Guidelines for Certificates of Confidentiality

Certificates of Confidentiality (CoCs) are intended to protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive information to anyone not connected to the research except when the subject consents, or in a few other specific situations. CoCs are issued by the National Institutes of Health (NIH) and other Health and Human Services agencies. All ongoing or new research funded by NIH, that is collecting or using identifiable, sensitive information is automatically issued a Certificate of Confidentiality.

If your research meets any of the following criteria, then the research data or information is automatically protected by a CoC from NIH:

- Meets the definition of human subjects’ research, including exempt research in which subjects can be identified
- Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable
- Involves the generation of individual level human genomic data
- Involves any other information that identify a person

Health-related research that is not federally funded in which identifiable, sensitive information is collected or used, may request a CoC but in such situations the COC is granted at the discretion of the issuing agency.

A CoC provides protection for the Investigator and the participants against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research. This means that Investigators may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify their participants.

CoCs do not take the place of good data security or clear policies and procedures for data protection, which are essential to the protection of research participants' privacy. Researchers should take appropriate steps to safeguard research data and findings. Unauthorized individuals must not access the research data or learn the identity of research participants.

A CoCs do not protect information voluntarily disclosed or information that must be disclosed under particular mandatory reporting laws. Examples include voluntary disclosures by the participant themselves or disclosures to which the participant has consented. Mandatory disclosures include disclosures on matters such as child abuse, reportable communicable diseases, or possible threat to self or others.
Points to Address

New Study Application:

*Cayuse Section 12 Confidentiality of Research Data:* Please indicate “A Certificate of Confidentiality will be used.

Consent Document:

Confidentiality: If a Certificate of Confidentiality is valid for your study, briefly provide participants with a clear explanation of the protection that the Certificate of Confidentiality affords, including the limitations and exceptions. Also, ensure that an explanation of how identifiable information will be used or disclosed is provided.

References & Links

*How to Get a Certificate of Confidentiality*

*What is a Certificate of Confidentiality*
https://grants.nih.gov/policy/humansubjects/coc/what-is.htm

*Who Can Get a Certificate of Confidentiality*