Certificates of Confidentiality (CoCs)

This guidance provides information pertaining to the policy for NIH Funded and Conducted Research.

As of October 2, 2017, for NIH funded and conducted research – CoCs will automatically be issued to people engaged in biomedical, behavioral, clinical, or other research, in which identifiable sensitive information is collected. Per the PHS Act, subsection 301(d)(1), Certificates protect identifiable, sensitive information collected and all copies, in perpetuity. This means CoC protections for already-collected or used information remain in force even if NIH funding ends; however, a new CoC must be obtained to cover any new data collected from already enrolled participants or any new participants after the funding period concludes. CoC protections do continue for the duration of a no-cost extension.

Identifiable Sensitive Information

The CoC policy and 42 U.S. Code §241(d) defines **identifiable, sensitive information** as information that is about an individual and that is gathered or used during the course of research where the following may occur:

- Through which 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 identify of an individual.

Applicability of NIH COC 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 CRF 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.

Non-Federally Funded or Unfunded Research

Investigators conducting research that is not federally funded in which identifiable, sensitive information is collected or used, may request a Certificate of Confidentiality (CoC) from NIH.

Responsibilities Under a CoC

The recipient of the 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 only permitted 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.

Investigators must inform subjects (for example, in the consent document) of the protections and limitations of certificates of confidentiality. For studies that were previously issued a Certificate, and subjects were notified of the protections provided by that Certificate, NIH does not expect subjects to be notified that the protections afforded by the Certificate have changed. 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 subjects 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 subjects who were previously consented to be re-contacted to be informed of the Certificate.

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. Consistent with the April 2024 revision to the NIH Grants Policy Statement (NIHGPS §4.1.4), recipients are also responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving identifiable, sensitive information protected by a Certificate understands it is likewise subject to subsection 301(d) of the Public Health Service Act. Recipients must establish and maintain effective internal controls—such as written policies and procedures—that provide reasonable assurance the award is managed in compliance with these requirements.

Considerations for VA Studies

When VA research involves a certificate of confidentiality:

- For studies which will include information about the subject's participation in the subject's VHA medical record, information must be given to the prospective subjects as part of the informed consent process.
- For studies in which the IRB requires a written informed consent, the informed consent document approved by the IRB must include a statement that the study has a Certificate of Confidentiality.
- For studies involving a medical intervention, a progress note in the medical record should be made, indicating the individual has been enrolled in a research study, any details that would impact clinical care, and the name and contact information of the researcher conducting the study.

Considerations for research funded by National Institute of Justice (NIJ) funded

- All projects are required to have a privacy certificate approved by the NIJ Human Subjects Protection Officer.
- All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.

For more information regarding this NIH Policy and Certificates of Confidentiality, please see the NIH Certificates of Confidentiality (CoC) webpage homepage at:
https://grants.nih.gov/grants/policy/nihgps/HTML5/section_4/4.1.4_confidentiality.htm