

National Institutes of Health (NIH) Suggested Consent Language Describing the Certificate of Confidentiality (CoC) Protections

- If the researcher obtains informed consent for research covered by a [Certificate of Confidentiality](#), NIH expects that the researcher will tell participants about the protections afforded by the Certificate and any exceptions to that protection.
- Sample consent language describing the protections, limitations and exceptions afforded by a Certificate 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.
- It also may be necessary to include language relating to Certificates as part of the statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained as required by 45 CFR 46.
- In addition, researchers and their institutions 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.
- Confidentiality and the intentions of the researchers and institutions to use these protections as necessary.
- For non-NIH-funded research, the proposed consent form must be submitted as part of the application and will be reviewed for accuracy.

Note: You should edit the Suggested Consent Language as necessary for your study population, (for example lower literacy or non-English speakers), so long as all relevant points related to disclosure and consent are covered.



CERTIFICATE OF CONFIDENTIALITY CONSENT FORM

Sample Text

To help us protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

[Use the following language as applicable] The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by *[the agency]*, which is funding this project 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 from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

[language such as the following should be included if researcher intends to disclose information covered by a Certificate, such as potential child abuse, or intent to hurt self or others in response to specific federal, state, or local laws.] The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of *[list what will be reported, such as child abuse and neglect, or harm to self or others]*.

[language such as the following should be included if researcher intends to disclose information covered by a Certificate, with the consent of research participants.] The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document *[restate what will be disclosed, such as including research data in the medical record]*.