



WORKSHEET: Certificate of Confidentiality

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4.206 (HRP-333)	5/1/24	1 of 1

The purpose of this worksheet is to provide guidance for the convened IRB or Designated Reviewer when evaluating whether a Certificate of Confidentiality is required or appropriate for the research and to assist the reviewer(s) in providing an explanation for this determination. The worksheet should be used for any study for which a Certificate is necessary regardless of funding source. This worksheet is to be used. It does not need to be completed or retained.

1 Research Funded by the National Institutes of Health (NIH) (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 3.207 (HRP-310) - WORKSHEET - Human Research Determination)

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.

The consent document reflects information about the Certificate of Confidentiality as outlined in Box 3 below.

2 Unfunded Research for which a Certificate of Confidentiality will be Obtained from the NIH-Kiosk. (Check if “Yes”)

A Certificate of Confidentiality will be sought for unfunded research because the research is biomedical, behavioral, clinical or other health-related research which involves human subjects defined by the DHHS or FDA regulations, it proposes to collect or use personally identifiable information, the subject matter is sensitive and the information, if disclosed, could significantly harm or damage the interests of the subject.

The consent document reflects information about the Certificate of Confidentiality as outlined Box 3 below.

3 Consent Language for Research with a Certificate of Confidentiality Issued by NIH or the NIH-Kiosk (Check if “Yes” to confirm Certificate language is present in the consent form.)

COC Consent Language:

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

4 Research is Funded by Other U.S. Government Dept. or Agency (Check if “Yes”)

A Certificate of Confidentiality is required by an Dept. Or Agency other than NIH, and the PI has supplied the consent language required or recommended by the Government Department or Agency issuing the Certificate.

The language required or recommended by the Government Dept. or Agency appears in the consent form.

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).