

## CERTIFICATES OF CONFIDENTIALITY

### Description

Data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) requires the protection of confidentiality beyond preventing accidental disclosures. Under Federal law, Investigators can obtain an advance grant of confidentiality, known as a Certificate of Confidentiality that will provide protection against compulsory disclosure, such as a subpoena, for research data.

Federal funding is not a prerequisite for requesting a Certificate of Confidentiality. Any research that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate.

A Certificate of Confidentiality provides protection for the Investigator and the participants against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research (Public Health Service Act '301(d), 42 U.S.C. '241(d)). Under this Act, the Secretary of Health and Human Services (HHS) may authorize persons engaged in research to protect the privacy of participants by withholding from all persons not connected with the conduct of the research the names or other identifying characteristics of the participant. This means that Investigators may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify their participants.

The protection is available only when the research is of a sensitive nature where the protection is judged necessary to achieve the research objectives. Examples of studies that would **not** qualify for a certificate of confidentiality are:

- Projects that are not research based;
- Projects that are not approved by an IRB in accordance with the NIH guidelines governing Certificates of Confidentiality;
- Projects that do not collect sensitive information or information that might harm the research participants; or
- Projects that do not collect personally identifiable information.

An investigator should consider applying for a Certificate of Confidentiality when the results of research participation could yield information in one or more of the following categories:

- HIV status, AIDS related complications, or other sexually transmitted diseases;
- Information relating to sexual attitudes, preferences, or practices;
- Information relating to the use of alcohol, drugs or other addictive products;
- Information pertaining to substance abuse, illegal conduct, or other risk behaviors;
- Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;
- Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination;
- Information where subjects may be involved in litigation related to exposures under study (e.g. breast implants, environmental or occupational exposures);
- Information pertaining to an individual's psychological well-being or mental health;
- Information collected that may be considered sensitive in connection with behavioral interventions and epidemiologic studies; and
- Genetic information.

Certificates of Confidentiality do not take the place of good data security or clear policies and procedures for data protection, which are essential to the protection of research participants' privacy. Researchers should take appropriate steps to safeguard research data and findings. Unauthorized individuals must not access the research data or learn the identity of research

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.

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participants.

The Certificate of Confidentiality does not govern the voluntary disclosure of identifying characteristics of research participants but only protects participants from compelled disclosure of identifying characteristics by the Investigator. Investigators, therefore, are not prevented from the voluntary disclosure of matters such as child abuse or a subject's threatened violence to self or others. However, if an Investigator intends to make such voluntary disclosures, the consent form should clearly indicate this.

## Applying for the Certificate of Confidentiality

Applications for a Certificate of Confidentiality should be submitted to the NIH at least three (3) months prior to the date on which enrollment is expected to begin. If the Investigator has not already applied for a Certificate of Confidentiality, upon its review of the research, the IRB may recommend that an Investigator apply for a Certificate of Confidentiality. NIH provides detailed instructions for investigators wishing to make an application. See below under References and Links.

It must be noted that the issuance of this certificate is up to the discretion of the NIH. If granted, the Certificate provides indefinite protection from compulsory disclosure, such as subpoena for research data.

## Points to Address

<b>New Study Application:</b>	1. <b>Data Monitoring Page, Confidentiality Precautions:</b> Please select "A Certificate of Confidentiality (from the NIH) will be used". State whether the certificate has been requested or has been obtained and is in effect for the study.
<b>Consent Document:</b>	1. <b>Confidentiality:</b> Please state that a Certificate of Confidentiality is in effect for the study. 2. <b>Confidentiality:</b> Please briefly provide participants with a clear explanation of the protection that the Certificate of Confidentiality affords, including the limitations and exceptions. For example, "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." Also, ensure that an explanation of how identifiable information will be used or disclosed is provided.
<b>After receipt of IRB approval:</b>	1. A copy of the IRB approval letter must be forwarded by the Investigator to the agency, in which the certificate was applied, for final review and determination.

## References & Links

DHHS Certificates of Confidentiality Kiosk	<a href="http://grants.nih.gov/grants/policy/coc/index.htm">http://grants.nih.gov/grants/policy/coc/index.htm</a>
DHHS Certificates of Confidentiality Instructions for Applicants	<a href="http://grants.nih.gov/grants/policy/coc/background.htm">http://grants.nih.gov/grants/policy/coc/background.htm</a>
DHHS Certificates of Confidentiality FAQ	<a href="http://grants.nih.gov/grants/policy/coc/faqs.htm">http://grants.nih.gov/grants/policy/coc/faqs.htm</a>

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