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Certificates of Confidentiality

Introduction

Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH) and other DHHS agencies on behalf of the Department of Justice (DoJ) in order to protect the confidentiality of “sensitive” information obtained from research subjects. They do this by protecting investigators and institutions from being compelled to release information about research subjects, which is considered confidential because it is sensitive and identifiable. Certificates thus help to achieve the research objectives, promote participation in studies by assuring privacy to subjects, and ensure that subjects will not be harmed as a result of their taking part in research. A Certificate does not, however, take the place of good data security or clear policies and procedures for data protection, which are always essential to protect the privacy of research subjects.

This document describes when a Certificate of Confidentiality may be required by the OHSU IRB for the conduct of human subject research and the process for securing a CoC.

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1. About CoCs

Under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the National Institutes of Health (NIH).

Persons authorized by the NIH to protect the privacy of research subjects pursuant to a CoC may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify them by name or other identifying characteristic.

CoCs are issued to the institutions or universities where the research is conducted (see below for exception concerning multi-site research). In general, certificates are issued for single, well-

defined research projects rather than groups or classes of projects. In some instances, they can be issued for cooperative multi-site projects. It is an authorization by the NIH on behalf of the DoJ to allow an investigator 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.

While CoCs protect against involuntary disclosure, subjects may voluntarily disclose, or request investigator to disclose, their research data or information. Subjects may, for example, authorize the investigator in writing to release the information to physicians, insurers, employers, or other third parties. In such cases, researchers may not use the CoC to refuse disclosure. CoCs do not, however, authorize researchers to refuse to disclose information about subjects if authorized DHHS personnel or authorized OHSU reviewers request such information for an audit or program evaluation. Neither can researchers refuse to disclose such information if it is required to be disclosed by the Federal Food, Drug, and Cosmetic Act.

Researchers are also not prevented from disclosure of child abuse, reportable communicable diseases, or a subject's threat of violence to self or others. If, however, the researcher intends to make such disclosures, that must be clearly stated in the consent form.

2. General Guidelines

- A.** The OHSU IRB may require CoCs for studies involving sensitive information. Investigators are expected to plan for this requirement when conducting studies involving sensitive information.
- B.** When a CoC is required, the IRB may approve a study contingent upon the issuance of a CoC by the NIH. Once the CoC is issued and documentation of such is submitted to the IRB, final approval will be granted.
- C.** Projects generally not eligible for a CoC are:
 - Projects that are not research;
 - Projects that do not collect personally identifiable information;
 - Projects that are not reviewed and approved by an IRB; and
 - Projects collecting information that, if disclosed, would not significantly harm or damage the subject.
- D.** For foreign studies, if the data obtained from a study done outside the U.S. are maintained within the U.S., a researcher may obtain a CoC. If the data are only maintained in a foreign country, a CoC's legal protections are not effective.
- E.** OHSU researchers are expected to comply with State and Local requirements to report communicable diseases, and also to meet other requirements, such as reporting suspected child and elder abuse. Any researcher desiring not to comply with reporting requirements must justify the request to IRB and obtain IRB approval of the non-disclosure plan. Requests must be based on the welfare and rights of the subjects.

3. When Is a Certificate of Confidentiality Appropriate?

- A.** An OHSU Principal Investigator who plans a study in which sensitive and identifiable information will be obtained should consider applying to a DHHS agency for a Certificate. By "sensitive," DHHS means identifiable information which, if disclosed, could have adverse consequences for subjects or damage their financial standing,

employability, insurability or reputation. Examples of sensitive information may include, but are not limited to:

- Information on the psychological state of subjects;
 - Subjects' sexual attitudes, preferences or practices;
 - Information about substance abuse or other illegal behavioral; and
 - Studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).
 - Results of genetic tests.
 - For CoC purposes, genetic tests may be considered to be tests that indicate a participant's risk of developing a health condition.
 - Tests for non-CLIA approved labs are typically not considered a valid estimate of risk of developing a health condition.
- B.** If the IRB determines that a study meets the definition of sensitive and that disclosure of such information could have adverse consequences for subjects or damage their financial standing, employability, insurability or reputation, a CoC will be required for approval.

4. IRB Review and Approval of a Study that Requires a CoC

A. Initial review of a Study for IRB Review that involves Sensitive Information

- Investigators who are submitting a study for review which involves information that could be considered sensitive, should submit a memo commenting on the need for a CoC and any intentions of seeking or not seeking a CoC. If a CoC is not being sought, please describe why. The basis could include, but is not limited to, an opinion that the data is not sensitive or that the data is not identifiable.
- The IRB or its designee will review the submission and communicate its requirement for a CoC.
- The decision may be appealed back to the IRB. In cases of expedited review, the appeal will go to full board.
- **Multi-site studies**
 - If OHSU is the lead institution on a multi-site study or a coordinating center the PI can apply for and receive a CoC on behalf of all member institutions. The application must list each participating unit, its address, and project director. In addition, the OHSU PI (as lead site) must indicate that it has on file a copy of the IRB approval and IRB-approved consent form(s) from each site, which will be made available to the COC granting agency upon request.
 - If OHSU is a site in a multi-site study and the lead site or coordinating center has a CoC to cover all of the sites, the OHSU PI does not need a CoC for the OHSU site. The PI and OHSU is covered by the CoC once it goes into effect.
- **Informed Consent**
 - The consent form must inform subjects that a CoC is in effect and must describe both the protections afforded by the CoC and any limitations or exceptions to this protection. If the investigators apply for a CoC before the IRB approves the study, or intend to apply for one after IRB approval, the consent form(s) submitted for IRB review should include the CoC language.
 - The CoC should not, however, be represented as an endorsement of the study by the DHHS or as a means of coercing recruitment of subjects. If OHSU is the lead institution on a multi-site study or a coordinating center and holds a CoC

for the collaborating institutions, the consent form(s) for each site must describe the protections and limitations of the CoC.

- Investigators who decide to apply for and obtain a CoC after IRB approval of their study, must notify subjects of the protections provided by the CoC. This should be done by a consent addendum, for already enrolled subjects, and a revised consent form that includes the appropriate language concerning the CoC for new enrollees.

B. The Approval Process

- If a CoC is required by the IRB, the approval for the study will be granted, contingent upon the issuance of a CoC.
- Once the CoC is issued, the investigator should submit a copy of the official letter to the IRB and if all other requirements for approval have been met, final IRB approval will be granted.
- If a CoC has been required, contact with human subjects may not commence until the CoC is issued. Only the IRB can remove or alter this limitation.
- CoC's go into effect either on the date of issuance, if the study already has IRB approval, or on the date of final approval.

C. Modifications

- Modifications to studies with a CoC come through the IRB per standard modification procedures.
- If a significant change in your research project is proposed after a CoC is issued, you must inform the Certificate Coordinator of the Institute issuing the certificate by submitting an amended application for a CoC (in the same form and manner as your original application for a CoC). Significant changes include: major changes in the scope or direction of the research protocol, changes in personnel having major responsibilities in the project, or changes in the drugs to be administered (if any) and the persons who will administer them.

5. Applying for a CoC

- A.** Application for a CoC should be made after IRB reviews and gives contingent approval of the research plan. This is because CoCs will not be issued until IRB approval has been obtained. Approximately three months should be allowed for receipt of the CoC.
- B.** Investigators may apply for a CoC by completing the application found at the NIH CoC Kiosk at <http://grants.nih.gov/grants/policy/coc/>. Investigators should review the instructions and other information concerning CoCs at the Kiosk.
- C.** A CoC can be awarded whether or not a research project is federally funded. Contact the NIH to determine which institute will issue the CoC.

6. Mandatory Reporting Requirements

- A.** Even under a CoC, the standard is to comply with State reporting requirements unless there is sound scientific or ethical justification not to do so. The consent form must notify subjects of intended compliance with reporting requirements.
- B.** When a researcher desires to not comply with reporting requirements a memo should be submitted to the IRB with justification for the request and a non-disclosure plan. In the disclosure plan, the PI must describe either:

- An agreement that the applicant has made with the health department to cooperate in ways that serve the purposes of communicable disease reporting requirements, or
 - The specific reasons related to confidentiality requirements of the research that preclude such reporting.
- C. When physicians conducting research also provide clinical care for the subjects in a non-research relationship, the protections of the certificate do not apply to the non-research relationship and those physicians are considered the referring physicians for purposes of this guidance.

7. What to do when a request is made for data protected by a CoC

- A. The PI should contact the IRB Office immediately. The IRB Office will contact General Counsel on behalf of the PI.
- B. The PI should also immediately inform the Certificate Coordinator who issued the Certificate. The Office of the NIH Legal Advisor is willing to discuss the regulations with the OHSU General Counsel.

Additional Resources

NIH Certificate of Confidentiality Kiosk: <http://grants.nih.gov/grants/policy/coc/>