



Guidance

Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. A CoC allows 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. A project does not have to receive NIH funds to request a CoC.

However, all NIH funded awards are automatically issued a CoC as part of the grant award terms, whenever the study is funded in whole or in part by NIH. This policy applies to all NIH research commenced or ongoing on or after December 13, 2016. A CoC is intended to prohibit disclosure of sensitive, identifiable information in response to legal demands including:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- 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;
- Research that involves 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 subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- 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, as defined in subsection 301(d) of the Public Health Service (PHS) Act.

For non-federally funded research, Food and Drug Administration (FDA) also has the authority (by delegation) to issue CoCs related to the study of products subject to FDA jurisdiction and to which FDA regulations apply, in compliance with the PHS Act. For non-federally funded research regulated by FDA, issuance of CoCs is not required but *may* be issued at the discretion of FDA (i.e., discretionary CoCs).



Certificates of Confidentiality

What is protected?

A CoC protects names or any information, documents, or biospecimens containing identifiable sensitive information known as 'covered information.' Identifiable, sensitive information is defined as:

- Information about an individual, gathered or used during the course of biomedical, behavioral, clinical or other research, through which the individual is identified, or there is at least a very small risk that some combination of the information, a request for the information, and other available data sources could be used to determine the identity of an individual. The policy defines this as "covered information."
- Identifiable, sensitive information includes but is not limited to name, address, social security number or other identifying number; and fingerprints, voiceprints, photographs, genetic information, tissue samples, or data fields that when used in combination with other information may lead to identification of an individual.

What are the recipient's responsibilities?

Any investigator or institution issued a CoC shall not:

- Disclose or provide covered information, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding; or
- Disclose or provide covered information to any other person not connected with the research.

Researchers with a CoC may ONLY disclose identifiable, sensitive information in the following circumstances:

- If required by other Federal, State, or local laws, such as for reporting of communicable diseases;
- If necessary for the medical treatment of the individual to whom the information, document, or biospecimens pertains and is made with the consent of the individual;
- If the subject consents;
- For the purposes of scientific research that is compliant with human subjects regulations.

Written materials require that researchers conducting NIH-supported research covered by a CoC must ensure that if identifiable, sensitive information is provided to other researchers or organizations, regardless of whether or not the research is federally funded, the other researcher or organization must comply with applicable requirements when research is covered by a CoC.

Informed Consent Requirements for CoCs:

The informed consent must include language that explains to potential research subjects that a CoC is part of the research study, and the scope and limits to which the CoC applies.



Certificates of Confidentiality

NIH Example CoC language:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Resources

The NIH maintains a website with all the necessary information on CoCs:

<https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/coc>.

For questions on the terms and use of a CoC see the NIH FAQ page:

<https://grants.nih.gov/faqs#/certificates-of-confidentiality.htm>.

Issuance of CoCs by the FDA: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality>.