A **Certificate of Confidentiality** helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive health-related research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant.

Sensitive information includes (but is not limited to) information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples.

Researchers can use a Certificate to avoid compelled "involuntary disclosure" (e.g., subpoenas) of names and other identifying information about any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during any time the Certificate is in effect. It does not protect against voluntary disclosures by the researcher, but those disclosures must
be specified in the informed consent form. A researcher may not rely on the Certificate to withhold data if the participant consents in writing to the disclosure.

**Suggested Consent Form Language Describing the CoC Protections**


When a CoC is obtained, the research subjects must be told about the protections afforded by the Certificate and any exceptions to that protection. That information should be included in the informed consent form. Sample consent language describing the CoC is below. Researchers may adapt the language to the needs of the research participants and to the subject matter of the study. However, the language used must cover the basic points noted below.

In addition, researchers should review boilerplate language about confidentiality and data security that is routinely included in consent forms to ensure that it is consistent with the protections of the Certificate of Confidentiality and the intentions of the researchers to use these protections as necessary.

Your consent form must be submitted as part of the application and will be reviewed for accuracy.

**Sample Consent Language:**

Note that the text in [brackets] is instructional and not part of the consent from language

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, *except as explained below.*
[Use the following language as applicable] The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

[language such as the following should be included if researcher intend to make voluntary disclosure about information obtained in the research such as child abuse, or intent to hurt self or others.] The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of [list what will be reported, such as child abuse and neglect, or harm to self or others].