Certificate of Confidentiality (CoC) Guidance

What is a certificate of confidential?

A certificate of confidentiality provides an extra layer of privacy protection for human subjects research participants by prohibiting the forced disclosure (e.g., in cases of compulsory legal demands, such as court orders and subpoenas) of identifiable, sensitive research information to anyone not associated with the research project.

Certificates of Confidentiality (CoC) protect research information by prohibiting certain disclosures and conditioning others upon consent from the subject. The protections and requirements of CoC's are outlined in 42 U.S.C. 241(d) and in written policies and requirements of certain Federal agencies such as NIH and CDC and are summarized below.

How to obtain a certificate of confidentiality?

- CoC's are issued *automatically* when research is conducted or supported by NIH and falls within the scope of the NIH policy. Examples include:
    - Biomedical, behavioral, clinical or other research, including exempt research, except where 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.
    - 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.
    - 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.
    - 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.

- CoC's are issued *automatically* when research is conducted or supported by the CDC and involves the collection of identifiable, sensitive information.

- Research that is not supported by NIH or CDC may still have the protections afforded by CoC's through successful application to the NIH, FDA, HRSA, SAMHSA, or other authorized Federal agencies or departments.

Additional information about CoC's and the application process for research not covered by the NIH policy is available on the NIH CoC Website.

What are researchers responsibilities when obtaining a CoC?

When research is covered by certificate of confidentiality, researchers:

- May 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

- May not 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.

- May disclose information 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.

When research is covered by a certificate of confidentiality, investigators must inform subjects (e.g., in the consent document) of the protections and limitations of certificates of confidentiality in the following situations:

- 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, although IRBs may determine whether it is appropriate to inform subjects.

- 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, although IRBs may determine whether it is appropriate to inform subjects.

When providing information to other investigators or organizations:

- Investigators conducting NIH supported research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other investigators or organizations, regardless of whether the research is federally funded, the other investigator or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

- Investigators conducting research covered by a certificate of confidentiality, even if the research is not federally funded, must ensure that if identifiable, sensitive information is provided to other investigators or organizations, the other investigator or organization must comply with applicable requirements when research is covered by a certificate of confidentiality.

Genomic Data Sharing (GDS)

Because of the potential for re-identification of genomic data, CoC's are *automatically* issued by the NIH for any research it supports, in part or in whole, 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 the Federal Policy for the Protection of Human Subjects (45 CFR 46).” Research covered by the NIH policy and/or the underlying PHS Act is protected by the CoC in perpetuity; as such any downstream recipients of such information must comply with the requirements of the PHS Act.

Investigators without NIH support who intend to submit genomic data to an NIH repository are encouraged to obtain a CoC. Investigators conducting research generating or using genomic data are encouraged to obtain a CoC when one is not already in place (e.g., for downstream use of data that was collected under a CoC.

Communication with McLaren IRB Review

Investigators are responsible for clearly representing in the *initial* IRB submission that a CoC is in place, or that an application for CoC has been submitted or is pending. When the CoC application is in-process or pending, the McLaren IRB (MHC IRB) may condition final approval upon its receipt.

For studies that are already underway, investigators must submit a *modification form* to the MHC IRB, along with updated consent language (if applicable), when a CoC is applied for, or when automatically issued under the NIH policy or CDC requirements.

When reviewing research under a CoC, the MHC IRB will evaluate whether the research plan is consistent with the obligations to protect information and specimens under a CoC and, when consent will be obtained, whether the proposed consent language or other form of notification properly discloses the CoC and appropriately describes the associated protections and limitations. Sample consent language is available on the NIH CoC Website and in the template informed consent forms available on the MHC IRB website at https://www.mclaren.org/main/irb-templates.

When research is not under a CoC, the MHC IRB may require an investigator to apply for a CoC if the research includes identifiable, sensitive information and the MHC IRB determines that a CoC is necessary to minimize risks and adequately protect subjects’ privacy and the confidentiality of subjects’ information or specimens.