



WORKSHEET: Certificate of Confidentiality

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The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating whether a Certificate of Confidentiality (CoC) is automatically issued per NIH policy, should be required or is appropriate for a study. This worksheet is to be used. It does not have to be completed or retained.

1 Considerations for Certificate of Confidentiality (Check if "Yes") If checked, a CoC covers the research.

<input type="checkbox"/>	The research involves Human Subjects as defined by DHHS regulations, is funded by the National Institutes of Health (NIH) and is biomedical, behavioral, clinical, or other research ⁱ . If "Yes," answer the following:
<input type="checkbox"/>	The research involves collecting or using biospecimens that are identifiable to an individual or there is a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
<input type="checkbox"/>	The research involves the generation of individual level, human genomic data.
<input type="checkbox"/>	The research is collecting, obtaining or creating personally identifiable sensitive ⁱⁱ information.
If any of the 3 items above are "Yes", the research is automatically covered by a CoC.	

2 Suggested Consent Language for Research with a Certificate of Confidentiality (Check if present in the consent form)

<input type="checkbox"/>	<p>"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.</p> <p>The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency 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, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.</p> <p><i>[language such as the above should be included if researcher intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.]</i> The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of <i>[list what will be reported, such as child abuse and neglect, or harm to self or others].</i>"</p>
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ⁱ NOT-OD-17-109: Notice of Changes to NIH Policy for Issuing Certificates of Confidentiality; <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>

ⁱⁱ Per NOT-OD-17-109, the term "identifiable, sensitive information" is broadly defined and means "information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

- An individual is identified; or
- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual."