



National Institutes of Health (NIH): Certificate of Confidentiality

Certificates of Confidentiality protect identifiable, sensitive research information from disclosure. NIH automatically issues Certificates of Confidentiality (CoC) to all NIH funded or conducted research studies that are collecting or using identifiable, sensitive information (see *Determining CoC Policy Applicability below*).

Researchers who are collecting identifiable, sensitive information who do not have NIH funding can request a certificate to extend the same protections that are issued for NIH funded research.

Note: NIH changed their CoC policy on October 1, 2017 making the CoC a term and condition of the NIH award for qualifying studies. The CoC is now automatically issued with the NIH award when the applicable. This policy change is retroactive to December 13, 2016.

[Visit the NIH CoC Kiosk](#) for more information!

Questions for Determining NIH CoC Policy Applicability

- Is the activity biomedical, behavioral, clinical, or other research?

If the answer to this question is no, then the activity is not issued a Certificate. If the answer is yes, then investigators will need to answer the following questions:

- Does the research involve Human Subjects as defined by 45 CFR Part 46?
- Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
- If collecting or using biospecimens as part of the research, is there a 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?
- Does the research involve the generation of individual level, human genomic data?

If the answer is yes to one the above questions the policy applies and NIH will automatically issue a CoC.

Submitting to the IRB

Initial Submissions

When the policy applies please include consent document(s) language provided with the CoC.

Current Submissions

If the study is a NIH funded or conducted study, please review the Determining Applicability questions above. If the policy applies and a CoC is issued to investigators, an amendment should be submitted to the IRB with the updated consent language.

In addition, at the point of continuing review the IRB Administration Office will review NIH submissions to determine if certificate of confidentiality language is needed.

[Review suggested CoC consent form language.](#)

Extending or Amending Current CoC with NIH

Not sure if you need to extend or amend an existing CoC with NIH? [View the NIH kiosk page](#) on extending and amending an existing Certificate of Confidentiality.

Obtaining a Certificate of Confidentiality for research funded by other HHS Agencies (non-NIH)

Several non-NIH agencies, including CDC, FDA, HRSA, and SAMHSA issue Certificates of Confidentiality. If your research is funded by one of these agencies or is operating under the authority of the FDA, please contact the Certificate Coordinators at the funding agency to determine how to obtain a CoC.

If your research is funded by an HHS agency other than NIH, CDC, HRSA or SAMHSA, that do not issue CoCs, you may request a Certificate of Confidentiality for specific health-related projects using sensitive, identifiable information using the NIH online system. NIH issues CoCs on behalf of these HHS agencies. Visit the [NIH Policy and Compliance website](#) for information about how to request a CoC and contact information for these agencies.

Obtaining a Certificate of Confidentiality for Non-Federally Funded Research:

Investigators may also apply for a certificate of confidentiality for non-federally funded research. On February 28, 2020 NIH announced changes to their process for receiving CoC requests for non-NIH funded research. These key changes include:

- NIH will no longer accept Certificate of Confidentiality requests through the current system as of March 11, 2020.
- Current users who need a copy of their Certificate or associated documentation should access the [Certificate of Confidentiality system](#) to download these files prior to March 13, 2020. Users will no longer have access to the current Certificate of Confidentiality system as of March 13, 2020.
- The new system streamlines and simplifies the Certificate of Confidentiality request process by utilizing self-certification statements and shortened text fields, rather than attachments
- The new CoC system requires direct submission by the authorized institutional official, rather than by the investigator or another research team member.

See the full Notice [for Transition to New System for Issuing Certificates of Confidentiality for Non-NIH Funded Research](#) for more information.

Disclosing Data Protected under a Certificate of Confidentiality:

Written materials specify that when research is covered by a certificate of confidentiality, investigators:

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

Investigators may disclose information only when:

- 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.

- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual.
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable federal regulations governing the protection of human participants in research.

Requirements of a Certificate of Confidentiality:

Investigators conducting NIH- supported research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other investigators 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 certificate of confidentiality.

When research is covered by a certificate of confidentiality, investigators 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 participants were notified 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 actively 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.