

Keith A. Tucker,

Office of the Secretary, Paperwork Reduction Act Clearance Officer.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the National Biodefense Science Board

**AGENCY:** Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services is hereby giving notice that the National Biodefense Science Board (NBSB) will be holding two closed sessions by teleconference under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. section 552b(c).

**DATES:** The March 29, 2012, and April 30, 2012, NBSB closed sessions by teleconference are tentatively scheduled from 1 p.m. to 5 p.m. The agenda and time are subject to change as priorities dictate.

**ADDRESSES:** The closed sessions will occur by teleconference and will not be open to the public as stipulated under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. section 552b(c).

**FOR FURTHER INFORMATION CONTACT:** MacKenzie Robertson, Acting Executive Director, NBSB, Office of the Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services; Email: [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV).

**SUPPLEMENTARY INFORMATION:** Pursuant to section 319M of the Public Health Service Act (42 U.S.C. 247d-7f) and section 222 of the Public Health Service Act (42 U.S.C. 217a), the Department of Health and Human Services established the National Biodefense Science Board. The Board shall provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to the Department of Health and Human Services regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. The Board may also provide advice and guidance to the Secretary and/or the Assistant Secretary for Preparedness and Response on other matters related to public health emergency preparedness and response.

*Background:* The Board is being asked to review and evaluate the 2012 Public

Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan (SIP). Until a final document is approved by the Secretary of the Department of Health and Human Services (HHS), the development of PHEMCE SIP requires consideration and discussion of procurement-sensitive information that should not be released to the public prior to the Secretary's final decision. Premature public disclosure of the draft PHEMCE SIP would limit the Secretary's decision-making ability to effectively prioritize HHS expenditures on critical medical countermeasures. Therefore, the Board's deliberations on the new task will be conducted in closed sessions in accordance with provisions set forth under exemption 9(B) of the Government in Sunshine Act, 5 U.S.C. section 552b(c), and with approval by the Assistant Secretary for Preparedness and Response.

*Availability of Materials:* All public materials will be posted on the NBSB Web site at [www.phe.gov/nbsb](http://www.phe.gov/nbsb).

*Procedures for Providing Public Input:* All written comments should be sent by email to [NBSB@HHS.GOV](mailto:NBSB@HHS.GOV) with "NBSB Public Comment" as the subject line.

Dated: February 27, 2012.

**Nicole Lurie,**

Assistant Secretary for Preparedness and Response.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Proposed Information Collection Activity; Comment Request

##### Proposed Projects

*Title:* National Child Abuse and Neglect Data System.

*OMB No:* 0980-0229.

*Description:* The Administration on Children, Youth and Families in the U.S. Department of Health and Human Services (HHS) established the National Child Abuse and Neglect Data System (NCANDS) to respond to the 1988 and 1992 amendments (Pub. L. 100-294 and Pub. L. 102-295) to the Child Abuse Prevention and Treatment Act (42 U.S.C. 5101 *et seq.*), which called for the creation of a coordinated national data collection and analysis program, both universal and case specific in scope, to examine standardized data on false, unfounded, or unsubstantiated reports.

In 1996, the Child Abuse Prevention and Treatment Act was amended by

Public Law 104-235 to require that any State receiving the Basic State Grant work with the Secretary of the Department of Health and Human Services (HHS) to provide specific data on child maltreatment, to the extent practicable. These provisions were retained in the 2010 reauthorization of CAPTA (Pub. L. 113-320).

Each State to which a grant is made under this section shall annually work with the Secretary to provide, to the maximum extent practicable, a report that includes the following:

1. The number of children who were reported to the State during the year as victims of child abuse or neglect.

2. Of the number of children described in paragraph (1), the number with respect to whom such reports were—

- A. substantiated;
- B. unsubstantiated; or
- C. determined to be false.

3. Of the number of children described in paragraph (2)—

A. the number that did not receive services during the year under the State program funded under this section or an equivalent State program;

B. the number that received services during the year under the State program funded under this section or an equivalent State program; and

C. the number that were removed from their families during the year by disposition of the case.

4. The number of families that received preventive services, including use of differential response, from the State during the year.

5. The number of deaths in the State during the year resulting from child abuse or neglect.

6. Of the number of children described in paragraph (5), the number of such children who were in foster care.

7.A. The number of child protective service personnel responsible for the—

- i. intake of reports filed in the previous year;

- ii. screening of such reports;
- iii. assessment of such reports; and
- iv. investigation of such reports.

B. The average caseload for the workers described in subparagraph (A).

8. The agency response time with respect to each such report with respect to initial investigation of reports of child abuse or neglect.

9. The response time with respect to the provision of services to families and children where an allegation of child abuse or neglect has been made.

10. For child protective service personnel responsible for intake, screening, assessment, and investigation of child abuse and neglect reports in the State—

A. information on the education, qualifications, and training requirements established by the State for child protective service professionals, including for entry and advancement in the profession, including advancement to supervisory positions;

B. data of the education, qualifications, and training of such personnel;

C. demographic information of the child protective service personnel; and

D. information on caseload or workload requirements for such personnel, including requirements for average number and maximum number of cases per child protective service worker and supervisor.

11. The number of children reunited with their families or receiving family preservation services that, within five years, result in subsequent substantiated reports of child abuse or neglect, including the death of the child.

12. The number of children for whom individuals were appointed by the court to represent the best interests of such children and the average number of out of court contacts between such individuals and children.

13. The annual report containing the summary of activities of the citizen review panels of the State required by subsection (c)(6).

14. The number of children under the care of the State child protection system who are transferred into the custody of the State juvenile justice system.

15. The number of children referred to a child protective services system under subsection (b)(2)(B)(ii).

16. The number of children determined to be eligible for referral, and the number of children referred, under subsection (b)(2)(B)(xxi), to agencies providing early intervention services under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*).

The Children’s Bureau proposes to continue collecting the NCANDS data through the two files of the Detailed Case Data Component, the Child File (the case-level component of NCANDS) and the Agency File (additional aggregate data, which cannot be collected at the case level). Technical assistance will be provided so that all

States may provide the Child File and Agency File data to NCANDS.

The Children’s Bureau proposes to modify the Child File by adding five new fields.

- Field 147, Report Time: The Report Time field will collect the hour and minutes when the report was received. Currently NCANDS collects only the date when the report was received. Adding the time field will allow for a more accurate computation of the time between receipt of the report and the start of the investigation or other response.

- Field 148, Investigation Start Time: The Investigation Start Time field will collect the hour and minutes when the investigation or other response was initiated. Currently NCANDS collects only the date the investigation or other response was started. Adding the time field will allow for a more accurate computation of the time between receipt of the report and the start of the investigation or other response.

- Field 149, Maltreatment Death Date: The Maltreatment Death Date field will collect the date when a child who died of child abuse or neglect died. Currently NCANDS only collects that the child was determined to have died due to maltreatment, but does not collect the date. Since determinations of cause of death can take several months, adding the date of death will allow for more accurate counts of deaths that occurred during the reporting period in addition to the ability to count those for which the finding was established during the reporting period.

- Field 150, Near Fatality: The Near Fatality field will establish a flag as to whether the State has determined that the child was so severely injured that it should be classified as a near fatality. A focus on near fatalities is evident in CAPTA (Sec.106 (b)(2)(B)(x)) and the counts of such cases will be useful in establishing prevention activities.

- Field 151, Foster Care Discharge Date: The Foster Care Discharge Date field will collect the date of discharge, if discharge has occurred, for each child who has the Removal Date field. Currently NCANDS collects only the start of foster care but does not collect the end of foster care, when a child is returned home or has another

permanent outcome. Adding this field will allow a more accurate computation of the number of children who were maltreated in foster care.

The reauthorization of CAPTA specifies for two counts, “The number of children determined to be eligible for referral, and the number of children referred, under subsection (b)(2)(B)(xxi), to agencies providing early intervention services under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*)” (Sec. 106(d)(16)).

The children under subsection (b)(2)(B)(xxi) are defined as, “\* \* \* a child under the age of 3 who is involved in a substantiated case of child abuse or neglect [referred] to early intervention services funded under part C of the Individuals with Disabilities Education Act (20 U.S.C. 1431 *et seq.*)”

The Children’s Bureau proposes to modify the Agency File by adding two new fields.

- Field 5.1, Number of Children Eligible for Referral to Agencies Providing Early Intervention Services Under Part C of the Individuals With Disabilities Education Act: This field will collect the number of children who are considered by the State to be eligible for referral to Part C agencies.

- Field 5.2, Number of Children Referred to Agencies Providing Early Intervention Services Under Part C of the Individuals With Disabilities Education Act: This field will collect the number of children who were actually referred to Part C agencies.

The information collected by NCANDS will be used to better understand the experiences of children and families served by State and local child protective services agencies and to guide policy and program development at the national and local levels. Data collected through the NCANDS will also be used to support HHS with responding to the requirements of the Government Performance and Results Act (GPRA); reporting to Congress on States’ performance on national child welfare outcomes; and monitoring States through the CFSRs.

*Respondents:* State governments, the District of Columbia, and the Commonwealth of Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Detailed Case Data Component Child File and Agency File .....	52	1	121	6,292

Estimated Total Annual Burden Hours: 6,292.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information may be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection activity—National Child Abuse and Neglect Data System.

The Department specifically requests comments on: (a) The proposed change to the two data collection instruments—the Child File and the Agency File; (b) 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; (c) the quality, utility, and clarity of the information to be collected; (d) the accuracy of the agency's estimate of the burden of the proposed collection of information; and (e) 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.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0001]

#### Advisory Committees; Filing of Closed Meeting Reports

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2011.

**ADDRESSES:** Copies are available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301-827-6860.

**FOR FURTHER INFORMATION CONTACT:** Teresa L. Hays, Advisory Committee and Oversight Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-8220.

**SUPPLEMENTARY INFORMATION:** Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2010 through September 30, 2011:

#### Center for Biologics Evaluation and Research

Allergenic Products Advisory Committee

Blood Products Advisory Committee  
Cellular, Tissue and Gene Therapies Advisory Committee

Vaccines and Related Biological Products Advisory Committee

#### Center for Drug Evaluation and Research

Cardiovascular and Renal Drugs Advisory Committee

Gastrointestinal Drug Advisory Committee

#### National Center for Toxicological Research

Science Board to the National Center for Toxicological Research

#### Center for Tobacco Products

Tobacco Products Scientific Advisory Committee

Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday.

- The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., Rm. 133, Washington, DC; and

- The Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 23, 2012.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Proposed Collection: Comment Request Post-Award Reporting Requirements Including New Research Performance Progress Report Collection

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director, National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

*Proposed Collection: Title:* Public Health Service (PHS) Post-award Reporting Requirements. *Type of Information Collection Request:* Revision. This collection represents a consolidation of post-award reporting requirements under the PRA, and includes the new Research Performance Progress Report (RPPR). *Need and Use of Information Collection:* The RPPR will replace existing interim performance reports used by all NIH, Food and Drug Administration, Centers for Disease Control and Prevention, and Agency for Healthcare Research and Quality (AHRQ) grantees. Interim progress reports are required to continue support of a PHS grant for each budget year within a competitive segment. The phased transition to the RPPR requires the maintenance of dual reporting processes for a period of time. Thus this information collection is for the new use of the RPPR, and continued use of the PHS Non-competing Continuation Progress Report (PHS 2590, currently approved under 0925-0001), and the NIH AHRQ Ruth L. Kirschstein National Research Service Award (NRSA) Individual Fellowship Progress Report for Continuation Support (PHS 416-9, currently approved under 0925-0002). Only one interim progress report (RPPR or PHS2590/416-9) will be utilized for any given award. This collection also includes other PHS post-award reporting requirements: PHS 416-7 NRSA Termination Notice, PHS 2271 Statement of Appointment, 6031-1 NRSA Annual Payback Activities Certification, (currently approved under 0925-0002, expiration 6/30/2012); and HHS 568 Final Invention Statement and Certification, Final Progress Report instructions, and iEdison, and PHS 3734 Statement Relinquishing Interests and Rights in a PHS Research Grant