



Guidance Document

Certificate of Confidentiality

Overview

NIH has updated its policy regarding Certificates of Confidentiality in order to implement Section 2012 of the 21st Century Cures Act, enacted December 13, 2016. Effective October 1, 2017, NIH funded (partially or wholly) research studies that are collecting identifiable, sensitive information will automatically be issued a Certificate of Confidentiality as part of the terms and conditions of the award (<https://humansubjects.nih.gov/coc/index>).

The 21st Century Cures Act amended Title 42 of U.S. Code, Section 241(d) Protection of privacy of individuals who are research subjects. The term “identifiable, sensitive information” is broadly defined and in effect includes all human subjects research.

If you are conducting human subjects research **funded by NIH** that was commenced or ongoing on or after December 13, 2016, you are subject to the new law and policy, even if you have not applied for a Certificate of Confidentiality.

Under the new law and policy, 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.

Under the new law, the identifiable, sensitive information protected by 42 USC 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.” These protections are new and untested in case law. Please contact your institutional legal counsel immediately if you receive a subpoena for research records.

Researchers funded by NIH no longer need apply for a Certificate of Confidentiality. Researchers conducting human subjects research which is not funded by NIH, will need to apply for a Certificate of Confidentiality if one is deemed necessary following the previously established process.

FAQ

Q: I already have a Certificate of Confidentiality for my research. Do I need to amend my consent form?

A: No, it is not necessary to change the wording in your approved consent form.

Q: My research is subject to the new policy, but my consent form does not discuss Certificates of Confidentiality. Should I amend my consent form?

A: Yes. Please include the new template language in your consent form. Template language has been included on the CU IRB website:

<https://www.colorado.edu/researchinnovation/irb/investigator-resources/forms-templates>

Q: Do I need to re-consent subjects enrolled prior to this change?

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

Q: Is there a deadline for submitting a revised consent form?

A: Please submit an amendment by your next continuing review. Note that if you are conducting NIH-funded research, you and your research data are subject to the new law, even if the consent form has not been updated.

A: If you are following best practices to protect identifiable research data, you probably do not need to change any practices, but you do need to inform any research collaborators if the data you are sharing was collected under a Certificate of Confidentiality since the new restrictions would apply to your colleagues as well. You should also educate your research team about these new changes, and you should amend your consent form if it does not address Certificates of Confidentiality.

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

A: Yes, if your human subjects research is funded by NIH. However, NIH will not send you a copy of a certificate.

Q: I applied for a Certificate of Confidentiality but have not yet received it. Will I be notified by NIH when my Certificate of Confidentiality has been issued?

A: If your research is NIH-funded, a Certificate of Confidentiality is deemed to have been issued. Do not expect to receive a copy of the certificate. If your research is not NIH-funded, you should be notified once a certificate once it has been issued.

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

A: Contact your institutional legal counsel immediately.

Q: Where can I get more information?

A: <https://humansubjects.nih.gov/coc/index>

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