VCU
Office of the Vice President
for 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 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.

Certificate of Confidentiality – Issued by NIH (National Institutes of Health) to protect privacy of research subjects by protecting investigators and institutions from being compelled to release information that could be used to identify subjects with a research project. A Certificate of Confidentiality can also be issued for non-NIH funded research.

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.
- **Sensitive** means that disclosure of **identifying information** could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.
- **See WPP for examples of sensitive research**

Obtaining a Certificate of Confidentiality

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

"***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

- Responsibility is on investigator to determine if research falls within scope of policy (see below)

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

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

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46)
- 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;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- 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, as defined in subsection 301(d) of the Public Health Service Act.

Determining Applicability of NIH COC Policy – 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 *<u>either</u>* 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:

1. Does the research involve human subjects as defined by 45 CFR Part 46? ☐Yes ☐No
2. Are you collecting or using biospecimens that are identifiable to an individual as part of the research? ☐Yes ☐No
3. 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? ☐Yes ☐No
4. Does the research involve the generation of individual level, human genomic data? ☐Yes ☐No

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

<u>Non-NIH Funded Research</u>: COCs are available through the normal application process.

- Also subject to the requirements of subsection 301(d) of the Public Health and Service Act.
- Investigator is responsible for applying for a COC prior to IRB submission (or based on a request from the IRB)
- IRB approval is required before a COC will be issued

Informed Consent Implications
The informed consent form may state a COC was requested, and a modification to the ICF may be made when the COC is issued and in effect.

- Include explanation of protections, limitations, and exceptions
- It may be necessary to include the extent (if any) of which identifiable records will be maintained as required by 45 CFR 46.
- Consent language guidance available HERE

Scope & Terms of COC
Protection of identifiable information in the research project while the certificate is in effect. The COC will state the effective and expiration dates. All identifiable information maintained while the COC is in effect is protected permanently. Participants may voluntarily disclose their data or information, or authorize in writing permission to the investigator to release information.

- Effective: COCs are generally effective the date they are issued, or commencement of the research project if that is after the date it is issued.
- Expire: COCs expiration corresponds to the completion of the study.

Disclosure
The investigator ***may NOT*** disclose or provide:

- Any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- To any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

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.

Resources:
NIH Policy

HRP Consulting Guidance