Table of Contents

1. Overview

This document describes the purpose, applicability, and procedures for obtaining and implementing a Certificate of Confidentiality (CoC) for research studies involving sensitive, identifiable information.

These procedures apply to all Drexel University research personnel involved in human subjects research that collects or uses identifiable, sensitive information, including studies funded by the National Institutes of Health (NIH), the Food and Drug Administration (FDA), or other sources.

2. Definitions

A **Certificate of Confidentiality (CoC)** is issued by the NIH or the FDA to protect sensitive, identifiable research information from forced disclosure in response to legal demands such as subpoenas, court orders, or other legal proceedings. CoCs are intended to encourage participation in research by ensuring that sensitive personal information (e.g., health data, genetic data, substance use, mental health, or illegal behaviors) is not disclosed without participant consent.

3. Benefits of a Certificate of Confidentiality

A CoC provides several key protections and benefits:

- **Legal protection against forced disclosure**. Researchers cannot be compelled to disclose identifiable, sensitive information in legal proceedings.
- **Enhanced participant trust**: Participants may be more willing to enroll and provide accurate information.
- **Protection** during the study and after study completion.
- **Broad applicability** covering data in any form (paper, electronic, biospecimens).

However, note that a CoC does not prevent voluntary disclosures (e.g., participant consent, mandatory reporting laws such as child abuse or threats of harm). Additionally, a CoC does not replace data security or IRB requirements.

4. Automatic Issuance for NIH-Funded Research

For eligible research studies funded wholly or in part by the NIH that involve identifiable, sensitive information:

- A CoC is automatically issued under NIH policy.
- No separate application is required.
- Investigators are responsible for:
    - Understanding CoC protections and limitations.
    - Including appropriate CoC language in informed consent documents.
    - Ensuring compliance with CoC requirements.

A CoC protects the information collected and used during the period in which the research is funded by the NIH. If the study continues after NIH funding ends and new information is being collected or new participants are being enrolled, follow the process to request a certificate for non-NIH funded research. If funding changes, and a project is no longer supported by NIH, the CoC does not automatically continue, and participants may need to be informed of the change. (Note that if a study was issued a CoC and is continuing under a no-cost extension, the research is covered by the CoC for the duration of the no-cost extension).

It is the responsibility of CoC recipients/investigators to determine if their research is collecting or using covered information.

5. When a Certificate of Confidentiality Must be Requested

If a study is **not NIH-funded** but involves sensitive, identifiable information, investigators may still obtain a CoC through an application process. The IRB may require investigators to request a CoC for studies involving sensitive information that could have significant negative consequences to the participants, including damage to their financial standing, employability, insurability, or reputation (e.g., communicable diseases, use of alcohol, drugs, or other illicit products, illegal behaviors, etc.).

Typical scenarios in which a CoC must be requested include:

- Privately funded research
- Institutionally funded studies
- FDA-regulated studies not covered by NIH policy

Specifically, investigators whose research is funded by the Biomedical Advanced Research and Development Authority (BARDA), Centers for Disease Control and Prevention (CDC), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and Substance Abuse and Mental Health Services Administration (SAMHSA), or is under the authority of the Food and Drug Administration (FDA) may need to request a CoC. Investigators should contact the CoC Coordinator at the appropriate funding agency for questions on how to obtain a CoC through the agency.

For additional tools and guidance, please see the NIH Certificates of Confidentiality webpage.

6. Obtaining a Certificate of Confidentiality from the NIH for Non-NIH Funded Studies

Investigators and/or institutions that are participating in non-federally funded research, in which identifiable, sensitive information is collected or used, are not required to obtain a Certificate of Confidentiality. However, investigators and/or institutions conducting biomedical, behavioral, clinical or other research within the NIH mission in which identifiable, sensitive information is collected or used may still request a CoC NIH. Note there are additional eligibility requirements.

Refer to NIH guidance to identify the appropriate agency and determine what information is needed for your CoC request.

Access the NIH Certificate of Confidentiality System and login with NIH single sign-on to provide the requested information, including the following:

- Project details, including study title, start date, projected end date, and description
- Institution and performance site details, including names and addresses
- Authorized Institutional Official name, email address, and phone number (For CoC, this is the Executive Director of HRP)
- Principal Investigator name, phone number, address, degree, position
- Key personnel names, degrees, positions
- If applicable:
    - Names of drugs that will be administered, route of administration, and dosage
    - A copy of DEA certificate(s)/registration for studies in which a controlled drug will be administered

After submitting this request, the authorized institutional official will receive notification to review and submit the CoC request to the NIH. The PI will then receive notification that this has been submitted by the authorized institutional official and will again be notified by the NIH upon approval of the CoC request. The Executive Director of the HRP is authorized to submit the CoC request to the NIH.

7. Obtaining a CoC from the FDA

The FDA is authorized to issue a Certificate Confidentiality for studies with an IND or IDE that do not have any other HHS funding.

Review FDA guidance on CoC before submitting a request. After determining that the study is eligible for a CoC from the FDA:

- Determine the correct Center and submit the request in the form of a letter to one of the following:
    - Center for Drug Evaluation and Research (CDER) at: CDER-CoC-Requests@fda.hhs.gov
    - Center for Biologics Evaluation and Research (CBER) at: CBERBIMONotification@fda.hhs.gov
    - Center for Devices and Radiological Health (CDRH) at: CDRH-CoC@fda.hhs.gov
    - Center for Tobacco Products (CTP) at: CTP_RIHSC@fda.hhs.gov
    - Center for Food Safety and Applied Nutrition (CFSAN) at: CFSAN-CoC-Requests@fds.hhs.gov
    - Center for Veterinary Medicine (CVM) at: AskCVM@fda.hhs.gov

- The request letter should include the following information:
    - Sponsor or sponsor-investigator name (or authorized representative), address (same as on file with FDA), and email address

- FDA Application Number, as applicable (e.g., IND/NDA/BLA/IDE/HDE/PMA/PMTA/ITP)
- ClinicalTrials.gov Numerical Identifier (if applicable)
- Study Title
- Signature of sponsor, sponsor-investigator, or authorized representative submitting the CoC request

8. Responsibilities

8.1 Office for Research & Innovation Responsibilities

The Office for Research & Innovation is responsible for maintaining this guidance document, applicable tools, and monitoring. The Executive Director for Human Research Protections, as part of ORI, has signatory authority by the Institutional Official for CoC. For inquiries regarding these procedures, please contact the Associate Vice Provost for Research Compliance and Regulatory Affairs, as part of the Office for Research & Innovation (ORI).

8.2 Principal Investigator Responsibilities

The principal investigator is responsible for determining when to apply for a Certificate of Confidentiality through the NIH or FDA, to maintain all appropriate documentation, maintain confidentiality of protected data, and to understand limitations and permitted disclosures related to CoCs.

9. Resources

- NIH Certificates of Confidentiality Webpage
- NIH Guidance - Requesting a CoC for Non-NIH Funded Research
- FDA Guidance on CoC

10. Revision

Version 001/Effective Date 05/22/2026 – Original Document: Obtaining a Certificate of Confidentiality