

Certificates of Confidentiality (CoCs)

***NEW* Policy for NIH Funded and Conducted Research** –CoCs will automatically be issued to people engaged in biomedical, behavioral, clinical, or other research, in which *identifiable sensitive* information is collected.

- Responsibility is on investigator and institution to determine if research falls within scope of policy
- See below for additional details

Note: New policy effective October 1, 2017 & retroactively applies to research that began on or after 12/13/16.

Purpose

Certificates of Confidentiality allow the 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. Certificates can be used for biomedical, behavioral, clinical or other types of research that is sensitive.

- **Identifying information** is any item(s) in the research data that could lead directly or indirectly to the identification of a research subject.

Protections Afforded by a CoC

When a CoC is in effect, the investigator and others involved with the research **may not:**

- disclose or provide any information or biospecimen that contains identifiable information about a participant to anyone outside of the research unless the participant authorizes in writing, permission to release information or voluntarily discloses their information.

Disclosure is only permitted when:

1. Required by Federal, State, or local laws (ex. Federal Food, Drug, and Cosmetic Act), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding
2. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
3. Made with the consent of the individual to whom the information, document, or biospecimen pertains;
or
4. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

Obtaining a Certificate of Confidentiality

NIH Funded Research - *NEW* [NIH Policy](#) - COCs will automatically be issued to individuals engaged in biomedical, behavioral, clinical, or other research, in which **identifiable sensitive information** is collected. The Notice of Award and the Grants Policy Statement will serve as documentation of the CoC. A physical certificate will not be issued.

“Identifiable sensitive information” – information about an individual gathered or used during the course of the research where:

- An individual is identified, or
- There is at least a very small risk that some combination of information, a request for information, or other available data sources could be used to deduce the identity of an individual

Responsibility is on the investigator and institution to determine if research falls within the scope of policy (see below).

Effective: October 1, 2017 & retroactively applies to research that began on or after 12/13/16.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

- All human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), except research that meets an Exemption and information obtained is recorded without identifiers or the identity of participants cannot be readily ascertained;
- 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;
- Any research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data regardless of identifiability;
- Any other research that involves information about an individual for which 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 deduce the identity of an individual.

Research Supported by CDC, HRSA, or SAMHSA, or under the authority of FDA:

These agencies issue their own certificates of confidentiality. Contact the [Certificate Coordinator](#) at the funding agency to determine how to obtain a CoC.

Other Non-DHHS, Federally Funded Research and Non-Federally Funded Research:

Health-related research that is not federally funded may request a CoC using the [online application system](#) hosted by NIH. The proposed informed consent form must be submitted as part of the CoC application. Direct a CoC request to the NIH Institute or Center (IC) that supports similar research. NIH recommends verifying this with the appropriate [IC coordinator](#) before submitting an application. If unsure about which IC is most appropriate for the research topic, contact the NIH Central Coordinator at NIH-COC-Coordinator@mail.nih.gov.

Informed Consent Implications

When research is covered by a CoC, NIH and the IRB expect that the informed consent document will describe to participants the protections afforded by a CoC. The NIH provides suggested [informed consent language](#).

If the research is automatically covered by a CoC:

- submit to the IRB the consent documents with the CoC language included.

If the research is not automatically covered, and a CoC is being requested:

- submit to the IRB a consent document that states a COC was requested. Once the CoC is approved, modify the consent to address the protections in place.

NIH Studies Funded on or after December 13, 2016

Any NIH study funded on or after December 13, 2016 that meets the above criteria for a CoC has automatically been issued a CoC. Existing informed consent documents likely do not include CoC language.

Investigators conducting studies for which a CoC has automatically been issued and for which enrollment is ongoing should submit an amendment to the reviewing IRB to add CoC language to the informed consent document(s). Newly enrolled participants should be consented with an informed consent form that included CoC language. The NIH does not require that currently enrolled participants be re-consented, but the investigator may choose to do so.

Determining Applicability of NIH COC Policy – If the research began on or after 12/13/16

1. Is the research conducted or funded by NIH? Yes No
2. Is the activity biomedical, behavioral, clinical, or other research? Yes No

If the answer to *either* of these questions is **No**, then the activity is not issued a CoC and the policy does not apply. If the answer to both is **Yes**, answer the following questions:

1. Does the research involve human subjects as defined by 45 CFR Part 46? Yes No
2. Are you collecting or using information or biospecimens that are identifiable to an individual as part of the research? Yes No
3. If collecting or using information or biospecimens as part of the research, is there a small risk that some combination of the information or biospecimen, a request for the information or biospecimen, and other available data sources could be used to deduce the identity of an individual? Yes No
4. Does the research involve the generation of individual level, human genomic data? Yes No

If the answer to *any one of these questions* is **Yes**, then a CoC is automatically issued and the policy applies.

Resources:

- [NIH Policy](#)
- [NIH CoC Website](#)