Ascension Wisconsin IRB

Certificate of Confidentiality (CoC)

A Certificate of Confidentiality (Certificate) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena.

The 21st Century Cures Act removed the requirement for NIH awardees to have to apply for a CoC- instead a CoC is issued automatically for any NIH-funded project using identifiable, sensitive information that was on-going on or after December 13, 2016.

CoCs are also available for research that is not NIH funded, and each agency has their own CoC application process.

The most complete and detailed source of information is the National Institutes of Health FAQ about Certificates of Confidentiality (CoC). Much of the information below is taken from this source.

Below are some common questions and additional references about Certificates of Confidentiality (CoC)

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What is a Certificate of Confidentiality (CoC)?

A Certificate of Confidentiality (CoC) is a legal protection that agencies within the federal Department of Health and Human Services can issue to researchers to protect identifiable, sensitive information collected as part of a study. It allows researchers to refuse to disclose names or any information, documents or biospecimens containing identifiable information about the research subjects. The Certificate specifically prohibits disclosure of the information in response to legal demands, such as a subpoena, Public Records request, or Freedom of Information Act (FOIA) request.

CoCs are issued by most agencies of the federal Department of Health and Human Services.

How do I get a CoC?

NIH-funded research. All research funded wholly or in part by NIH is issued a CoC as a term of the grant or contract, if the research involves identifiable, sensitive information as defined above. In other words, researchers are no longer required to specifically apply for a CoC. This policy was implemented on October 1, 2017. It is retroactive – that is, it applies to existing active NIH grants and contracts. All NIH Notices of Award (competing and noncompeting) now specifically mention the CoC. The NIH does not issue a separate CoC document. If NIH funding ends while subjects are still being enrolled, the researcher must obtain a new CoC using the applicable application process described below.

All other research. The researcher must apply to the appropriate federal agency for a CoC at least 3 months prior to the date on which subject enrollment is expected to begin. The agency will provide documentation of the CoC when it has been granted. Note that issuance of CoCs is at the discretion of the agency, if the research is not funded by the issuing agency. Multisite studies: A coordinating center or lead institution can apply for a CoC on behalf of all participating sites.

For research that is not funded by NIH, the IRB may require the researcher to obtain a CoC as a condition for IRB approval. IRB approval cannot be granted for the components of the study that will be covered by the CoC (including subject recruiting and consenting for those components) until the CoC is received from the researcher.

See the NIH CoC Kiosk for more information about getting and maintaiing a CoC from any agency.

Researcher Responsibilities

- Do not disclose the information in these circumstances:
  - Any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding; or
  - To any other person not connected with the research.
- Disclosure of covered information is allowed ONLY in the following circumstances:
  - If required by other Federal, State, or local laws, such as for reporting of communicable diseases;
  - If the subject consents; or
  - For the purposes of scientific research that is compliant with human subjects protections.
- Inform the study subjects about the CoC.
- Inform recipients of copies of the protected information (for example, when sending covered biospecimens to another investigator for a secondary study) that they are also subject to the requirements of the CoC.
- Inform subrecipients of any study funding whose study responsibilities involve a copy of the protected information that they are also subject to the requirements of the CoC.
- Researchers cannot use the CoC to refuse to release information to other individuals or institutions when the subject has requested it and provided authorization for the release (though other legal constraints may apply).
- Researchers cannot use the CoC to refuse to provide information necessary to meet institutional requirements. For example, researchers may be required to insert information into medical records.

Researchers who receive a legally-based request for information (e.g., public records request; legal subpoena; grand jury investigation) should immediately contact their department chair or administrator, and the Ascension Wisconsin Office of General Council.

What is "Identifiable Sensitive Information"?

The 21st Century Cures Act (passed in December 2016) significantly broadened the type of information that is protected by a CoC, by essentially interpreting "sensitive" to mean "identifiable or possibly identifiable". Identifiable sensitive information is now defined to include:

- All human subjects research, including exempt research (except category 4 exempt research)
- 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 are identifiable or can be readily 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 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.

This broad definition applies to all current, future, and past CoCs, because the 21st Century Cures Act was explicitly written by Congress to be retroactive.

Data collected from subjects recruited in another country are protected by the CoC, if the data are maintained within the U.S. If the data are maintained only in the foreign country, a CoC may not be effective.

Informing Subjects about a CoC

For all studies that will obtain informed consent, subjects must be told about the protections provided by the Certificate, and any exceptions to those protections (such as state mandatory reporting). The Ascension Wisconsin IRB has standardized language in the Consent Form Template.

Maintaining a CoC

Data collected while the CoC is active are permanently protected. It continues even after study funding has ended and the study has been completed. Each CoC has an expiration date; data collected after the expiration date are not protected.

For NIH-funded research, the expiration date is the end of the NIH funding, including any no-cost extensions. For all other research, the expiration date is stated on the CoC document issued by the federal agency. The expiration date can be extended, by specific request of the researcher to the agency that issued the CoC. See this NIH website for information about the NIH online process for extending the expiration date.

With the automatic NIH-issued CoC, researchers do not have to amend or extend the CoC as previously required under the old CoC policy.

For non-NIH funded research, CoCs must be amended (modified) 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)
- Changes in the drugs to be administered (if any) and the persons who will administer them

Relationship with Other Privacy and Data Protections

HIPAA. CoC protections apply to Protected Health Information (PHI) if it is collected or created as part of a research study. The HIPAA Privacy Rule permits use or disclosure of PHI in response to certain judicial or administrative orders, a CoC does not. Therefore CoCs protect researchers from being forced to disclose identifiable, sensitive information collected or used in research that might otherwise have to be disclosed under the HIPAA Privacy Rule.

DOJ Privacy Certificate. Research that is covered by a Department of Justice (DOJ) Privacy Certificate does not need to apply for a CoC. The DOJ Certificate provides essentially the same protections.

AHRQ Confidentiality Statute. Research funded by the federal Agency for Healthcare Research and Quality (AHRQ) does not need to apply for a CoC. An AHRQ confidentiality statute provides similar protections.

References

- National Institutes of Health, "Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality". Notice Number: NOT-OD-17-109, released September 7, 2017.
- National Institutes of Health Certificate of Confidentiality Kiosk
- National Institutes of Health FAQs about Certificates of Confidentiality