Guidance:

Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. By protecting researchers and institutions from being compelled to disclose information that would identify research subjects, Certificates of Confidentiality help achieve the research objectives and promote participation in studies by helping assure confidentiality and privacy to participants.

The NIH maintains a web Kiosk with all the necessary information to obtain a CoC: http://grants.nih.gov/grants/policy/coc/index.htm.

Informed Consent Requirements for CoCs:

The informed consent must address that a CoC has been obtained. A CoC must be obtained and language must be approved by the IRB prior to adding language to the informed consent document. Many times, investigators will be asked by the IRB to re-consent subjects with the new language.

Example CoC language:

We have obtained a Certificate of Confidentiality (CoC) issued by the National Institutes of Health (NIH). The CoC is issued to protect the investigators on this study from being forced to tell anyone about your participation in this study, even under a subpoena.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for an insurer, employer, or lawyer to receive information about your participation in the research, then we may not use the CoC to withhold this information.

CoC FAQs:

- **What is a Certificate of Confidentiality (CoC)?** It is an authorization from the Department of Health and Human Services (HHS) that helps researchers and their institutions safeguard the privacy of research participants enrolled in sensitive biomedical and behavioral research by protecting against compulsory legal demands such as subpoenas for identifying information.
Certificates of Confidentiality

• **What does it do?** Research institutions can use a CoC to avoid forced disclosure of names and other identifying characteristics about research participants. It is used to oppose subpoenas and other compulsory demands.

• **Who is responsible for using the CoC to resist disclosures?** The research institution is expected to implement the privacy protections offered by the CoC. As part of the application process, an institutional official agrees to use the CoC and to defend its authority against legal challenges. You should be sure that these arrangements are in place at your institution.

To obtain the Institutional Official signature on the CoC, please submit materials to the HSPP with your IRB application materials.

• **Are there circumstances where a CoC cannot be used to resist disclosures?**
  - When the disclosure is requested in writing by the research participant, their legal guardian, or their legal representative.
  - To HHS or FDA in certain situations such as research audits as required by law.

• **Are there circumstances where information about study participants may be voluntarily disclosed by the Investigator or Institution?** Investigators and their institutions may (and should be prepared to) make disclosures to prevent serious harm to the participant or to someone else, including child abuse and to voluntarily comply with state and local reporting requirements for communicable diseases. The consent form should explain these and any other circumstances of voluntary disclosures.

• **What do the Assurances that institutional officials sign require?** The CoC application requires the inclusion of Assurances which are signed by the Principal Investigator and the Institutional Official. These Assurances document that the institution will use the CoC to protect against compelled disclosure and defend the authority of the Certificate against legal challenges; they also indicate what participants are to be told about the CoC. Please see details at: [http://grants.nih.gov/grants/policy/coc/appl_extramural.htm](http://grants.nih.gov/grants/policy/coc/appl_extramural.htm).

• **What if I am the lead site in a multi-site study?** To avoid confusion and possible gaps in protecting the participants in a multi-site research study, a lead institution is asked to apply for a CoC on behalf of all member institutions. The lead site has the following responsibilities:
  - maintaining a list of all participating sites/institutions;
  - obtaining signed Assurances and IRB approvals from each participating institution;
  - reviewing the consent forms used at each institution to be sure that the CoC protections and voluntary disclosures are appropriately described;
  - making suitable agreements among the institutions to use the CoC to resist compelled disclosures; and
  - maintaining control over project research records related to the CoC.
As the institutional official for the lead site, your institution must exercise oversight to be sure that the participating sites meet the obligations outlined above with respect to the Assurances. You also must develop appropriate mechanisms and agreements among the participating institutions to handle any legal actions needed to implement the CoC protections.

**Additional Resources for Certificate of Confidentiality**

- Centers for Disease Control FAQs on Certificates of Confidentiality: [http://www.cdc.gov/od/science/integrity/confidentiality/faq_confidentiality.htm](http://www.cdc.gov/od/science/integrity/confidentiality/faq_confidentiality.htm)
- Substance Abuse and Mental Health Service Administration (SAMHSA) Certificate of Confidentiality information: [http://www.samhsa.gov/grants/certconf.aspx](http://www.samhsa.gov/grants/certconf.aspx)