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.

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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.

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.

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

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 or used, are not required to obtain a Certificate. However, NIH will continue to consider requests for Certificates for non-federally funded studies. 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 during the time a CoC is in effect, are protected permanently, even after funding ends, including data collected before the CoC was issued. 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).

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. If the research was issued a CoC through an application, such as for a CoC issued prior to October 1, 2017 or for research not funded by NIH, the investigator should also inform the NIH Certificate Coordinator who issued the Certificate.

H. CoC Online Application for Non Federally-Funded Studies

All requests for a CoC must be made through the NIH online application system. Investigators will fill out the CoC application and attach the required documents in the online system (i.e., current CPHS approval letter, CPHS-approved consent form, a signed assurance document using this assurance template).

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. Investigators are encouraged to apply for a CoC when necessary, regardless of when they expect to start their research.

Modifying a CoC:
A CoC must be amended if a significant change is being 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.

I. 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.

UC Berkeley Institutional Official Signature
For non-federally funded research needing a CoC, the NIH requires that both the Principal Investigator and the UC Berkeley Institutional Official sign the assurances requested in the application for a CoC. In order to obtain the UC Berkeley Institutional Official's signature, the PI should contact OPHS for further instructions.

J. 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) Kiosk

National Institutes of Health FAQs about Certificates of Confidentiality

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.