



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2019-D-3592]

### Certificates of Confidentiality; 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 final guidance entitled “Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.” This 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. This guidance finalizes the draft guidance of the same title issued on November 25, 2019.

**DATES:** The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

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 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 final guidance document.

**FOR FURTHER INFORMATION CONTACT:** Jarilyn Dupont, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4248, Silver Spring, MD 20993-0002, 301-796-4716.

**SUPPLEMENTARY INFORMATION:**

I. Background

FDA is announcing the availability of a final guidance to explain FDA's 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 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 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 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 guidance finalizes the draft guidance entitled “Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff” issued on November 25, 2019 (84 FR 64906). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance were made to address requests for definitional and process clarity.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The 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

While this guidance contains no collection of information, it does refer to a previously approved FDA collection of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information have been approved under OMB control number 0910-0130.

## III. Electronic Access

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

Dated: November 9, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-25238 Filed: 11/13/2020 8:45 am; Publication Date: 11/16/2020]