VCU Office of Research and Innovation

Certificates of Confidentiality (CoCs)

***NEW* Policy for NIH Funded and Conducted Research** –CoCs will automatically be issued to people engaged in biomedical, behavioral, clinical, or other research, in which *identifiable sensitive* information is collected.

- Responsibility is on investigator and institution to determine if research falls within scope of policy
- See below for additional details

Note: New policy effective October 1, 2017 & retroactively applies to research that began on or after 12/13/16.

Purpose

Certificates of Confidentiality 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. Certificates can be used for biomedical, behavioral, clinical or other types of research that is sensitive.

- **Identifying information** is any item(s) in the research data that could lead directly or indirectly to the identification of a research subject.

Protections Afforded by a CoC

When a CoC is in effect, the investigator and others involved with the research **may not**:

- disclose or provide any information or biospecimen that contains identifiable information about a participant to anyone outside of the research unless the participant authorizes in writing, permission to release information or voluntarily discloses their information.

Disclosure is only permitted when:

1. Required by Federal, State, or local laws (ex. Federal Food, Drug, and Cosmetic Act), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding
2. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
3. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
4. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

Obtaining a Certificate of Confidentiality

NIH Funded Research

NEW NIH Policy - COCs will automatically be issued to individuals engaged in biomedical, behavioral, clinical, or other research, in which ***identifiable sensitive information*** is collected. The Notice of Award and the Grants Policy Statement will serve as documentation of the CoC. A physical certificate will not be issued.

Effective: October 1, 2017 & retroactively applies to research that began on or after 12/13/16.
Note: Responsibility is on the investigator and institution to determine if research falls within the scope of policy (see below).

"*Identifiable sensitive information*" – information about an individual gathered or used during the course of the research where:

- An individual is identified, or
- There is at least a very small risk that some combination of information, a request for information, or other available data sources could be used to deduce the identity of an individual

NIH considers research in which identifiable, sensitive information is collected or used, to include:

- *All human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), except research that meets an Exemption and information obtained is recorded without identifiers or the identity of participants cannot be readily ascertained;*
- *Research involving 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;*
- *Any research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data regardless of identifiability;*
- *Any other research that involves information about an individual 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.*

Process of Obtaining Certificate of Confidentiality for NIH FUNDED RESEARCH:

1) Determine applicability - *If the research began on or after 12/13/16*

1. Is the research conducted or funded by NIH? ☐ Yes ☐ No
2. Is the activity biomedical, behavioral, clinical, or other research? ☐ Yes ☐ No

*If the answer to either of these questions is **No**, then the activity is **not issued a CoC** and the policy does not apply. If the answer to **both is Yes,** answer the following questions:*

3. Does the research involve human subjects as defined by 45 CFR Part 46? ☐ Yes ☐ No
4. Are you collecting or using information or biospecimens that are identifiable to an individual as part of the research? ☐ Yes ☐ No
5. If collecting or using information or biospecimens as part of the research, is there a small risk that some combination of the information or biospecimen, a request for the information or biospecimen, and other available data sources could be used to deduce the identity of an individual? ☐ Yes ☐ No
6. Does the research involve the generation of individual level, human genomic data? ☐ Yes ☐ No

---

If the answer to *any one of these questions* is **Yes**, then a **CoC is automatically issued, and the policy applies.**

IRB Implications if Research is Automatically Covered by a CoC:

→ Submit to the IRB the consent documents with the CoC language included. The NIH provides suggested informed consent language.

Note: NIH Studies Funded on or after December 13, 2016

Any NIH study funded on or after December 13, 2016 that meets the above criteria for a CoC has automatically been issued a CoC. Existing informed consent documents likely do not include CoC language. Investigators conducting studies for which a CoC has automatically been issued and for which enrollment is ongoing should submit an amendment to the reviewing IRB to add CoC language to the informed consent document(s). Newly enrolled participants should be consented with an informed consent form that included CoC language. The NIH does not require that currently enrolled participants be re-consented, but the investigator may choose to do so.

→ The Notice of Award and the Grants Policy Statement will serve as documentation of the CoC. A physical certificate will not be issued.

Process of Obtaining Certificate of Confidentiality for Research Supported by CDC, HRSA, or SAMHSA, or under the authority of FDA

These agencies issue their own certificates of confidentiality. Contact the Certificate Coordinator at the respective funding agency to determine how to obtain a CoC.

IRB Implications

→ If your research requires a CoC, please include that language in the Informed Consent Form.

Process of Obtaining Certificate of Confidentiality for Other Non-DHHS, Federally Funded Research and Non-Federally Funded Research:

*The IRB will review all protocols for the possible necessity of a CoC, if not automatically issued.

Health-related research without federal funding that is not automatically issued a CoC, but may still benefit from a CoC. If you believe your research could benefit from a CoC, use the following process:

1) Submit your IRB application, including your informed consent form stating that a CoC is going to be requested.

2) Request a CoC using the online application system hosted by NIH. This application requires:

    a. A copy of final IRB approval * OR approval contingent ONLY on getting a CoC
    b. A copy of the IRB approved consent form with appropriate language about the CoC. Click here for sample consent language.
    c. A copy of the DEA certificate/registration for studies in which a controlled drug will be administered.
    d. A signed assurance document. Click here for the assurance template.

Direct a CoC request to the NIH Institute or Center (IC) that supports similar research. NIH recommends verifying this with the appropriate IC Coordinator before submitting an application. Click here for help in determining the appropriate NIH IC. Additionally, you can use the NIH Research Portfolio Online Reporting Tool (RePORT) to identify which IC funds similar research. If unsure about which IC is most appropriate for the research topic, contact the NIH Central Coordinator at NIH-COC-Coordinator@mail.nih.gov.

- Once the CoC is approved, submit an amendment to the IRB to modify the consent to address the protections in place.

PLEASE REFER TO THE NIH WEBSITE FOR MORE DETAILS ABOUT THE APPLICATION PROCESS

Re**sources:**

NIH Policy
NIH CoC Website
HRP Consulting Guidance