



PARTICIPANT ENROLLMENT IN STUDIES INVOLVING A CERTIFICATE OF CONFIDENTIALITY

11/22/2023

A Certificate of Confidentiality (CoC) provides additional protections against compulsory disclosure of identifying information about participants enrolled in research that collects identifiable, sensitive information.

NIH Funded Research

Research funded wholly or in part by the National Institutes of Health (NIH) that was commenced or ongoing on or after December 13, 2016 and collects or uses identifiable, sensitive information, is automatically issued a CoC by NIH. For the purposes of the NIH policy, “identifiable, sensitive information” 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 the individual.

For the purposes of this policy, NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research except for human subjects research that is determined to be exempt from all or some of the requirements of 45 CFR 46 if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
- Research involving the collection or use of biospecimens that are identifiable to an individual or 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;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, 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 as defined in 45 CFR 46; or

- Any other research that involves 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, as defined in subsection 301(d) of the Public Health Service Act.

If NIH funding for a study has ended but the collection of new data from research participants will continue, the investigator must apply for an additional CoC for continuity of protections. If NIH funding has ended and all enrollment and data collection is complete, the data that was collected is permanently protected under the original CoC.

Non NIH Funded Research

For research not funded by NIH, the Principal Investigator shall make the initial determination regarding the appropriateness of obtaining a CoC for the protocol. As part of the review process, the IRB Primary Reviewer shall make an independent assessment of the need for a CoC for the protocol. The IRB will make the final determination regarding the requirement for a CoC, and approval for the study will not be issued until the requirement has been met by the Principal Investigator.

The IRB shall consider the following parameters in making its determination of the need for a CoC: nature of the research activities, characterization of the disease/disorder, age/gender/ethnicity of the participant population, social/legal implications of the results of the research, effect of the results of the research on the individual participant, their family, and the local community, and the risks to the participant and their family regarding the possibility of loss of confidentiality regarding the research and its results.

Investigators for studies that are not funded by NIH may apply for a CoC via NIH's CoC web site: <https://grants.nih.gov/policy/humansubjects/coc.htm>

Responsibilities Under a CoC

An investigator and institution issued a CoC shall:

- Abide by the disclosure requirements of the CoC
- If there are any sub-awardees, inform them that a CoC is in place
- Inform others who receive a copy of protected information in the conduct of the research of the requirements of the CoC
- Inform research participants (for example, in the consent form) about the protections and limits to the CoC, using language approved by the DUHS IRB.

An investigator or institution issued a Certificate shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Disclosure is permitted only when:

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act; or State laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

For studies that were previously issued a Certificate, and participants were notified of the protections provided by that Certificate, NIH does **not** expect participants to be notified that the protections afforded by the Certificate have changed, although the IRB may determine whether it is appropriate to inform participants.

If part of the study cohort was recruited prior to issuance of the Certificate, but are no longer actively participating in the study, NIH does **not** expect participants consented prior to the change in authority, or prior to the issuance of a Certificate, to be notified that the protections afforded by the Certificate have changed, or that participants who were previously consented have to be re-

contacted to be informed of the Certificate, although the IRB may determine whether it is appropriate to inform those participants.

It is the responsibility of the Principal Investigator to ensure that the CoC is valid at all times during the study. If, at any time during the course of the study, the CoC expires or is terminated, the Principal Investigator must immediately file an amendment with the IRB to remove the CoC wording from the consent form. Furthermore, the Principal Investigator cannot enroll subjects past the termination/expiration date of the CoC until such amendment has been approved, and the PI must inform current participants through a letter approved by the IRB that data collected during the period of lapsed CoC coverage will not be protected.

Investigators conducting NIH-supported research covered by a CoC, and investigators conducting research covered by a CoC but NOT federally funded, must ensure that if identifiable, sensitive information is provided to other investigators or organizations, regardless of whether or not the research is federally funded, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

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