Dated: November 4, 2019.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2019–25430 Filed 11–22–19; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Form ACF–196, TANF Financial Reporting Form for States

AGENCY: Office of Family Assistance; Administration for Children and Families; HHS.

ACTION: Request for public comment.

SUMMARY: The Administration for Children and Families (ACF) is requesting to renew approval of the ACF–196 Temporary Assistance for Needy Families (TANF) Financial Reporting Form. The ACF–196 is the form used by states to estimate funding needs and request grant awards under the TANF program. In addition, the form is used to report data in substantiation of state claims and to certify the availability of the legislatively mandated state match. ACF will use the financial data provided by states to estimate quarterly funding needs, calculate award amounts, and assess compliance with statutory and regulatory requirements relating to administrative costs and state matching requirements. No changes are proposed to the form.

DATES: *Comments due within 60 days of publication.* 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.

ADDRESSES: Copies of the proposed collection of information can be obtained and comments may be forwarded by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation (OPRE), 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: This information collection is authorized under Section 411(a)(3) of the Social Security Act. This request is for renewal of approval to the ACF–196 form for periodic financial reporting under the TANF program. States participating in the TANF program are required by statute to report financial data on a quarterly basis. This form meets the legal standard and provides essential data on the use of federal funds. Failure to collect the data would seriously compromise ACF's ability to monitor program expenditures, estimate funding needs, and to prepare budget submissions required by Congress. Financial reporting under the TANF program is governed by 45 CFR part 265.

Respondents: TANF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
ACF–196	51	4	10	2,040

Estimated Total Annual Burden Hours: 2,040.

Comments: The Department specifically requests comments on (a) 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; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: U.S.C. Section 402 of the Social Security Act (42 U.S.C. 602).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–25432 Filed 11–22–19; 8:45 am]

BILLING CODE 4184–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3592]

Certificates of Confidentiality; Draft Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance entitled ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.'' This draft guidance is intended to explain FDA implementation of the revised statutory provisions applicable to the request for, and issuance of, a Certificate of Confidentiality (CoC). The 21st Century Cures Act (Cures Act) amended the statutory provisions relating to the issuance of CoCs. A CoC is intended to help protect the privacy of human subject research participants from whom sensitive and identifiable information is being collected or used in furtherance of the research. Historically, a CoC generally protected a researcher from being compelled in a legal proceeding to disclose identifiable sensitive information about the research participant, created or compiled for the research. As amended, a CoC prohibits a researcher from disclosing such information unless a specified exception applies.

DATES: Submit either electronic or written comments on the draft guidance by January 9, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed information collection burden in the draft guidance by January 24, 2020.

ADDRESSES: You may submit either electronic or written comments on any guidance 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–2019–D–3592 for ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.'' 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 this draft guidance to the Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4248, Silver Spring, MD 20993–0002. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4248, Silver Spring, MD 20993–0002, 301–796–4850.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance to explain FDA's proposed implementation of the revised provisions applicable to the request for, and issuance of, a discretionary CoC. The Cures Act (Pub. L. 114–255, section 2012) amended the Public Health Service Act, section 301(d) (42 U.S.C. 241(d)), relating to the issuance of CoCs. A CoC is intended to help protect the privacy of human subject research participants from whom identifiable, sensitive information is being collected or used in furtherance of the research. Historically, a CoC generally protected a researcher from being compelled in a legal proceeding (such as by subpoena or court order) to disclose identifiable and sensitive information about the research participant, created or compiled for purposes of the human subject research. The Cures Act broadened the protections of the statutory provision by affirmatively prohibiting holders of CoCs from disclosing such information unless a specific exception applies.

The Cures Act simplified certain aspects of the issuance of CoCs by requiring that CoCs be issued for federally funded human subject research that collects or uses identifiable, sensitive information (referred to in the draft guidance as mandatory CoCs). For non-federally funded research, issuance of CoCs is not required but may be issued at the discretion of FDA (referred to in the draft guidance as discretionary CoCs) when the study involves a product subject to FDA's jurisdiction and regulatory authority. FDA intends to continue receiving such requests and will issue discretionary CoCs as appropriate. This draft guidance is intended to provide information on how to request a discretionary CoC, the statutory requirements for requesting such a CoC, and the statutory responsibilities associated with possessing a CoC. Although the mandatory CoC and the discretionary CoC are issued under different processes, the protections afforded by the issuance of either CoC are identical and the statutory responsibilities are applicable to both.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the current thinking of FDA on ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.'' It does not establish any rights for any person and

is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), 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 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.

Protection of Human Subjects

OMB Control Number 0910–0755—Revision

CoCs are intended to help protect the privacy of human subject research participants from whom identifiable, sensitive information is being collected in furtherance of the research. A CoC generally protects a researcher from being compelled to disclose identifiable sensitive information about the research participant, created or compiled for purposes of the human subject research. The holder of the CoC may not disclose such information unless a specified exception applies. For non-federally funded research, issuance of CoCs is not required but may be issued at the discretion of FDA (discretionary CoCs) when the study involves a product subject to FDA's jurisdiction and regulatory authority. The draft guidance is intended to provide information on how to request a discretionary CoC, the statutory requirements for requesting such a CoC, and the statutory responsibilities associated with possessing a CoC. We already receive such CoC requests and will issue discretionary CoCs as appropriate. As discussed in the draft guidance, to help ensure that discretionary CoCs are issued to those entities who can comply with the requirements of the statutory provision, we recommend that only sponsors or sponsor-investigators submit requests for discretionary CoCs (as defined in 21 CFR 50.3, 312.3, and 812.3) (*i.e.,* the individual who takes responsibility for or initiates the clinical investigation). This will help eliminate duplicative requests to FDA for the same human subject research. Accordingly, we are revising the information collection approved under OMB control number 0910–0755 (Protection of Human Subjects) to include the additional information collection elements recommended in the draft guidance.

A. Descriptive Information

To facilitate our review and expedite consideration of a discretionary CoC request, sponsors, sponsor-investigators, or the authorized representative should include descriptive information in their submission. The information is listed below and in ''Section IV. Request for Discretionary CoCs From FDA'' of the draft guidance.

- Sponsor or Sponsor-Investigator Name or authorized representative (*e.g.,* the individual who takes responsibility for or initiates the clinical investigation).
- Sponsor or Sponsor-Investigator or authorized representative Address (same as on file with FDA).
- Sponsor or Sponsor-Investigator or authorized representative email address.
- FDA Application Number, as available (*e.g.,* IND/NDA/BLA/IDE/HDE/PMA/PMTA/ITP).[1]
- *ClinicalTrials.gov* numerical identifier (if applicable) (number provided upon registration on *www.ClinicalTrials.gov*).
- Title of research.
- If conducting human subject research that is subject to FDA's jurisdiction but the sponsor or sponsor-investigator is exempt from submitting an application (*e.g.,* IND/IDE), submit all of the above information, with the exception of the FDA application number.
- Signature of Sponsor, Sponsor-Investigator, or authorized representative who submits the CoC request.

B. Assurances

Sponsors, sponsor-investigators, and authorized representatives who receive a CoC must also comply with the statutory provisions for CoCs to protect the confidentiality of identifiable, sensitive information that is collected or used for purposes of the research. Such requestors of a CoC should include the following assurances in their submission as described in detail in ''Section IV. Request for Discretionary CoCs From FDA'' of the draft guidance.

- The requestor is engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected or used.
- The research involves a product subject to FDA's jurisdiction and regulatory authority.
- The requestor will be responsible for complying with the requirements to protect the confidentiality of identifiable, sensitive information collected or used in biomedical, behavioral, clinical, or other research.
- The requestor will not disclose in any legal proceeding or to any other individual unless the requestor has the individual's consent or provide the name of an individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research.

The requestor understands and agrees that disclosure is permitted by the recipient of a CoC only when required by Federal, State, or local laws, or it is:

- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that complies with applicable Federal regulations governing the protection of human subjects in research.

- The requestor understands that the identifiable sensitive information collected by a researcher to whom a certificate is issued and all copies thereof, shall be subject to the

[1] Investigational New Drug Application/New Drug Application/Biologics License Application/Investigational Device Exemption/Humanitarian Device Exemption/Premarket Application/Premarket Tobacco Product Application/Investigational Tobacco Product.

protections afforded by this section for perpetuity.

Based on the number of CoC requests we have received prior to the Cures Act, we estimate receiving approximately 150 discretionary CoC requests annually. We estimate that approximately 150 sponsors, sponsor-investigators, or authorized representatives will submit requests. Preparing and sending each request would take approximately 2 hours.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Draft guidance for sponsors, sponsor-investigators, researchers, industry, and FDA staff on CoCs	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submissions of CoC Requests From Sponsors, Sponsor-Investigators, or Authorized Representatives	150	1	150	2	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/RegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: November 20, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25551 Filed 11–22–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Biodefense Science Board: Public Meeting

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The HHS Office of the Secretary is hosting the National Biodefense Science Board (NBSB) Public Meeting in Washington, DC, December 3, 2019. The purpose of the meeting is to gather information to develop expert advice provided by NBSB and guidance to the Secretary on scientific, technical, and other matters of special interest to HHS regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate. Retiring NBSB board members will also be presented with certificates and a signed letter of appreciation.

DATES: The NBSB Public Meeting is being held December 3, 2019, from 10:30 a.m. to 4:30 p.m. Eastern Daylight Time (EDT).

ADDRESSES: Please visit the NBSB website (*https://www.phe.gov/nbsb*) for all additional information regarding the NBSB or meeting details.

FOR FURTHER INFORMATION CONTACT: CAPT Christopher Perdue, MD, MPH, Designated Federal Official, NBSB, ASPR, HHS; 202–401–5837; *christopher.perdue@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to section 319M of the Public Health Service Act, HHS has established the NBSB to provide expert advice and guidance to the Secretary on scientific, technical, and other matters of special interest to HHS regarding current and future chemical, biological, nuclear, and radiological agents, whether naturally occurring, accidental, or deliberate.

Availability of Materials: Participants are encouraged to visit the NBSB website (*http://www.phe.gov/nbsb*) for information about the meeting, including the agenda.

Procedures for Providing Public Input: Members of the public are encouraged to go to the NBSB website (*http://www.phe.gov/nbsb*) for instructions about the submission of written comments.

Dated: November 20, 2019.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2019–25544 Filed 11–22–19; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Advisory Committee to the Director, National Institutes of Health, December 12, 2019, 9:00 a.m. to December 13, 2019, 1:00 p.m., NIH, Building 1, Wilson Hall, 1 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on May 2, 2019, 84 FR 18853.

The meeting notice is amended to add an additional agenda topic entitled, NIH Wide Strategic Plan for Fiscal Years 2021–2025. The meeting is open to the public.

Dated: November 19, 2019.

Natasha M. Copeland,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–25478 Filed 11–22–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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 materials, 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: National Library of Medicine Special Emphasis Panel; COI/Career Award.

Date: March 19, 2020.

Time: 11:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Library of Medicine/Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Yanli Wang, Ph.D., Scientific Review Officer, Division of Extramural Programs, National Library of Medicine, NIH, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20892–7968, 301–827–7092, *yawang@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library