

**Guidance for Investigators:
Certificates of Confidentiality**

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Approved by: Human Protections Administrator,
Director of OPRS, and Executive IRB Chair

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- I. Certificates of Confidentiality are issued by the NIH and other federal agencies, such as the CDC and the FDA, to protect identifiable research information from forced disclosure.
 - A. It allows the investigators 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.
 - B. Investigators should refer to the NIH Certificate of Confidentiality Kiosk (<http://grants.nih.gov/grants/policy/coc/index.htm>) for further information and instructions.

- II. Federal funding is not a prerequisite for an NIH-issued Certificate. They may be requested for any biomedical, behavioral or other type of research involving sensitive information.
 - A. Not all activities are eligible for a certificate. To be eligible, an activity must meet all of the following criteria:
 1. Meets definition of research involving human subjects,
 2. Involves collection of personally identifiable information,
 3. Has been reviewed and approved by the IRB, and
 4. Involves collection of information that if disclosed would significantly harm participants.
 - B. Sensitive is defined by NIH as 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
 - C. Examples of research areas that are eligible for a certificate are studies collecting information:
 1. related to the use of alcohol, drugs, or other addictive products,
 2. pertaining to illegal conduct,
 3. on sexual attitudes, preferences, or practices,
 4. on genetics,
 5. for tissue or data repositories, and
 6. on subjects' psychological well-being or mental health.

- III. If applicable, the consent form should clearly indicate that the Certificate of Confidentiality only applies to compelled disclosures, not the voluntary disclosure of information. Therefore, an investigator is free to voluntarily disclose

information, particularly information required to be disclosed by Illinois state law (i.e., infectious disease reporting, child abuse, elder abuse, child neglect), federal regulations (Food, Drug, and Cosmetic Act disclosure requirements), and in instances in which a subject threatens to injure him or herself or others. (Refer to UIC HSP policy [Ethical Standards and Legal Principles](#) for more information). In the same way, the information that a subject voluntarily discloses to other people, including subjects in focus groups, is not covered by the Certificate of Confidentiality.

- IV. The investigator is responsible for submitting the request for a Certificate of Confidentiality to NIH or other federal agency following IRB approval.
- A. Refer to the NIH Certificate of Confidentiality Kiosk (<http://grants.nih.gov/grants/policy/coc/index.htm>) for further information and instructions on the information to be submitted, format for the request letter and recommended informed consent language.
 - B. Once the material for submission has been gathered, the investigator should submit an amendment to the OPRS to allow the signature of the institutional official to be obtained. The material will then be returned to the investigator for submission to the relevant agency.
 - C. After the approval from the agency has been obtained, the approval notification along with any revisions in the consent should be submitted to OPRS.
- V. Informed Consent Form Template Language for Studies with Certificates of Confidentiality.
- A. delete any template language that refers to releasing data or subject information “required by law”, and
 - B. include the following paragraphs:

“To help us protect you and the information we will be collecting from you, this study has been given a Certificate of Confidentiality by [identify provider of certificate]. This Certificate means that the researchers cannot be forced, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, to disclose any information that may identify you. The researchers will use the Certificate to resist any demands of information that would identify you, except as explained below.”

“The Certificate cannot be used to resist a request for information from United States government employees if the request is for auditing or evaluation of federally funded projects [*include the following statement only if FDA regulated research*: or for information that must be disclosed to meet the requirements of the federal Food and Drug Administration (FDA)].”

“The Certificate does not stop you or a member of our family from voluntarily disclosing to any person information about yourself or your involvement in the study. If you give your written consent to release study information to an insurer, employer or other person, the Certificate cannot be used to withhold this information.”

If applicable:

“If any study information is placed into your medical records, the Certificate does not protect that study information.”

If applicable:

“If the researchers become aware of possible child abuse or elder abuse, or that you may cause serious harm to yourself or others, the researchers may report this to the appropriate authorities without your consent.”

If applicable:

“If the research shows that you have a reportable communicable disease (for example, tuberculosis [TB] or HIV/AIDS), the researchers may report this to state and/or federal public health authorities without your consent.”