CERTIFICATE OF CONFIDENTIALITY (CoC) GUIDANCE

This guidance document is intended to facilitate determinations of whether or not a research study is subject to the NIH policy on Certificates of Confidentiality (CoC). Should you need additional assistance, please contact OPHS at 510-642-7461 or ophs@berkeley.edu.

Table of Contents:

A. Introduction

A Certificate of Confidentiality (CoC) is issued to research studies funded by the National Institutes of Health (NIH) and other Department of Health and Human Services (HHS) agencies (e.g., the CDC); as well as those regulated by the Food and Drug Administration (FDA). It is intended to provide legal protection against forced disclosure, even against a subpoena, of research data or biospecimens containing identifiable, sensitive information. A CoC allows investigators and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative or other proceeding, whether at the federal, state, or local level.

B. NIH Definition of Identifiable, Sensitive Information

The updated NIH CoC policy has broadened the meaning of identifiable, sensitive information to focus more on identifiability. NIH considers identifiable, sensitive information as "covered information" about an individual, gathered or used during the course of biomedical, behavioral, clinical or other research, and is now defined to include:

1. All human subjects research as defined in 45 CFR 46, including exempt research, **except** category 4 exempt research;
2. 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;

3. Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data are identifiable or can be readily ascertained; or,
4. 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.

C. Certificate Applicability Relative to Funding

1. NIH-Funded Studies

With the NIH policy update that took effect on October 1, 2017, all ongoing or new research funded by the NIH as of December 13, 2016 that is collecting or using identifiable, sensitive information is automatically issued a CoC through a standard term and condition of award. To determine if this policy applies to research conducted or supported by NIH, investigators will need to answer a series of questions (see Appendix 1) .

2. Non-Federally Funded Studies

Investigators and/or institutions engaged in non-federally funded research, in which identifiable, sensitive information is collected, used, or stored in the US, are not required to obtain a Certificate. However, the NIH will continue to consider requests for Certificates for non-federally funded studies. Considerations will be made if the research project involves a topic that meets the NIH mission or HHS health-related research mission. See section H for this submission process to NIH .

3. Collecting Data from Subjects in a Foreign Country:

A CoC will be issued to recipients for applicable research regardless of the country where the investigator or the covered information resides. Data collected from subjects recruited in another country is protected by the CoC if the data is maintained within the U.S. However, a CoC may not be effective for data held in foreign countries.

D. Consent Forms

When a research study obtains a CoC, the research subjects must be informed of the protections afforded by the certificate, and any limitations and exceptions to that protection (such as state mandatory reporting of child abuse, harm to self or others, etc.). Therefore, the informed consent form must include the consent language describing the CoC protections, limitations, and disclosures. Please see CPHS consent templates and the NIH CoC website for suggested informed consent language. Investigators should tailor the language as necessary for the study population, (e.g., lower literacy or non-English speakers) so long as all relevant points related to disclosure and consent are covered.

E. What a CoC Does Not Protect Against

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

1. 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;
2. Voluntary disclosure/compliance 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 and intention to report are spelled out in the informed consent form;
3. 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.)

F. Duration of CoC

Identifiable, sensitive research information, and all copies thereof, collected by investigators are protected permanently, even after funding ends, including data collected before the CoC is issued if subjects participate in the study during any time the CoC is in effect. If the NIH funding is nearly finished or has ended, and the study has completed all enrollment and data collection, there is no need to extend the CoC. If a research study was issued a CoC and continues under a no-cost extension, the research is covered by the Certificate for the duration of the no-cost extension. However, new data collected/obtained after NIH funding has ended is not protected unless an application for a CoC is sought following the process for non-federally funded research.

Is re-consent required?
For ongoing studies that did not have a CoC and now receive one as part of the new policy, re-consent is **not** required for currently-enrolled participants. For new subjects who have not yet been enrolled, a revised consent form (containing the suggested language described above) should be submitted at the next amendment or continuing review application (whichever is sooner).

Significant Changes to Research under a CoC:
The NIH requires that a new CoC is obtained if a significant change is made to a research project. Significant changes include, but are not limited to:

- Major changes in the scope or direction of the research protocol;
- Changes in personnel having major responsibilities in the project (such as the PI); and/or
- Changes in the drugs to be administered (if any) and the persons who will administer them.

G. Investigator's Responsibilities

1. Do not disclose or provide covered specimens or information to anyone not connected with the research or for any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding **UNLESS**:
    a. Required by other Federal, State, or local laws (e.g., reporting to FDA, reporting communicable diseases to health departments); or
    b. The subject has consented to such disclosure (e.g., necessary for medical treatment); or
    c. The disclosure is for the purpose of scientific research that is compliant with applicable Federal regulations governing the protection of human subjects in research.

2. Inform the research subjects about the CoC, as described in section D.
3. Inform recipients of covered specimens or information (e.g., when sending covered biospecimens/data to another investigator/collaborator) that they are also subject to the requirements of the CoC even if not funded by NIH.
4. Inform sub-recipients of any study funding whose study responsibilities involve the use of the covered information that they are also subject to the requirements of the CoC.
5. Keep current records of correspondence with agency and CPHS.
6. Investigators who receive a legally-based request for information (e.g., public records request, legal subpoena, grand jury investigation) should immediately contact their department chair and the UC Berkeley legal counsel.

H. CoC Online Application for Non NIH-Funded Studies

All requests for a CoC must be made through the NIH online application system. Investigators will complete the online application by answering questions on CoC eligibility, funding source, project title, project start date, project end date, project description, institution, performance site, principal investigator and other key personnel, and any drugs that will be administered in the study (if applicable).

Investigators intending to apply for a CoC should inform OPHS in advance. This information should also be included in the confidentiality section of the associated CPHS application/research protocol.

UC Berkeley Institutional Official Certification

The NIH requires that the authorized institutional official (IO) submit the CoC request. After the online application is submitted by the PI, the NIH will send an automated email to the UC Berkeley IO listed on the CoC request with instructions to verify the CoC application, certify that the institutional assurance statement is accurate, and submit the request. The PI and the IO will both receive a confirmation email to indicate that the CoC application had been submitted. The NIH will process the CoC request within one week after receipt of the request.

Per NIH guidelines, CoC applications should be submitted **at least three (3) months** prior to the date on which enrollment of research subjects is expected to begin. A CoC is issued by the NIH Office of the Director, and investigators of non-federally funded studies should contact the NIH CoC Coordinator at the NIH Office of Extramural Research for additional information (NIH-CoC-Coordinator@mail.nih.gov) Investigators are encouraged to apply for a CoC when necessary, regardless of when they expect to start their research.

Note: CoCs for non-NIH funded studies issued on or after January 12, 2021 do not have an expiration date.

I. CoC Online Application for Studies Funded by Other HHS (non-NIH) or Other Federal Agencies

Each federal agency has separate application processes for requesting a CoC. Instructions and contact information for the relevant federal agency can be found in section K below (Table of CoC Issuance by Funding Agency).

J. OPHS/CPHS Review

In the UC Berkeley eProtocol online application system, investigators should indicate when a CoC will be requested for a research study. During its review of research for which an investigator has not identified the need for a CoC, CPHS may recommend a CoC as an appropriate protection for the proposed research.

K. Table of CoC Issuance by Funding Agency

Funding Agency	Process/Issuance	Contact Information
NIH	Automatic	
CDC	Automatic	Office of Scientific Integrity Centers for Disease Control and Prevention Atlanta, GA 30333 Phone: 404-639-4642 cdccoc@cdc.gov
Substance Abuse and Mental Health Services Administration (SAMHSA)	PI should contact the agency to apply for a CoC	Carlos D. Graham SAMHSA Reports Clearance Officer CBHSQ/OPAC Substance Abuse and Mental Health Services Administration (SAMHSA) 5600 Fishers Lane, 15E57A Rockville, MD 20857 Phone: 240-276-0361 Email: Carlos.Graham@samhsa.hhs.gov
Health Resources and Services Administration (HRSA)	PI should contact the agency to apply for a CoC	Lisa Wright-Solomon Office of Planning, Analysis, and Evaluation Health Resources and Services Administration 5600 Fishers Lane, Room 14N136-B Rockville, MD 20857 Phone: 301-443-1984 Email: lwright-solomon@hrsa.gov
Indian Health Service (HIS)	PI should contact the agency to apply for a CoC	Rachael L. Tracy Research Director, Division of Planning, Evaluation, and Research Office of Public Health Support 5600 Fishers Lane, MS 09E10D Rockville, MD 20857 Phone: 301-443-2029 Email: rachael.tracy@ihs.gov
Agency for Healthcare Research and Quality (AHRQ)	A CoC is not necessary for a research study supported by AHRQ, but their own privacy regulations may apply.	Agency for Healthcare Research and Quality Office of Communications 5600 Fishers Lane, 7th Floor Rockville, MD 20857
Under the authority of the Food and Drug Administration (FDA) operating under IND or IDE	FDA will issue discretionary CoC on a case-by-case basis. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality	Center for Drug Evaluation and Research (CDER): CDER-CoC-Requests@fda.hhs.gov Center for Biologics Evaluation and Research (CBER): CBERBIMONotification@fda.hhs.gov Center for Devices and Radiological Health (CDRH): CDRH-CoC@fda.hhs.gov

L. Additional Information

For additional information on Certificate of Confidentiality, please visit the links below and/or contact the Office for Protection of Human Subjects.

National Institutes of Health, "Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality" Notice Number: NOT-OD-17-109, Release date: September 7, 2017.

National Institutes of Health Certificate of Confidentiality (CoC)

National Institutes of Health FAQs about Certificates of Confidentiality

Online CoC System User Guide

Appendix 1: Questions to determine if the NIH CoC Policy applies

1.Was the research completed on or before December 13, 2016?
___ Yes ___ No

If the answer is Yes (i.e., the research was completed prior to 12/13/16), the policy does not apply. If the answer is No, answer the following questions:

2. Is the research conducted or funded by NIH?
___ Yes ___ No

If the answer to question #2 is No, then the activity is not issued a CoC, and the policy does not apply. If the answer is Yes, answer the following questions:

3. Does the research involve human subjects as defined by 45 CFR Part 46?
___ Yes ___ No

4. Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
____Yes ___ No

5. If collecting or using biospecimens as part of the research, is there a 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?
___ Yes ___ No

6. Does the research involve the generation of individual level, human genomic data?
___ Yes ___ No

If the answer to any of one of the questions #3 - #6 is Yes, then a CoC is automatically issued and the policy applies.