

## Certificates of Confidentiality

Per Section 2012 of the 21<sup>st</sup> Century Cures Act, all NIH-funded research that collects identifiable, sensitive data are automatically issued a Certificate of Confidentiality (CoC) as part of the terms and conditions of the award.

[NIH: Certificates of Confidentiality](#)

A CoC protects research participants' privacy by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research study in which the information was collected. This policy applies to studies that received NIH funding (in part or in whole) on or after December 13, 2016.

The NIH defines the term "identifiable, sensitive information" broadly: in practice, it includes any and all identifiable data collected in a human subjects research study. If you are conducting research that is subject to the NIH CoC policy, the data collected in your study are protected by a CoC, regardless of whether you have formally applied for one. The CoC policy and 42 U.S.C. §241(d) require that investigators working on NIH-funded human subjects research shall 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
- 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.

Disclosure is permitted 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 subjects in research.

Identifiable, sensitive information protected by 42 U.S.C §241 “shall be immune from the legal process, and shall not, without the consent of the individual to whom the information pertains, be admissible as evidence or used for any purpose in any action, suit, or other judicial, legislative, or administrative proceeding,” and “shall be subject to the protections afforded by this section for perpetuity.” Please contact your institutional legal counsel immediately if you receive a subpoena for research records.

### [Discretionary CoCs for non-NIH funded research](#)

NIH will consider [requests for CoCs](#) for single studies that are not funded by NIH if the research studies human health and collects identifiable, sensitive information. NIH will not issue discretionary CoCs for research programs or repositories, or when the main source of the data and/or biospecimens was originally obtained for clinical care.

For research funded by the CDC, HRSA, IHS, or SAMHSA, or research conducted under the authority of the FDA, contact the [CoC Coordinator at the funding agency](#). If you are conducting DoD-funded research, your research data are not automatically protected by a CoC; however, per [DoD policy](#), if the study collects Large-Scale Genomic Data from DoD personnel, Department of Health and Human Services (DHHS) will issue a CoC to protect those data. For all other DoD-funded research, investigators must request a discretionary CoC from DHHS if desired.

The NIH will not issue a CoC for research funded by AHRQ or DoJ. The DoJ requires funding applicants to submit a Privacy Certificate. See the [DoJ website](#) for more information.

### [FAQ:](#)

Q: I have obtained a new NIH award for a study that was initially approved before I received this funding. Do I need to amend my consent form to include Certificate of Confidentiality language?

A: Yes. Please submit a revised consent form for review. Template CoC language can be found [here](#).

You should also educate your research team about CoCs, and inform any research collaborators if the data you are sharing were collected under a Certificate of Confidentiality since the new restrictions would apply to your colleagues as well.

Q: Do I need to re-consent subjects enrolled prior to a CoC being in effect?

A: No. Re-consent is not generally required if this is the only change to the consent form.

Q: Will I be issued a Certificate of Confidentiality for my research even if I do not want one?

A: If your human subjects research is funded by NIH, it is covered by a CoC. However, NIH does not issue formal certificates.

Q: How do I apply for a CoC?

A: If your research is not NIH-funded, you should first revise your consent form to include the CoC language and obtain COMIRB approval. Once the amendment has been approved, you may apply for a CoC [online here](#). If NIH determines that your study qualifies for a CoC, it will contact the University's Associate Vice Chancellor for Regulatory Compliance, who will provide NIH with an institutional certification.

Q: If I receive a subpoena for research records, what do I do?

A: Contact institutional legal counsel immediately.

Q: Where can I get more information?

A: <https://grants.nih.gov/policy/humansubjects/coc.htm>