CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 6.6: Conduct of Research: CERTIFICATES OF CONFIDENTIALITY	
Original Date: May 2024	**Date of Last Revision:**
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To outline protections covered by Certificates of Confidentiality (CoCs) and to establish guidelines for requesting a Certificate of Confidentiality from the National Institutes of Health (NIH) as it relates to research that is not funded by the Federal Government.

General Description:

Certificates of Confidentiality (CoCs) serve to protect the privacy of individuals who are the subjects of research that is conducted by investigators or institutions engaged in biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected, if the research is funded wholly or in part by the National Institutes of Health.

A CoC prohibits the disclosure of names of participants or any information, documents, or biospecimens that contain identifiable, sensitive information collected or used in research by an investigator or institution with a Certificate. CoCs can be issued for research that is not funded by the NIH to an investigator or institution engaged in such research upon application.

CoCs are automatically generated as a condition of research that is wholly or partially funded by the NIH, therefore, investigators and institutions only need to apply for a CoC if the research is not wholly or partially funded by the NIH.

Procedure:

Information protected by a CoC

CoCs protect information, in perpetuity, to include documents, and/or biospecimens that contain identifiable, sensitive information related to a participant. Once a CoC has been established, coverage is retroactive to the start of the study and applies to all information collected during the study, including information collected before the CoC was issued. Coverage also extends to participants who did not participate but signed up or who are included in data even if the project is no longer active.

Identifiable, sensitive information is defined as information that is about an individual and is gathered or used during the course of research 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 identity of an individual. A CoC will cover all copies of information, documents, or biospecimens gathered or used by the investigator during the research including copies that are shared for other research activities.

Responsibilities for Investigators and Institutions: Federally Funded Research

As of December 13th 2016 CoCs are automatically deemed to be issued for any research that is collecting or using identifiable, sensitive information and is funded wholly or in part by the NIH. This is a term and condition of all NIH grant awards and contract solicitations.

Investigators and institutions with a CoC have the following responsibilities:

- Inform participants about the CoC.
- Not disclose information in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding OR to any other person not connected with the research except under limited circumstances.
- Limited circumstances are as follows:
    - If required by other Federal, State, or local laws, such as for public health reporting of communicable diseases or child or elder abuse reporting. Disclosure of identifiable, sensitive information (information, physical documents, or biospecimens) protected by a CoC MUST be done when such disclosure is required by other applicable Federal, State, or local laws.
    - If the participant consents.
    - If it is necessary for the medical treatment of the participant and made with the consent of the participant.
    - For the purposes of scientific research that is compliant with human subjects' regulations.
- Uphold the CoC protections from compelled disclosure and support and defend the authority of the CoC against legal challenges.

Responsibilities for Investigators and Institutions: Research Not Federally Funded

Issuance of a CoC for research that is not funded by the NIH is at the discretion of the NIH. Considerations for the issuance of a CoC are as follows:

- Collecting or using identifiable, sensitive information,
- On a topic that is within the NIH mission or HHS health-related research mission, and
- Research information that is collected, used, or stored in the U.S.

Research in which identifiable, sensitive information is collected or used includes research that:

- Meets the definition of human subjects' research, including exempt research in which participants can be identified;
- Is collecting or using human biospecimens that are identifiable or have even a small risk of being identifiable;
- Involves the generation or use of individual level human genomic data; or
- Involves any other information that might identify a person.

For research not funded by the NIH, NIH limits issuance of a CoC to single projects or individual studies.

Please note the following conditions under which NIH will **not** issue a CoC:

- Requests for the establishment and maintenance of a data or biospecimens repository that include plans to conduct studies and projects with those data and/or biospecimens. These repositories are considered to be research programs and will **not** be approved in research **not** funded by NIH.

- Requests for repositories where the main source of the data and/or biospecimens was originally obtained for clinical care or other purposes in research **not** funded by the NIH.
- Requests for a CoC for non-NIH funded research can be made through their online CoC system.

Process for Obtaining a CoC

Investigators seeking a CoC for NIH funded research must apply directly to the NIH for the CoC https://grants.nih.gov/policy/humansubjects/coc/request-certificate.htm

- Include the IRB number in the Title section of the request for all research that is taking place at a Carilion facility.
- Include the name, email address, and phone number of the Carilion Clinic Institutional Official. The Institutional Official can be found here: https://www.carilionclinic.org/IRB/Administrative-Resources#human-research-protections-office
- Once you receive the CoC from the NIH, forward it to the Carilion Clinic Human Research Protections Office (HRPO). Research subject enrollment may not begin until the CoC is obtained.
- If you have a CoC issued prior to January 12th, 2021, and the research project extends beyond the expiration date on the CoC, the investigator must submit a written request to the NIH for extension of the date. If the request is approved, an amended CoC will be issued. The amended CoC approval letter must be forwarded to the HRPO immediately upon receipt.

Required Consent Form Language

Consent forms must contain language that informs participants of the use of a COC. Required language can be found in the Carilion Clinic Biomedical Consent Template.

Significant Changes to the Research

If there is a significant change in a non-NIH funded research project after the CoC has been issued, the investigator will need to request a new certificate through the NIH online CoC system. Significant changes include the following:

- A change in the primary institution where research will be conducted;
- A major change in the scope or direction of the research study;
- Changes in the drugs that will be administered;
- A change in the Principal Investigator.

The following are not considered to be a significant change and do not require a new certificate:

- Minor changes, such as the addition of a new survey instrument or clinical test or adding a participating research site to a multisite study.

NIH Funding Ending for NIH Funded Study

When NIH funding ends, the study will no longer be deemed issued a CoC. CoC protections will remain in place in perpetuity for already collected or used information, however a new CoC will need to be obtained to cover any new data collected from already enrolled participants or any new participants. If study enrollment and data collection have been completed there is no need to request a new certificate.

Research funded by non-NIH Health and Human Services-Agencies and other Federal Departments and Agencies.

The following Health and Human Services agencies issue CoC's including the Biomedical Advanced Research and development Authority (BARDA), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Indian Health Service (IHS) and Substance Abuse and Mental Health Services Administration (SAMHSA). Investigators whose research is funded by these agencies should contact the agency to determine how to obtain a CoC. Investigators whose research is operating under an IND or IDE and is under the authority of the FDA should contact the FDA Certificate Coordinators at the relevant center.

References:

NIH (2024) *Certificates of Confidentiality: https://grants.nih.gov/policy/humansubjects/coc.htm*

https://research.unc.edu/2018/05/21/nih-policy-change-regarding-certificates-of-confidentiality/