

## Guideline for Obtaining and Maintaining a Certificate of Confidentiality

### Background

The National Institutes of Health (NIH) issues Certificates of Confidentiality to protect identifiable, sensitive research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose all copies of the research record and prohibits disclosure of name, information and biospecimens in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality (CoCs) are granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, CoCs help achieve the research objectives and promote participation in studies by assuring confidentiality and privacy to participants.

As of 10/1/17, a new NIH policy (NOT-OD-17-109) went into effect. The policy indicates that all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of the Policy is *deemed to be issued a Certificate*. It requires recipients to establish and maintain effective internal controls (policies and procedures) to protect the privacy of individuals who are participants in such research in accordance with [subsection 301\(d\) of the PHS Act](#). Investigators not funded by NIH may also apply for a CoC. Thus, it is important to develop guidelines defining when a CoC is appropriate based on the risk of a breach in confidentiality as well as the nature of the information that may be compromised.

For more information regarding the protections and limitations of CoCs:  
<https://humansubjects.nih.gov/coc/index>

### Considerations

- Identifiable, sensitive research, as defined by NIH, includes:
  - Research as defined in 45 CFR 46, including exempt research unless the information obtained is recorded in a de-identified manner;
  - 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 available data sources could be used to deduce the identity of an individual;
  - Research that involves the generation or use of individual level human genomic data from biospecimens, regardless of identifiability; or
  - Any other research that involves information about an individual for which there is at least a very small risk that available data sources could be used to deduce the identity of an individual.
- Types of projects that may warrant obtaining a CoC include those which are:
  - Related to sexual attitudes, preferences, or practices;
  - Related to the use of alcohol, drugs or other addictive substances pertaining to illegal

- conduct;
- If released, might lead to social stigmatization or discrimination;
- Pertaining to individual's psychological well-being or mental health;
- Genetic information or genetic specimens;
- Projects where participants may be involved in litigation related to exposures under study (e.g. breast implants, environmental exposures).
- CoCs protect all copies of the research record in perpetuity and prohibits disclosure of name, information and biospecimens.
- CoCs are not limited to federally supported research; any study collecting sensitive information as described above may apply.
- CoCs for NIH funded research end when the project funding ends.
- If a CoC is obtained, the project must be reviewed according to federal regulations (aka Common Rule), even if it is not federally funded.
- Individuals who participate in the project during any time the CoC is in effect are permanently protected - even if the participant provided the data prior to the CoC being issued.

### **Recommended Guidelines**

- A CoC is appropriate when identifiable research information is maintained (for any length of time) AND that information could be damaging to participants if disclosed.
- Projects that do not involve the collection of sensitive information (as defined above) would not be appropriate for a CoC because it would only provide minimal benefit given the nature of the information collected.
- The consent form must tell participants that a CoC is in effect and it must provide a fair and clear explanation of the CoC's protections, limitations and exceptions (see sample language below).
- All research staff must be trained on privacy considerations related to maintaining a CoC. The CoC cannot protect data comprised by the study participant, project team personnel or the institution.
- The CoC also applies to any Subawards or data sharing that is carried out as part of the project.

### **IRB Requirements when Applying for a CoC**

1. It is important for investigators to inform the IRB if they have obtained or intend to apply for a CoC in their protocol.
2. Before the CoC is obtained, the consent form should state "the researcher will apply for a certificate of confidentiality".
3. Researchers are required to apply for a CoC within one month of obtaining IRB approval.
4. Once a CoC is granted, the researcher must submit an amendment to the IRB to change the protocol and consent language from "will apply for a CoC" to "have obtained a CoC". Unless required by the IRB, participants enrolled prior to this change will not need to be re-consented.
5. If a CoC is not granted, the IRB should be immediately notified to consider whether other additional confidentiality protections are necessary and whether previously enrolled participants must be notified.

## Sample Consent Form Language

### **Confidentiality of your information:**

To help us protect your information, this research study has a Certificate of Confidentiality from the National Institutes of Health (NIH). With this Certificate, the research team cannot be forced to provide your name or any identifiable research data or specimens in any Federal, state or local proceedings unless you agree that we can share it. However, we still must report information to local authorities if we learn about child abuse or neglect, or intent to harm yourself or others. Disclosure will also be necessary upon request from the Department of Health and Human Services (DHHS) or other federal agencies for audits or program evaluations (If not funded by DHHS, delete previous sentence.)