



Certificates of Confidentiality

What is a Certificate of Confidentiality?

A Certificate of Confidentiality helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical, and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, to identify information or characteristics of a research participant.

What kind of research is eligible for a Certificate?

Any research project that collects personally identifiable, sensitive information, and that has been approved by an Institutional Review Board (IRB), is eligible for a Certificate. NIH or other federal funding is not a prerequisite for a Certificate.

What is meant by sensitive information?

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

Who may apply for a Certificate of Confidentiality?

Any person engaged in research in which sensitive information is gathered from human research participants (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality.

Is NIH required to give all who apply a Certificate of Confidentiality?

No. No project is entitled to a Certificate; its issuance is discretionary.

How long does a Certificate's protection last?

Individuals who participate as research subjects (i.e., about whom the investigator maintains identifying information) in the specified research project during the period the Certificate is in effect are protected permanently.

What is the researcher's responsibility to participants regarding a Certificate of Confidentiality?

When a researcher obtains a Certificate of Confidentiality, the subjects must be told about protections afforded by the Certificate and any exceptions to those protections. This information should be included in the informed consent form, unless the research subjects are no longer actively participating in the project. In addition, researchers may not represent the Certificate as an endorsement of the research

project by the Department of Health and Human Services, or use it in a coercive manner when recruiting subjects.

When should one apply for a Certificate?

Inasmuch as IRB approval of a research project, or approval conditioned upon issuance of a Certificate of Confidentiality, is a prerequisite for issuance of a Certificate, in general, an application for a Certificate of Confidentiality is submitted after the IRB responsible for its review approves the research project. Since the informed consent form should include language that describes the Certificate and any voluntary disclosures specified by the investigator, the applicant may tell the IRB that he or she is applying for a Certificate of Confidentiality and has included appropriate language in the informed consent form. Applications for Certificates should be submitted at least three months prior to the date on which enrollment of research subjects is expected to begin.

Whom does one contact to apply for a Certificate of Confidentiality?

If NIH funds the research project for which a Certificate is sought, application may be made through the funding Institute. However, even if the research is not supported with NIH funding, one may apply for a Certificate through the NIH Institute or Center that funds research in a scientific area similar to that of the project's. Contact information is available on the NIH web site at:

<http://grants1.nih.gov/grants/policy/coc/index.htm>

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