Certificates of Confidentiality

Definitions

Identifiable Sensitive Information – At HHS, information that has a degree of confidentiality such that its loss, misuse, unauthorized access, or modification could compromise the element of confidentiality and thereby adversely affect national health interests, the conduct of HHS programs, or the privacy of individuals entitled under The Privacy Act or the Health Insurance Portability and Accountability Act (HIPAA).

Purpose

A Certificate of Confidentiality (CoC) is needed when disclosure of information may have consequences for subjects' financial standing, employment, insurability, or reputation.

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) or the FDA to protect identifiable research information from forced disclosure. They allow the investigator 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.

Certificates of Confidentiality may be granted for studies collecting information that if disclosed could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. Certificates of Confidentiality help to reduce the risk to research subjects by protecting researchers from being compelled to disclose private information and add additional privacy protection by maintaining confidentiality.

Research eligible for a CoC

As of October 1, 2017, all studies funded by the NIH that involve human subject research and involve identifiable, sensitive information will automatically be issued a Certificate of Confidentiality. Research this is not funded by the NIH/HHS may still be eligible for a CoC. NIH is authorized to issue CoCs for sensitive research that is not federally funded, at its discretion, if the research is related to the NIH mission. Additionally, the research must be approved by an IRB operating under an approved Federal-wide Assurance and must accurately reflect the protections and limitations of the CoC in the subject consent form. FDA is authorized to issue CoCs for studies with an IND/ IDE that do not have other HHS funding. For multi-site research, the lead institution may apply for a CoC to cover all sites involved in the research.

Examples of research automatically covered by a CoC include:

- Biomedical, behavioral, clinical, or other research, including exempt research, except where the information obtained is recorded in such a manner that human participants

cannot be identified or the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants.

- The collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small irsk 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.
- 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 participants can be identified or the identity of the human participants can readily be ascertained.
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practice 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.

Responsibilities of investigators

When research is covered by a CoC:

Researchers may not disclose, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for the purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains

Researchers may not disclose or provide to another person not connected with the research the name of such an individual or any information, document, of biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

May disclose information only when:

(A) Required by federal, state, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to state and local health departments), excluding instances of disclosure in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding.

(B) Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;

(C) Made with the consent of the individual to whom the information, document, or biospecimen pertains; or

(D) Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human participants in research.

Researchers conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other researchers or organizations, the other researcher or organization must comply with applicable requirements when research is covered by a Certificate of Confidentiality.

Disclosure of the CoC to participants

Written materials require that when research is covered by a Certificate of Confidentiality, researchers must inform participants (for example, in the consent document) of the protections and limitations of certificates of confidentiality.

For studies that were previously issued a Certificate, and notified participants of the protections provided by that Certificate, NIH does not expect participants to be notified that the protections afforded by the Certificate have changed, although IRBs may determine whether it is appropriate to inform participants. If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer activity participating in the study, NIH does not expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented to be re-contacted to be informed of the Certificate, although IRBs may determine whether it is appropriate to inform participants.

To explain the Certificate of Confidentiality in the consent form for participants, use the following language:

A Certificate of Confidentiality (CoC) issued by the NIH covers this research. A CoC protects your private information from disclosure for legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research.

- No one can be forced to share your identifiable information or biological samples for a lawsuit.
- Your information cannot be used as evidence even if there is a court subpoena.

If you consent, your information or biological samples could be shared for: *(restate what will be disclosed if there are other purposes listed in the consent form, such as "other scientific research" or "for your medical treatment" or any other purpose that may apply)*

The CoC does not prevent some disclosures. Only include the next statement if a US federal or state government agency is funding the research: The researchers can't refuse requests for information from those funding this research. The [Funding Agency] may need information to assess this project. If applicable add: Also, the US Food and Drug Administration (FDA) may need information.

You can still share information about yourself. You can also freely discuss your involvement in this research. The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others, or communicable diseases.

How to apply for a CoC:

At NIH, CoCs are issued by the individual NIH Institutes or Centers (ICs). Thus, CoC applications should be directed to the IC that is funding the research or that supports similar research. If you are uncertain about which IC is appropriate, contact the NIH CoC Central Resource person (http://grants.nih.gov/grants/policy/coc/contacts.htm).

Apply online for a CoC from the NIH for non-NIH funded research:

https://grants.nih.gov/policy/humansubjects/coc.htm