

HUMAN RESEARCH AFFAIRS CERTIFICATES OF CONFIDENTIALITY (CoC)

Certificates of Confidentiality (CoCs) are issued by the National Institutes of Health (NIH) and other HHS agencies to protect identifiable, sensitive research information from forced disclosure in civil, criminal, administrative, legislative, or other proceedings, whether federal, state, or local. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help to minimize risks to subjects by adding an additional level of protection for maintaining confidentiality of private information.

Any investigator or institution conducting research protected by a Certificate of Confidentiality **shall not**, without the specific consent of the individual to whom the information pertains, disclose identifying information to any court or other person not connected with the research.

Disclosure of protected information is permitted only when:

1. Required by Federal, State, or local laws;
2. Made with the consent of the individual to whom the information, document, or biospecimen pertain, including disclosure necessary for an individual's medical treatment; or
3. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

The consent form must include information about the protections provided by the certificate and any restrictions.

Requests for Information Pursuant to Subpoena, or Federal, State or Local Civil, Criminal, Administrative, Legislative or Other Proceeding

Whenever you receive requests for information related to the above, contact the Office of the General Counsel.

Frequently Asked Questions (FAQs):

What is a Certificate of Confidentiality?

A certificate of Confidentiality 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.

What information is protected by a Certificate?

Certificates protect "covered information." Covered information includes names or any information, documents, or biospecimens containing identifiable, sensitive information related to a research participant. In addition, if there is at least a very small risk that information, documents, or biospecimens can be combined with other available data sources to determine the identity of an individual, then they are also protected by the Certificate.

Do the requirements of a Certificate apply to copies of information shared for other research?

Yes. The protection covers all copies of information collected or used by the investigator in the research covered by the Certificate, even those copies that are shared for other research.

How long does a Certificate's protection last?

The protection of the Certificate lasts in perpetuity. However, data collected after a Certificate expires, or NIH funding ends, may not be protected.

For NIH funded research, a Certificate protects the information that you collect or use during the period in which your research is funded by NIH. If the study continues after your NIH funding ends and you want Certificate protection for new information that will be collected, you should request a Certificate following the process for non-NIH funded research. You may want continued protection, for example, if you were collecting new information from participants or enrolling new participants after the period in which the research was funded by NIH.

If a research project was issued a Certificate and continues under a no-cost extension, the research is covered by the Certificate for the duration of the no-cost extension.

How long is a CoC Valid?

NIH Funded Studies: CoCs automatically cover research activities and do not need to be extended or amended while the research remains funded by NIH. If there is a lapse in funding for any reason, the CoC protections might not apply to information collected during that time period. However, CoC protections continue for the duration of a no-cost extension.

If the NIH funding ends, the study will no longer be deemed issued a CoC. While CoC protections remain in perpetuity for already collected or used information, a new CoC will need to be obtained in order to cover any new data collected from already enrolled participants or any new participants. See the [CoCs for Research Not Funded by NIH](#) page for additional information on requesting a non-NIH funded CoC through the online NIH CoC System. If NIH funding will or has ended and enrollment and data collection are complete, there is no need to request a new CoC.

Other CoCs: Check with the issuing agency for information about expiration.

Does the NIH CoC policy apply to training awards include F, K, and T awards?

CoCs are issued for applicable NIH funded research. In F and K awards, NIH is funding the research by providing direct support to the Principal Investigator (PI) to conduct a specific research project and a CoC would be automatically issued. In general, most T awards are not providing funding for a research project but instead are providing funding to allow trainees to work for a short time period on a mentor's project that has a separate source of funding. Thus, the T award would not provide CoC protection for the mentors' projects. Note that the mentor projects may have CoC protection if they are funded by NIH under another mechanism (such as an R01 award). In a minority of T awards, the trainees conduct their own unique research project; in such cases where the award is supporting the conduct of the research, the CoC would be issued automatically through this award. But most T awards simply provide a training opportunity by allowing trainees to work for a short time period on a mentor's project that has another separate source of funding (not through the T award).

What disclosures are allowed?

The CoC allows the following disclosures:

- If required by Federal, State or local laws (e.g., reporting child, elder abuse, communicable diseases) – but excluding civil, criminal, administrative, legislative proceedings
- For medical treatment with the consent of the individual
- With the consent of the individual
- For other research that is in compliance with human subjects protection regulations

What disclosures are prohibited?

- Disclosing or providing, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name or any information, document or biospecimen that contains identifiable sensitive information that was compiled or generated for the purposes of the research; unless, that individual gives consent for the disclosure.
- Disclosing or providing to any other person not connected with the research the name or any information, document or biospecimen that contains identifiable sensitive information that was compiled or generated for the purposes of the research; unless, that individual gives consent for the disclosure.

Which agencies issue a CoC?

The National Institutes of Health (NIH), the Centers for Disease Control (CDC), Food & Drug Administration (FDA), Substance Abuse and Mental Health Services Administration (SAMHSA), Indian Health Service (IHS), and Health Resources & Services Administration (HRSA) issue CoCs.

Investigators whose research is funded by CDC, HRSA, IHS, or SAMHSA should contact the Certificate Coordinators at their funding agency to determine how to obtain a CoC.

Investigators whose research is operating under an IND or IDE and is under the authority of the FDA should contact the FDA Certificate Coordinators at the relevant Center.

For more information about the agencies, review the table at the end of this guidance.

Which Federal agencies currently issue a CoC automatically upon award of funding?

The NIH, CDC, and the FDA* issue CoCs automatically as part of the funding for any research using identifiable, sensitive information.

*This applies to studies funded by the FDA. Research under FDA oversight but not funded by the FDA do not receive automatic CoCs.

What is meant by identifiable, sensitive information?

The statute that governs Certificates of Confidentiality broadened the meaning of sensitive, identifiable information and focuses more directly on identifiability. Identifiable, sensitive information is information about an individual, gathered or used during 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.

Identifiable, sensitive information includes but is not limited to name, address, social security 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 under a Certificate?

Any investigator or institution issued a Certificate 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 public health reporting of communicable diseases or child or elder abuse reporting
- If the subject consents; or
- for the purposes of scientific research that is compliant with human subjects' regulations

As a PI, what are my responsibilities if I have a CoC?

You are expected to:

- Be aware of which disclosures are permitted and which are prohibited.
- Notify sub-awardees and any secondary users of the covered data/specimens that there is a CoC and what protections and disclosure restrictions must be in place
- Contact the Office of General Counsel in the event of a request for identifiable sensitive data/biospecimens for the purposes of a legal proceeding. Do not disclose the information.

How will research participants be informed?

The only notification will be via the informed consent form (ICF) or an Information/Fact Sheet that includes language describing the protections with a CoC. The consent form must include information about the protections provided by the certificate and any restrictions.

Are summary results of research prohibited from disclosure by Certificates?

NIH generally does not consider summary research results, such as genomic summary results or summary results of clinical trials, to be identifiable, sensitive information as summary results are not "about an individual," but rather, are about a group of individuals. Moreover, summary results generally pose less than a very small risk that individuals could be re-identified, even when used in conjunction with other available data sources.

Is it possible to share information protected by a Certificate with other researchers? Can such information be shared openly (e.g., on a public website without any requirements for download)?

Information protected by a Certificate can be shared openly on a public website only where otherwise authorized to be disclosed by the statute, for example, if participants have consented to such sharing. The NIH Policy on Certificates of Confidentiality expects that the recipient of a Certificate will ensure that an investigator or institution who receives a copy of information protected by a Certificate understands that they are also subject to the requirements of subsection 301(d) of the Public Health Service Act.

CoCs are not new, what has changed?

The 21st Century Cures Act introduced two changes:

- (1) CoCs are now *automatically issued* for research involving identifiable sensitive data or biospecimens funded by an HHS Agency (NIH, FDA, CDC, HRSA, SAMHSA). There is no longer a need to proactively apply for a CoC if funded by one of these agencies.
- (2) The old CoC protects an investigator from being forced to disclose research information pursuant to Federal, State or local civil, criminal, or legislative proceedings. The new policy

states that investigators are prohibited from making any such disclosures of identifiable sensitive information.

Can the IRB require a CoC for my non-federally funded or unfunded research?

The IRB may require the researcher to obtain a CoC as a condition for IRB approval if identifiable sensitive information is being collected.

Can I obtain a CoC for my non-federally funded or unfunded research?

Investigators conducting research that is not federally funded in which identifiable, sensitive information is collected or used, may request a Certificate of Confidentiality (CoC) from NIH. Click [here](#) for more information.

What studies would NOT be eligible for a Certificate?

Examples of research that would be ineligible to receive a Certificate include:

- not research based,
- not collecting or using identifiable, sensitive information pertaining to research participants,
- a research program, rather than an individual research study/project
- establishing and maintaining a data and/or biospecimen repository where the main source of the data and/or biospecimens was originally obtained for clinical care or other purposes, rather than research purposes,
- not involving a topic that is within a mission area of the National Institutes of Health or the Department of Health and Human Services.

What kind of non-NIH-funded research is eligible for a Certificate?

Generally, any research project on a sensitive health-related topic that collects names or other identifiable, sensitive information pertaining to subjects, that has been approved by an IRB, and that is in compliance with the *Federal Policy for the Protection of Human Subjects* at 45 CFR 46 (the Common Rule) or follows relevant provisions of the Common Rule relating to consent, may be eligible for a Certificate. The study topic (e.g., purpose, objectives, aims) must fall within a mission area of the National Institutes of Health or the Department of Health and Human Services. NIH issuance of Certificates is discretionary.

Are there any costs or fees associated with requesting a Certificate of Confidentiality from NIH for a non-NIH funded research project?

There are no costs or fees associated with requesting a discretionary Certificate of Confidentiality for a non-NIH funded research project. Detailed information on Certificates of Confidentiality is available at the [Certificate of Confidentiality website](#).

Can NIH issue a Certificate to me for a non-research activity with a vulnerable population?

No. NIH is unable to issue a Certificate to an investigator or institution for non-research activities since these activities are not eligible for a Certificate of Confidentiality.

Where can I find more information about CoCs?

The table below provides agency-specific information about CoCs. For multi-site studies, a coordinating center or lead institution can apply for a CoC on behalf of all participating sites.

Agency	CoC Information
National Institutes of Health	<p>Automatically issued as a term of the grant or contract for NIH-funded research that involves collection of <i>sensitive identifiable information</i>.</p> <p>Researchers without NIH funding may submit an application for a NIH CoC.</p> <p>Click here for NIH CoC FAQs</p>
Food and Drug Administration	<p>Automatically issued as a term of the grant or contract for FDA-funded research that involves collection of <i>sensitive identifiable information</i>.</p> <p>For non-federally funded research operating under an IDE or IND, the FDA will consider requests to issue a <i>discretionary CoC</i>.</p>
Centers for Disease Control	<p>Automatically issued as a term of the grant or contract for CDC-funded research that involves collection of <i>sensitive identifiable information</i>.</p>
Health Resources & Services Administration (HRSA)	<p>Automatically issued as a term of the grant or contract for HRSA-funded research that involves collection of sensitive identifiable information.</p>
Indian Health Service	<p>Contact the IHS CoC Coordinator to request a CoC.</p>
Substance Abuse & Mental Health Services Administration (SAMHSA)	<p>Can be requested for studies with a SAMHSA grant or contract and that involve collection of <i>sensitive identifiable information</i>.</p>
Department of Defense	<p>Contact the Directorate of Human Research Protections for more information</p>
Other federal agencies and non-federally funded research	<p>Contact the federal agency for more information.</p> <p>The Agency for Healthcare Research & Quality (AHRQ) has its own privacy regulations which may apply; NIH will not issue a CoC for projects covered by AHRQ’s regulations. Contact AHRQ for further information about their privacy regulations.</p> <p>Issuance of a CoC for research that is not funded by NIH is at the discretion of NIH. Click here for more information.</p>