



WORKSHEET: Certificate of Confidentiality		
NUMBER	DATE	PAGE
HRP-333	3/31/2019	1 of 1

The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating whether a certificate of confidentiality is required or 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”)

- The research is funded by the National Institutes of Health (NIH) and is biomedical, behavioral, clinical, or other researchⁱ
If “Yes”, answer the following:
 - The research involves Human Subjects as defined by DHHS regulations. (See “WORKSHEET: Human Research Determination (HRP-310).”)
 - The research involves collecting or using biospecimens that are identifiable to an individual.
 - If collecting or using biospecimens as part of the research, 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 (N/A if not using biospecimens.) N/A
 - The research involves the generation of individual level, human genomic data.
- If any of the 4 items above are “Yes”, a certificate of confidentiality is required by NIH and applies to the research.**
- The research is collecting personally identifiable information.
- The research is sensitive.ⁱⁱ
- The research is collecting information that if disclosed could significantly harm or damage the participant.

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

- “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 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.

[language such as the following 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.] 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].*”

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 Examples of sensitive research activities include but are not limited to the following: Collecting genetic information; Collecting information on psychological well-being of subjects; Collecting information on subjects' sexual attitudes, preferences or practices; Collecting data on substance abuse or other illegal risk behaviors; Studies where subjects may be involved in litigation related to exposures under study (e.g., breast implants, environmental or occupational exposures).