Guidance
Certificates of Confidentiality

What are Certificates of Confidentiality?
Certificates of Confidentiality (CoC) are designed to help protect the privacy of human subjects enrolled in biomedical or behavioral research that involves sensitive information (e.g. HIV status, use of illegal substances, etc.) by allowing researchers to refuse to disclose names or other identifying characteristics of research subjects in response to legal requests (e.g. subpoenas).

CoCs protect researchers and institutions from being compelled to disclose information in response to legal demands that would identify their research subjects. At the beginning, the CoC process was designed to allow investigators to collect information on important public health questions (e.g., illegal drug use, sexual behavior) without having to worry about court subpoenas accessing the data for prosecutory or other non-research purposes.

These certificates are authorizations from the Department of Health and Human Services (HHS) issued by the following agencies for research that they fund:

- National Institutes of Health (NIH)
- Centers for Disease Control (CDC)
- Health Resources and Services Administration (HRSA)
- Indian Health Service (IHS)
- Substance Abuse and Mental Health Services Administration (SAMSA)

The FDA is also authorized to issue CoCs for studies with an IND/IDE that do not have other HHS funding.

On October 1, 2017 a new NIH policy about the Certificate of Confidentiality Process went into effect (NOT-OD-17-109). The new policy enhances the privacy protections of all individuals participating in NIH funded research studies and eliminates the need for NIH-funded investigators to apply for a Certificate of Confidentiality. The new CoCs apply to all research that began or was ongoing on or after December 13, 2016 and is within the scope of the policy.

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When are Certificates of Confidentiality used?
These are issued automatically for NIH funded grants, cooperative agreements, contracts, and intramural research projects – including subcontract awards - that collect or use sensitive identifiable information. Investigators are required to comply with the CoC conditions requirements (protecting the confidentiality of data) as a condition of award. The NIH can issue a CoC for sensitive research that is NOT federally funded at their discretion, if the sponsor or investigator applies for this and the research is related to its health research mission. The research must also be approved by an IRB with an approved Federalwide Assurance, such as the Children's Wisconsin Institutional Review Board (Children's IRB).

Projects that are not within the NIH mission or are not considered research are not eligible.

For research that will gather information from existing records, the CoC will not protect information contained in the primary records.

This is an illustrative (not exhaustive) list of sensitive topic research areas for which a CoC may be requested:

- Research on HIV, AIDS, and other STDs
- Studies that collect information on sexual attitudes, preferences, or practices
- Studies on the use of alcohol, drugs, or other addictive products
- Studies that collect information on illegal conduct
- Studies that gather information that if released could be damaging to a participant's financial standing, employability, or reputation within the community
- Research involving information that might lead to social stigmatization or discrimination if it were disclosed
- Research on participants' psychological well-being or mental health
- Genetic studies, including those that collect and store biological samples for future use
- Research on behavioral interventions and epidemiologic studies

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How do Certificates of Confidentiality get issued?
With enactment of the new policy, CoCs are issued **automatically** for NIH funded grants, cooperative agreements, contracts, and intramural research projects – including subcontract awards - that collect or use sensitive identifiable information. Investigators or sponsors will no longer receive an actual certificate for those CoCs that are issued automatically.

Prior to the new policy, these certifications were issued as the result of an application process submitted through the NIH's electronic application submission system at https://humansubjects.nih.gov/coc/how-apply2. This process still applies for non-NIH funded research for which a sponsor or investigator wants a CoC issued.

For CoCs obtained through an application process, typically, the sponsor of the research will apply for this certificate as it is felt to be appropriate. In cases where the Principal Investigator is also the sponsor (e.g. the PI holds the IND/IDE for a project, investigator initiated research) the PI would apply for a CoC if it is felt to be appropriate. For Multi-site studies, the lead institution would apply for a single CoC on behalf of all member institutions. The lead site responsibilities can be found here https://humansubjects.nih.gov/coc/faqs.

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How do Certificates of Confidentiality work?
In general, the identifiable, sensitive information will be protected from most civil lawsuit discovery subpoenas and law enforcement investigations. A research institution can use a CoC to avoid a forced disclosure of names and other identifying characteristic of research subjects. Most commonly, it is used to avoid having to disclose identifying information demanded as part of a subpoena. These certificates are time limited with a start date and an expiration date.

The institutional official, on behalf of the institution, is responsible for using the CoC to defend against disclosure of this information. As part of the application process, the institutional official agrees to this, and the institution is expected to implement the privacy protections offered as part of the CoC.

If you are planning to pursue issuance of a CoC, you should contact the HRPP/IRB Office for guidance and assistance in alerting the appropriate institutional officials.

Are there limitations?
In general, the CoC protects identifiable information about subjects that is maintained by an investigator during any time the CoC is in effect, even if the participant was enrolled before a study obtained a CoC.

A CoC protects the privacy of subjects by limiting the disclosure of identifiable, sensitive information. Under the new policy, disclosure is not up to the discretion of the investigator. Disclosure is only permitted in the following circumstances:

- If required by other Federal, State, or local laws, such as for reporting of communicable diseases; or,
- For the purposes of scientific research that is compliant with human subject regulations; or,
- If the subject consents

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What does this mean for our investigators and research teams?
It is important to understand that if an investigator's research is covered by a CoC, the investigator is required to ensure that any investigator or institution with whom he/she shares a copy of the identifiable sensitive information that is protected by the policy is put on notice (i.e., "downstream data users") that they are also subject to the CoC disclosure restrictions, even if they are not funded by NIH. This will usually be achieved by means of one or more contracts or non-disclosure agreements.

If the PI is planning on applying for a Certificate, contact the HRPP/IRB Office for guidance before you submit your project to the IRB.

Informing subjects:
The most important requirement in terms of investigator responsibility, whether they have applied for the CoC or it is included as part of study in which they are participating, is **informing the subjects** about the protections, **and limitations** (see above, e.g. voluntary disclosures), afforded by this certificate. This must be part of the consent discussions, and there must be language in the informed consent document regarding this certificate.

There is **consent language**, provided by the NIH, to include in the consent documents when appropriate. This can be found here https://humansubjects.nih.gov/coc/suggested-consent-language.

Informing the IRB:
When there is a Certificate included in a study, this information must be included in the summary/study application and provided to the IRB as part of the new study submission.

Determining if this policy applies to research conducted or supported by the NIH – ask and answer the following questions:

1. Is the activity biomedical, behavioral, clinical or other research?
   If **NO**, the activity is not issued a Certificate
   If **YES**, ask the following questions:

2. Does the research involve Human Subjects as defined by 45 CFR Part 46?

3. Are biospecimens that are identifiable to an individual being used or collected as part of the research?

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4. If collecting or using biospecimens as part of the research, is there a 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?

5. Does the research involve the generation of individual level, human genomic data?

   If the answer to any of these is **YES**, then this policy will apply to the research.

Where can I get more information?
See the following resources for more information:

- National Institutes of Health Certificates of Confidentiality Kiosk
- Certificates of Confidentiality FAQs
- Article: Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice