

Certificate of Confidentiality

Overview:

Certificates of Confidentiality can be useful tools for investigators conducting research in sensitive areas. They are granted by federal funding agencies to protect research data from forced disclosure in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates may be sought in instances when data are being collected about sensitive issues such as illegal behavior, alcohol or drug abuse, sexual practices or preferences, or whenever it is important that the confidentiality of research records be enhanced (e.g., genetics research; HIV infection; sexually transmitted diseases; mental health). It provides the investigator with a mechanism to assure the confidentiality of subjects' private information which may help facilitate enrollment and build trust between the researcher and the subject. The IRB recommends that investigators seek a Certificate of Confidentiality whenever their federally-funded studies collect data about subjects that may affect their financial standing, employability, insurability, or reputation if that information were to be disclosed.

If the study is not federally funded, University policy does not permit investigators to seek a federal Certificate of Confidentiality but the University of Pittsburgh Office of General Counsel will work vigorously with investigators to protect research data should a subpoena or other demands for research information be issued. Under those circumstances, the investigator should immediately contact the IRB Office, and the Office of General Counsel.

Considerations:

Consent Document: Language related to the Federal Certificate of Confidentiality must be included in the consent document. If a Federal Certificate of Confidentiality is not issued, a modification must be submitted to remove the language.

Carefully review the consent document to ensure that there is no conflicting language with regard to the protection and handling of confidential information

NIH Application for a Certificate of Confidentiality: Must be signed by the PI and by the Director of the University of Pittsburgh Office of Research

OSIRIS:

Section 5, question 5.9 must be answered "YES"

Consent:

Language related to the Federal Certificate of Confidentiality must be included in the initial IRB application. If a Federal Certificate of Confidentiality is not issued, a modification must be submitted to remove the language from the consent document.

Sample wording:

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. 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.

[The researchers should include language such as the following if they intend to make voluntary disclosures about things such as child abuse, intent to hurt self or others, or other voluntary disclosures.]

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].***

[Note: If a Certificate of Confidentiality has been obtained, the consent form should not include any language that contradicts the intent of the Certificate. For example, the following should not appear in a consent form when a Certificate has been obtained]: “In unusual cases, your research records may be released in response to an order from a court of law”

Additional Information:

NIH Certificates of Confidentiality Kiosk: <http://grants.nih.gov/grants/policy/coc/index.htm>

Application Instructions: http://grants.nih.gov/grants/policy/coc/appl_extramural.htm