

Certificate of Confidentiality Policy and Guidance

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, for identifying information or identifying characteristics of a research participant.

What kind of research is eligible for a Certificate?

As of October 1, 2017 a Certificate of Confidentiality became a term and condition for NIH grant awards that commenced or were ongoing after December 1, 2016. Any NIH-sponsored research that collects identifiable data or biospecimens or generates human genomic data automatically receives a Certificate.

In addition, any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. NIH or federal funding is not a prerequisite for a Certificate.

What is meant by sensitive information?

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.

Who may apply for a Certificate of Confidentiality?

As of October 1, 2017 a Certificate of Confidentiality became a term and condition for NIH grant awards that commenced or were ongoing after December 1, 2016. Any NIH-sponsored research that collects identifiable data or biospecimens or generates human genomic data automatically receives a Certificate.

In addition, 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. NIH issues these certificates at its own discretion.

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 any time the Certificate is in effect are protected permanently.

I am not NIH-funded. To whom should I apply for a Certificate of Confidentiality?

If your research is not supported with NIH funding, you may apply for a Certificate through the NIH Institute or Center (IC) funding research in a scientific area similar to your project. Contact information is available on the NIH website: <http://grants.nih.gov/grants/policy/coc/index.htm>

When should I apply for a Certificate?

As of October 1, 2017 a Certificate of Confidentiality became a term and condition for NIH grant awards that commenced or were ongoing after December 1, 2016. Any NIH-sponsored research that collects identifiable data or biospecimens or generates human genomic data automatically receives a Certificate.

If you do not have NIH funding, an application for a Certificate of Confidentiality should be submitted to the Einstein IRB after the Institutional Review Board (IRB) responsible for its review approves the research project (because IRB approval or approval conditioned upon issuance of a Certificate of Confidentiality is a prerequisite for issuance of a Certificate). Since the informed consent form should include language describing the Certificate and any voluntary disclosures specified by the investigator, the Applicant could tell the IRB that they are applying for a Certificate of Confidentiality and have 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.

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 - i.e., the circumstances in which the investigators plan to disclose, voluntarily, identifying information about research participants (e.g., child abuse, harm to self or others, etc.). This information should be included in the informed consent form unless a research subject is no longer actively participating in the project so amendment of the informed consent would be impractical. The researchers should eliminate provisions in consent form templates that may be inconsistent with the Certificate protections (such as references to disclosures required by law, since the Certificate enables researchers to resist disclosures that would otherwise be compelled by law). In addition, researchers may not represent the Certificate as an endorsement of the research project by the DHHS or use it in a coercive manner when recruiting subjects.

The Einstein IRB consent template has the following language:

As a way to protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health, which is funding this study. If information from this study was requested or subpoenaed by government agencies or the courts, we will use the Certificate to attempt to legally refuse to provide it. This is rare – in only a few cases did researchers have to use the Certificate, and it was honored most of the time, but not every time. There are several kinds of situations that the Certificate does not apply. For example, we are still required to report child abuse and some diseases, and we must make data available to the government for a review or evaluation of our research. The Certificate does not prevent you or a member of your family from voluntarily sharing information. Similarly, if an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Does the Privacy Rule preclude the need for Certificates of Confidentiality?

No. Certificates of Confidentiality offer an important protection for the privacy of research study participants by protecting identifiable health information from forced disclosure (e.g., by court order). While the Privacy Rule does establish protections for covered entities' use and disclosure of PHI, it permits use or disclosure in response to certain judicial or administrative orders. Therefore, researchers/contractors may obtain Certificates of Confidentiality to protect them from being forced to disclose information that would have to be disclosed under the Privacy Rule.

Does a Certificate of Confidentiality preclude the need to notify public health authorities regarding reportable diseases and conditions?

According to NIH, it generally requires that state reporting requirements be followed, and that Certificates of Confidentiality generally will not exempt reporting in accordance with state law. Researchers should notify public health authorities regarding all reportable diseases and conditions (<https://www.health.ny.gov/professionals/diseases/reporting/communicable/>) . For additional information on NIH's policy on reporting communicable diseases, see http://grants.nih.gov/grants/policy/coc/cd_policy.htm 2

Does a Certificate of Confidentiality preclude the need to report elder abuse, child abuse, or spouse abuse, as required by state laws?

As a policy matter, NIH generally is unwilling to issue a Certificate of Confidentiality that exempts reporting of child abuse. In addition, Section 413 of the New York State Social Services Law requires that suspected or actual instances of child abuse be reported to the appropriate authority. To date, it does not have similar policies on reporting of elder abuse or spouse abuse. Should you obtain a Certificate of Confidentiality for either spouse abuse or elder abuse, in the unlikely event you become aware of threatened or actual abuse which has not already been reported, contact the Einstein IRB for additional directions. Instances or suspected instances of child abuse always need to be reported to the New York State Child Protective Services Office (<http://ocfs.ny.gov/main/cps/Default.asp>).