

SUPPLEMENTARY INFORMATION: Section 106(b)(2)(B)(x) of CAPTA requires a certification by the State Governor that the State has in effect and is enforcing a State law, or has in effect and is operating a statewide program, relating to child abuse and neglect that includes “provisions which allow for public disclosure of the findings or information about the case of child abuse or neglect which has resulted in a child fatality or near fatality.” We revised our policy interpretation of the statutory provision regarding public disclosure of information in cases of child abuse or neglect which have resulted in a child fatality or near fatality found in section 106(b)(2)(B)(x) of CAPTA in September 2012 with the addition of CWPM question 2.1A.4 #8. This interpretation requires States to develop procedures for the release of information including, but not limited to: the cause of and circumstances regarding the fatality or near fatality; the age and gender of the child; information describing any previous reports or child abuse or neglect investigations that are pertinent to the child abuse or neglect that led to the fatality or near fatality; the result of any such investigations; and the services provided by and actions of the State on behalf of the child that are pertinent to the child abuse or neglect that led to the fatality or near fatality. States may allow exceptions to the release of information in order to ensure the safety and well-being of the child, parents and family or when releasing the information would jeopardize a criminal investigation, interfere with the protection of those who report child abuse or neglect or harm the child or the child’s family. States must also ensure compliance with other federal confidentiality restrictions when implementing the confidentiality provisions under CAPTA, including the confidentiality requirements applicable to titles IV–B and IV–E of the Social Security Act (the Act) and in accordance with 45 CFR 1355.30, which requires that records maintained under title IV–E and IV–B of the Act are subject to the confidentiality provisions in 45 CFR 205.50. Among other things, 45 CFR 205.50 restricts the release or use of information concerning individuals receiving financial assistance under these programs to certain persons or agencies that require the information for specified purposes.

We also revised several CWPM answers in section 2.1A to bring them in line with the policy as outlined in the new question and answer (Q/A). CWPM section 2.1A.1, questions 1, 2, 6, and 8; and CWPM section 2.1A.4, questions 3,

4, 5, 6, and 7 were all revised. At that time, Q/A 2.1A.4 #2, was deleted, but it was updated and reissued in August 2013. This Q/A clarifies that when child abuse or neglect results in the death or near death of a child, the State must provide for the disclosure of the information required by section 2.1A.4, Q/A #8 of the CWPM, but that the provision should not be interpreted to require disclosure of information which would fall within the specific exceptions that states are allowed to establish under section 2.1A.4, Q/A #8 of the CWPM. The full Q/A 2.1A.4 #2 can be found at: http://www.acf.hhs.gov/cwpm/programs/cb/laws_policies/laws/cwpm/policy_dsp.jsp?citID=68#320. The history of the modified Q/A’s is also available in the CWPM at: http://www.acf.hhs.gov/cwpm/programs/cb/laws_policies/laws/cwpm/policy_dsp.jsp?citID=68#2561.

We seek comment from state agencies and other stakeholders about the revised policy interpretation at CWPM, section 2.1A.4, Q/A #8, or any other revised policies in section 2.1A of the CWPM noted above.

We encourage stakeholder respondents to address the following questions:

- (1) Please describe any challenges you’ve had obtaining information about child fatalities and near fatalities which resulted from child abuse and neglect from a state. Have there been improvements in obtaining the information since CB revised the policy in CWPM section 2.1.A in September 2012?
- (2) What concerns, if any, do you have with the definition of near fatalities in a state?
- (3) Has a state responded that the state cannot disclose information due to confidentiality protections? If so, describe the information requested and the confidentiality provision cited by the state.
- (4) Does your state offer a public report of the child fatalities review panel/commission? If so, does the report contain the required disclosure of information? Is the report a barrier to obtaining information?

We encourage state agency respondents to address the following questions:

- (1) What challenges, if any, have you faced implementing the revised policy? Has the revised policy improved your disclosure process and policies?
- (2) Are there challenges in applying the disclosure policy while also ensuring that you adhere to confidentiality protections?

Dated: March 24, 2015.

Mark H. Greenberg,
Acting Assistant Secretary for Children and Families.

[FR Doc. 2015–07390 Filed 3–30–15; 8:45 am]

BILLING CODE 4184–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: AIDS and AIDS Related Research.

Date: April 8, 2015.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Mary Clare Walker, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5208, MSC 7852, Bethesda, MD 20892, (301) 435–1165, walkermc@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Topics in Bacterial Pathogenesis.

Date: April 9, 2015.

Time: 10:00 a.m. to 11:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Marci Scidmore, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3192, MSC 7808, Bethesda, MD 20892, 301–435–1149, marci.scidmore@nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Hypertension, Thrombosis, Vascular Inflammation and Dysfunction.

Date: April 23–24, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Natalia Komissarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, MSC 7846, Bethesda, MD 20892, 301-435-1206, kommisar@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: March 25, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-07256 Filed 3-30-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0815]

Electronic Study Data Submission; Data Standards; Recommending the Use of the World Health Organization Drug Dictionary

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing support for the World Health Organization (WHO) Drug Dictionary (available at <http://www.who-umc.org/>), which is maintained and updated by the Uppsala Monitoring Centre. FDA is encouraging sponsors and applicants to use WHO Drug Dictionary codes in investigational study data provided in regulatory submissions to the Center for Drug Evaluation and Research and to the Center for Biologics Evaluation and Research. The WHO Drug Dictionary contains unique codes for identifying drug names and evaluating medicinal product information, including active ingredients and therapeutic uses. Typically, WHO Drug Dictionary is used to code concomitant medications used by subjects during the course of a clinical trial. WHO Drug Dictionary will be listed in the FDA Data Standards Catalog posted to FDA's Study Data

Standards Resources Web site at <http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm>

DATES: Although you can comment on this notice at any time, to ensure that the Agency considers your comments submit either electronic or written comments by May 5, 2015.

ADDRESSES: Submit written requests for single copies of the documents 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 or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ron Fitzmartin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, rm. 1192, Silver Spring, MD 20993-002, ronald.fitzmartin@fda.hhs.gov; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993, stephen.ripley@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The use of a common dictionary to code concomitant medications is an important component of study data standardization. Generally, controlled terminology standards specify the key concepts that are represented as definitions, preferred terms, synonyms, codes, and code system. The analysis of study data is greatly facilitated by the use of controlled terms for clinical or scientific concepts that have standard, predefined meanings and representations. WHO Drug Dictionary contains unique codes as drug names and corresponding medicinal product information, including active ingredients and the Anatomical Therapeutic Chemical (ATC) classification system for the therapeutic uses. Typically, sponsors and applicants use WHO Drug Dictionary to code and

analyze concomitant medications taken by subjects during the course of clinical trials.

Although use of WHO Drug Dictionary codes are not required at this time, FDA now supports and encourages the use of WHO Drug Dictionary coded concomitant medications used in clinical trials. For purposes of this notice, "supported" means the receiving Center has established processes and technology to support receiving, processing, reviewing, and archiving files in the specified standard.

FDA is now encouraging sponsors and applicants to provide WHO Drug Dictionary codes for concomitant medication data in investigational studies provided in regulatory submissions (e.g., investigational new drug applications, new drug applications, abbreviated new drug applications, and biologics license applications). The codes should include the drug product trade name where available, the active ingredient(s) and the ATC class.

II. Comments

Interested persons may submit either electronic comments to <http://www.regulations.gov> or written comments regarding this notice to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: March 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-07269 Filed 3-30-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-0839]

Target Animal Safety Data Presentation and Statistical Analysis; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for