

# Certificates of Confidentiality

## **Updated NIH Certificate of Confidentiality (CoC) Policy Enhances Privacy Protections for Participants Enrolled in Clinical Research**

As of October 1, 2017, NIH funded researchers will no longer have to request a CoC. The CoC will be issued automatically to NIH funded grants, cooperative agreements, and contracts, funded wholly or in part by the NIH if the research collects or uses identifiable, sensitive information. Compliance with the requirements of the law will become a term and condition of award.

All research that was started or ongoing on or after December 13, 2016 and is within the scope of the policy is automatically issued a Certificate through this policy.

NIH will continue to consider applications for CoCs for applicable non-federally funded research submitted to NIH institutes and centers through the existing online CoC application system.

**[NOT-OD-17-109](#)**

## **What is a Certificate of Confidentiality (CoC)?**

Certificates of Confidentiality provide additional privacy protections to research participant by protecting investigators and institutions from being compelled to release information that could be used to identify subjects enrolled in a research study. Certificates are issued by NIH and other Department of Health and Human Services (HHS) agencies to institutions or universities where the research is conducted. They allow the investigator and others who have access to research records to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

## **Which research studies are eligible for Certificate of Confidentiality?**

Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects, such as damage to their financial standing, employability, insurability, or reputation.

Learn more about what types of research qualify for a Certificates of Confidentiality by visiting [Certificates of Confidentiality FAQ](#).

Additional information regarding which studies are eligible for a Certificates of Confidentiality can also be found in the NYCHP Office of Clinical Research [Certificate of Confidentiality Policy](#).

## **In what situations may personally identifiable information protected by a Certificate of Confidentiality be disclosed?**

Certificates of Confidentiality protect subjects from compelled disclosure of identifying information but do not prevent the voluntary disclosure of identifying characteristics of research participants. Investigators, therefore, are not prevented from voluntarily disclosing certain information about research participants, such as evidence of child abuse or a subject's threatened violence to self or others.

However, if a investigator intends to make such voluntary disclosures, consent documents should clearly indicate this. Furthermore, Certificates of Confidentiality do not prevent other types of intentional or unintentional breaches of confidentiality. As a result, investigators and IRBs must ensure that other appropriate mechanisms and procedures are in place to protect the confidentiality of the identifiable private information to be obtained in the proposed research.

## **Procedures for Obtaining a Certificate of Confidentiality**

Procedures for obtaining a Certificate of Confidentiality can be found in the NYCHP Office of Clinical Research [Certificate of Confidentiality Policy](#).

For additional information, visit the [Certificate of Confidentiality kiosk](#) or contact the appropriate program official. Contact information can be found at: [Certificate of Confidentiality Contacts at the National Institutes of Health](#).

## **Additional requirements**

1. Informed Consent Process - When an Investigator obtains a CoC, the subjects must be told about protections afforded by the CoC and any exceptions to those protections. In addition, researchers may not represent the CoC as an endorsement of the research project by the DHHS or use it in a coercive manner when recruiting subjects.
2. Significant Changes - If a significant change in the research project is proposed after a CoC is issued, the Investigator must inform the Certificate Coordinator of the Institute issuing the certificate by submitting an amended application for a CoC (in the same form and manner as the original application for a Certificate). Significant changes include: major changes in the scope or direction of the research protocol, changes in personnel having major responsibilities in the project, or changes in the drugs to be administered (if any) and the persons who will administer them.