authorities, as applicable. Under § 50.23(e)(4), the investigator provides the IRB with the information required by § 50.25 (21 CFR 50.25) (except for the information described in § 50.25(a)(8)) and the procedures that will be used to provide this information to each subject or the subject's legally authorized representative.

From its knowledge of the industry, FDA estimates that there are approximately 150 laboratories that could perform testing that uses investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents. FDA estimates that in the United States each year there are approximately 450 naturally occurring cases of diseases or conditions that are identified in the Centers for Disease Control's list of category ''A'' biological threat agents. The number of cases that would result from a terrorist event or other public health emergency is uncertain. Based on its knowledge of similar types of submissions, FDA estimates that it will take about 2 hours to prepare each certification.

Based on its knowledge of similar types of submissions, FDA estimates that it will take about 1 hour to prepare a report disclosing the investigational status of the in vitro diagnostic device and what is known about the performance characteristics of the device and submit it to the health care provider and, where appropriate, to public health authorities.

The June 7, 2006, interim final rule refers to previously approved collections of information found in FDA regulations. These collections of

information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in § 50.25 have been approved under 0910–0130.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Written certification (sent to FDA)—50.23(e)(3).	150	3	450	0.25 (15 minutes)	113	$100

[1] There are no capital costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total operating and maintenance costs
Written certification (sent to IRB)—50.23(e)(1) and (e)(2)	150	3	450	2	900	$0
Informed consent information—50.23(e)(4)	150	3	450	1	450	100
Total	.....	.....	.....	.....	1,350	100

[1] There are no capital costs associated with this collection of information.

Dated: April 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–08006 Filed 4–9–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Announcement of Agency Decision: Density of the Primary Living Space of Captive Chimpanzees Owned or Supported by the National Institutes of Health (NIH) or Used in NIH-Supported Research

SUMMARY: This notice summarizes the agency's actions to obtain additional scientific input and announces the agency's decision with respect to the space density of the primary living space of captive research chimpanzees owned or supported by the National Institutes of Health (NIH) or used in NIH-supported research. The NIH has prepared procedural guidance and technical assistance for researchers, facility staff, and agency staff to ensure proper implementation of the agency's decisions. Investigators should follow guidance (see NOT–OD–14–024 at *http://www.grants.nih.gov/grants/guide/notice-files/NOT-OD-14-024.html*) regarding the submission of applications, proposals, or protocols for research involving chimpanzees.

FOR FURTHER INFORMATION CONTACT: The Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH at *dpcpsi@od.nih.gov*.

SUPPLEMENTARY INFORMATION:

Background

In February 2012, the NIH charged a working group of the Council of Councils, a federal advisory committee, to provide advice on implementing recommendations made by the Institute of Medicine (IOM) Committee on the Use of Chimpanzees in Biomedical and Behavioral Research in its 2011 report, *Chimpanzees in Biomedical and Behavioral Research: Assessing the Necessity*. On January 22, 2013, the NIH Council of Councils (Council) accepted recommendations presented by the Working Group on the Use of Chimpanzees in NIH-Supported Research in its report (see *http://dpcpsi.nih.gov/sites/default/files/FNL_Report_WG_Chimpanzees_0.pdf*) and provided these recommendations to the NIH. The NIH subsequently issued a request for information, *http://www.gpo.gov/fdsys/pkg/FR-2013-02-05/html/2013-02507.htm,* to obtain broad public input on the 28 Council recommendations the NIH considered as it determined how to implement the IOM Committee's recommendations.

In June 2013, the NIH announced its decisions with respect to the Council of Councils' recommendations; see *http://dpcpsi.nih.gov/sites/default/files/NIH_response_to_Council_of_Councils_recommendations_62513.pdf*. The agency accepted 27 of the 28 Council recommendations. Included in these were 10 recommendations describing the characteristics of a captive environment that allow for and promote a full range of behaviors that are natural for chimpanzees—or ethologically appropriate environments (EAE). The NIH accepted 9 of the 10 Council's recommendations on EAE, including recommendations on enclosure height, foraging and diet, nesting materials, enrichment, a staff to chimpanzee ratio, staff training, and recordkeeping. The NIH did not accept Recommendation EA2—''The density of the primary living space of chimpanzees should be at least 1,000 ft^2 (93 m^2) per individual. Therefore, the minimum outdoor enclosure size for a group of 7 animals should be 7,000 ft^2 (651 m^2).''—based on comments received from the public. Because of concerns about the scientific basis for this recommendation and the expected costs of implementing it, the agency further reviewed the space density requirements with respect to the promotion of species-appropriate behavior.

While a large number of commenters who addressed Recommendation EA2 supported the recommendation, some commenters emphasized the amount of space recommended is the minimum needed and larger enclosures that more closely replicate the amount of space available to chimpanzees in the wild are