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|  |  | **Certificate of Confidentiality Supplement** |

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| **Date:** |  | **IR File#:** |  | **Protocol #:** |  |
| **Principal Investigator:** |  | | | | |
| **Study Title:** |  | | | | |

A [Certificate of Confidentiality](https://extranet.fredhutch.org/en/u/irb/special-topics/coc.html) (CoC) restricts disclosure of names or any information, documents, or biospecimens containing identifiable, sensitive information about research participants. Certificates are issued by the National Institutes of Health (NIH) and other Health and Human Services agencies to researchers to help protect the privacy of participants in research.

The NIH, CDC, and FDA now automatically issue a CoC to almost all research funded by those agencies. If your research is not automatically covered by a CoC, you may still apply for a CoC with the appropriate federal agency. For more information, please refer to IRB Policy 2.12, *Privacy and Confidentiality* (030) or visit: <https://humansubjects.nih.gov/coc/index>.

To see a decision tree of the below questions, visit <https://extranet.fredhutch.org/en/u/irb/special-topics/coc/decision-tree.html>.

**Answer the following questions to determine whether the study is covered by a Certificate of Confidentiality:**

1. Is the research funded or otherwise supported by NIH, FDA\*, or CDC?

\*Note: FDA here refers only to *funding* by FDA, not research *regulated* by FDA. Research subject to FDA oversight but not funded by FDA does not automatically receive a Certificate of Confidentiality

Yes → Go to question 2.

No → Skip to question 6.

1. Does the research involve *Human Subjects,* as defined by [45 CFR 46](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.102).102?

Yes → STOP. The study **is covered by a Certificate of Confidentiality** automatically issued by the NIH, CDC, or FDA at the time of award, and the investigator is obligated to uphold the disclosure restrictions.

No → Go to question 3.

1. Are you collecting or using **biospecimens** that either 1) are identifiable to an individual, or 2) for which there is at least a very 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?

Yes → STOP. The study **is covered by a Certificate of Confidentiality** automatically issued by the NIH, FDA, or CDC at the time of award, and the investigator is obligated to uphold the disclosure restrictions.

No → Go to question 4.

1. Does the research involve the generation or use of **individual level, human genomic data** from biospecimens, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained?

Yes → STOP. The study **is covered by a Certificate of Confidentiality** automatically issued by the NIH, FDA, or CDC at the time of award, and the investigator is obligated to uphold the disclosure restrictions.

No → Go to question 5.

1. If No to questions 2-4 above, will the research involve **information** about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, 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?

Yes → STOP. The study **is covered by a Certificate of Confidentiality** automatically issued by the NIH, FDA, or CDC at the time of award, and the investigator is obligated to uphold the disclosure restrictions.

No → Go to question 6.

1. Will this research project involve the use of biospecimens and/or data that are covered by a Certificate of Confidentiality (e.g., data from a NIH repository such as dbGaP or biospecimens and/or data collected or generated by another research project covered by a Certificate of Confidentiality)?

Yes → STOP. Those biospecimens and/or data **are covered by a Certificate of Confidentiality**, and the protections extend to the biospecimens and data permanently. When you receive such biospecimens or data, you are obligated to uphold the disclosure restrictions.

No → STOP. The study is not automatically covered by a Certificate of Confidentiality. Note, a Certificate may still apply if you plan to request one to protect participants’ sensitive information..

I do not know → The federal government expects that recipients of a Certificate will inform subrecipients, contractors, and others (e.g., secondary researchers) when information/biospecimens disclosed to them is protected by a Certificate. If uncertain, check with the data/specimen source.

Please refer to the Certificates of Confidentiality web page for additional information: <https://extranet.fredhutch.org/en/u/irb/special-topics/coc.html>