



Office of the Human Research Protection Program

Tip Sheet: Certificates of Confidentiality (last updated March 14, 2014)

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Overview

Certificates of Confidentiality (CoCs) are issued by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Centers for Disease Control (CDC) to protect identifiable research information from forced disclosure. It allows 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.

A Certificate of Confidentiality is usually employed in studies where investigators collect sensitive information, such as that which, "... if disclosed could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation." ([National Institutes of Health \(NIH\) "Certificates of Confidentiality Kiosk"](#))

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 on an application to obtain a Certificate of Confidentiality.

Certificate Applicability

Research projects that collect personally identifiable, sensitive information and have been approved by the UCLA IRB are eligible for a Certificate. Federal funding is not a prerequisite for an NIH-issued Certificate, but the subject matter of the study must fall within a mission area of the National Institutes of Health, including its Institutes, Centers and the National Library of Medicine.

Some research areas that are eligible for a Certificate are:

- Research on HIV, AIDS, and other STDs;
- Studies that collect information on sexual attitudes, preferences, or practices;
- Studies on the use of alcohol, drugs, or other addictive products;

- Studies that collect information on illegal conduct;
- Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community;
- Research involving information that might lead to social stigmatization or discrimination if it were disclosed;
- Research on participants' psychological well being or mental health;
- Genetic studies, including those that collect and store biological samples for future use;
- Research on behavioral interventions and epidemiologic studies.

Projects that are not eligible for a Certificate are:

- not research based,
- not collecting sensitive information or information that, if released publicly, might harm the research participants,
- not collecting personally identifiable information, or
- not involving a subject matter that is within a mission area of the National Institutes of Health.

Certificates are **granted** to institutions, based upon an investigator's application, for single, well-defined research projects. Certificates are **sometimes issued for cooperative multi-site projects** which must have a coordinating center or lead institution. The coordinating center/lead institution can apply on behalf of all institutions associated with the multi-site project and must ensure that all participating institutions conform to the application assurances.

For more information, please see the [National Institutes of Health \(NIH\) "Certificates of Confidentiality Kiosk"](#).

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.)

[Click here](#) for sample language.

IMPORTANT NOTE: As a Certificate specifically allows investigators to **refuse** to disclose identifying information, UCLA investigators must **replace** the following template language in the “Confidentiality” section of consent forms with study-specific language based upon the guidance provided in the [NIH Extramural application instructions](#).

[DELETE THIS LANGUAGE] No information about you, or provided by you during the research, will be disclosed to others without your written permission, except: if necessary to protect your rights or welfare (for example, if you are injured and need emergency care); or if required by law.

UCLA IRB Review Requirements

The UCLA webIRB application requests that investigators indicate when a Certificate of Confidentiality will be requested for a 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 will be obtained will be issued contingent upon UCLA OHRPP **receipt of the application** for UCLA Institutional Official signature. UCLA investigators must submit a copy of their Certificate of Confidentiality to the UCLA IRB within ten (10) working days of receipt.

Application Instructions

[Click here](#) for NIH background information and instructions on Certificates of Confidentiality.

The application should be written on the letterhead of the research applicant institution and submitted to the appropriate NIH Institute or Center (IC). If your research is funded by NIH, please submit your Certificate application to the Contact from the funding IC. If your research is not funded by NIH, your Certificate application will be reviewed by the IC that supports similar research. Please be aware that NIH Certificates of Confidentiality are issued for important research in its mission areas only.

The Food and Drug Administration (FDA) handles requests for Certificates of Confidentiality protection for studies that obtain an Investigational New Drug (IND) authorization or other FDA authorization.

The CDC Office of Scientific Integrity (OSI) handles the review and issuance of Certificates of Confidentiality (CoC) for research grants funded by CDC or ATSDR.

UCLA Institutional Official Signature

The NIH requires that both the Principal Investigator and the UCLA Institutional Official sign the assurances requested in the application for a Certificate of Confidentiality.

In order to obtain the UCLA Institutional Official's signature, please forward your completed application to OHRPP, attention to:

- OHRPP Director Kip Kantelo
(310) 825-5855 or Kip.kantelo@research.ucla.edu OR
- OHRPP Associate Director Alison Orkin
(310) 206-3969 or AOrkin@research.ucla.edu

References and Regulations

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

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

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

[Food and Drug Administration \(FDA\) contact to apply for Certificate for studies with INDs and IDEs](#)

[CDC Office of Scientific Integrity \(OSI\) Certificate of Confidentiality application instructions](#)