

Dartmouth CPHS Guidance Document Certificate of Confidentiality (CoC)

Reference : National Institutes of Health

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

Frequently asked Questions:

<https://grants.nih.gov/faqs#/certificates-of-confidentiality.htm>

A Certificate of Confidentiality (Certificate or CoC) protects the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations.

The CoC policy and 42 U.S. Code §241(d) defines identifiable, sensitive information as information that is about an individual and that is gathered or used during the course of research where the following may occur:

- Through which an individual is identified; or
- 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 identify of an individual.

Sensitive information includes (but is not limited to) information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.

Researchers can use a Certificate to avoid compelled "involuntary disclosure" (e.g., subpoenas) of names and other identifying information about any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect. It does not protect against voluntary disclosures by the researcher, but those disclosures must be specified in the informed consent form. A researcher may not rely on the Certificate to withhold data if the participant consents in writing to the disclosure.

Effective October 1, 2017 Certificates of Confidentiality (CoCs) are automatically deemed to be issued for any NIH-funded research that collects or uses identifiable, sensitive information that was on-going on or after December 13, 2016. For these projects:

- The CoC is issued as a term and condition of the award
- NIH does not issue a physical certificate

The NIH will continue to consider requests for Certificates of Confidentiality for specific projects that are not funded by NIH. For information regarding CoCs for non-NIH funded research, see the [CoCs for Research Not Funded by NIH page](#).

When a CoC is obtained, the research subjects must be told about the protections afforded by the Certificate and any exceptions to that protection. That information should be included in the informed consent form. Sample consent language describing the CoC is below. Researchers may adapt the language to the needs of the research participants and to the subject matter of the study. However, the language used must cover the basic points noted below.

In addition, researchers should review boilerplate language about confidentiality and data security that is routinely included in consent forms to ensure that it is consistent with the protections of the Certificate of Confidentiality and the intentions of the researchers to use these protections as necessary.

Your consent form must be submitted as part of the application and will be reviewed for accuracy.

Sample Consent Language:

[Example consent language regarding Certificates of Confidentiality.](https://grants.nih.gov/policy/humansubjects/coc/suggested-consent.htm)
<https://grants.nih.gov/policy/humansubjects/coc/suggested-consent.htm>

Note that the text in [brackets] is instructional and not part of the consent form language

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

[language such as the following should be included if researcher intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.] The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of *[list what will be reported, such as child abuse and neglect, or harm to self or others]*.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

