

## Tip Sheet: Certificates of Confidentiality (last updated February 22, 2021)

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## Overview

Certificates of Confidentiality (CoCs) are issued by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Centers for Disease Control (CDC) and other Federal agencies to protect identifiable research information from forced disclosure. CoCs allow the investigators and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

The [21st Century Cures Act \(Cures Act\)](#) (Public Law 114-255) amended the Public Health Service Act (PHS Act), section 301(d) (42 U.S.C. 241(d)) relating to the issuance of CoCs. The Cures Act was signed into law December 13, 2016.

CoCs that are now required to be issued for federally-funded human subject research that collects or uses identifiable, sensitive information are called **mandatory** CoCs.

CoCs that are not required but may be issued at the discretion of the NIH or FDA are referred to as **discretionary** CoCs.

### [What is a Certificate of Confidentiality?](#)

### [2017 NIH Certificates of Confidentiality Policy](#)

This guidance describes when research is eligible to obtain a Certificate, UCLA IRB review requirements, and how to obtain a UCLA Institutional Official's signature for your CoC Assurances/application for a Certificate of Confidentiality when applicable.

## Certificate Applicability

Research projects that collect personally identifiable, sensitive information and have been approved by the UCLA IRB are eligible for a Certificate.

2017 NIH Certificates of Confidentiality Policy states, "*For the purposes of this Policy, NIH considers research in which identifiable, sensitive information is collected or used, to include:*

- *Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;*
- *Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;*
- *Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or*
- *Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.”*

If you have questions about whether your research involves identifiable, sensitive information that could be protected by a Certificate of Confidentiality, please [contact UCLA OHRPP staff](#).

### [NIH guidance: Who can get a Certificate of Confidentiality](#)

Projects that are not eligible for a Certificate are:

- not research based,
- not collecting identifiable, sensitive information, or
- not involving a subject matter that is within a mission area of the National Institutes of Health.

## **What a Certificate of Confidentiality Does Not Protect Against**

Personally identifiable information protected by a COC may be disclosed under the following circumstances:

- Voluntary disclosure of information by study participants themselves or any disclosure that the study participant has consented to in writing, such as to insurers, employers, or other third parties;
- Voluntary disclosure by the researcher of information on such things as child abuse, reportable communicable diseases, possible threat to self or others, or other voluntary disclosures provided that such disclosures are spelled out in the informed consent form;
- Voluntary compliance by the researcher with reporting requirements of state laws, such as knowledge of communicable disease, provided such intention to report is specified in the informed consent form; or
- Release of information by researchers to DHHS as required for program evaluation or audits of research records or to the FDA as required under the federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)

## Consent Form Language

The informed consent form must include a description of the protections and limitations of the Certificate of Confidentiality, including the circumstances in which the investigators plan to disclose voluntarily identifying information about research participants (e.g., child abuse, harm to self or others, etc.)

### [Example Informed Consent Language](#)

## UCLA IRB Review Requirements

- **NIH-funded projects** – Investigators are asked to respond to questions in Section 2.2 of the webIRB application to: (a) indicate that the study is HHS-funded, and (b) choose the appropriate response option to indicate: (i) whether or not NIH is the funding agency and (ii) if so, to acknowledge that the study is automatically covered by a CoC and indicate understanding of the associated responsibilities or indicate if the CoC does not apply.
- **All other projects** - The UCLA webIRB application requests that investigators indicate in Section 2.3 if a Certificate of Confidentiality will be requested for a non-NIH funded research study.

During its review of research for which an investigator has not identified the need for a Certificate of Confidentiality, the UCLA IRB may recommend that a Certificate of Confidentiality is a necessary and appropriate protection for the proposed project. UCLA IRB approval for research studies for which a Certificate of Confidentiality requires an application will be issued contingent upon UCLA OHRPP **receipt of the application** for UCLA Institutional Official's signature.

Certificate by Issuer	Documentation Required by UCLA IRB
Certificates for NIH-funded research	CoCs are now issued automatically for any NIH-funded projects using identifiable, sensitive information that was on-going on/after December 13, 2016. The CoC will be issued as a term and condition of award.  There will be no physical certificate issued. UCLA investigators are not required to provide any documentation to the IRB.
Certificates for research funded by other federal agencies	UCLA investigators receiving a CoC from another federal agency must submit a copy of their Certificate of Confidentiality to the UCLA IRB within ten (10) working days of receipt.
Certificates for FDA-regulated research that is not federally funded	UCLA investigators receiving a CoC from the FDA must submit a copy of their Certificate of Confidentiality to the UCLA IRB within ten (10) working days of receipt.
Certificates for non-federally funded research that is not FDA regulated	CoCs issued by the NIH for non-federally funded projects are issued jointly to the UCLA IO/designee and the investigator.  UCLA investigators must submit a copy of their Certificate of Confidentiality to the UCLA IRB within ten (10) working days of receipt.

## Application Instructions

Certificate by Issuer	UCLA Investigator CoC application process
Certificates for NIH-funded research	<p>CoCs are now issued automatically for any NIH-funded projects using identifiable, sensitive information that was on-going on/after December 13, 2016. The CoC will be issued as a term and condition of award. There will be no physical certificate issued.</p>
Certificates for research funded by other federal agencies	<p>Each federal agency has separate application processes to request a CoC. Instructions and contact information for each agency can be found here: <a href="#">How to get a Certificate of Confidentiality</a></p> <p>Several non-NIH federal agencies require both the Principal Investigator and the UCLA Institutional Official sign the <a href="#">Institutional Assurance Statement</a> requested in the application for a Certificate of Confidentiality.</p> <p>In order to obtain the UCLA Institutional Official's signature, please forward the Assurances statement to OHRPP, attention to: OHRPP Associate Director Alison Orkin, <a href="mailto:AOrkin@research.ucla.edu">AOrkin@research.ucla.edu</a></p>
Certificates for FDA-regulated research that is not federally funded	<p>FDA guidance outlines how to request a <i>discretionary</i> CoC, the statutory requirements for requesting such a CoC, and the statutory responsibilities associated with possessing a CoC : <a href="https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality">https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality</a></p> <p>Submission of request for the FDA to issue a Certificate of confidentiality requires two signatures:</p> <ul style="list-style-type: none"> <li>• The FDA requires the signature of the Sponsor or Sponsor-Investigator or Authorized Representative's signature, and</li> <li>• University policy delegates institutional authorization to the OHRPP Director and Associate Director.</li> </ul> <p>In order to obtain the UCLA Institutional Official's signature for an electronic request for a CoC to be issued by the FDA, please create a request letter that meets the requirements outlined in the FDA guidance, including the Assurances and email the letter to OHRPP, attention to: OHRPP Associate Director Alison Orkin, <a href="mailto:AOrkin@research.ucla.edu">AOrkin@research.ucla.edu</a></p>
Certificates for non-federally funded research that is not FDA regulated	<p>NIH issues <i>discretionary</i> CoCs for research that is not federally funded AND not FDA regulated.</p> <p>Click here for the <a href="#">UCLA OHRPP Quick Guide: Certificate of Confidentiality (CoC) applications for Non-Federally funded research.</a></p>

## References and Regulations

Section 301(d) of the Public Health Service Act (42 U.S.C. 241(d))

[21st Century Cures Act \(Cures Act\) \(Public Law 114-255\)](#)

[National Institutes of Health \(NIH\) Certificates of Confidentiality FAQs](#)

[FDA Guidance on Certificates of Confidentiality \(November 2020\)](#)

[OHRP Guidance on Certificates of Confidentiality](#)

[UCLA Delegation of Authority 251.15: To Approve Applications for Certificates of Confidentiality and Privacy Certificates](#)

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### **Change history:**

2/11/2021: Updated weblinks, updated FDA guidance link to November 2020 final version

6/29/2020: Added link to Tip Sheet for CoC applications for non-Federally funded research, updated content to reflect 2017 NIH policy changes and 2020 NIH application changes.

8/30/2018: Updated to reflect October 1, 2017 NIH policy and edited Director contact information