

**IRB Approval Criteria:
Confidentiality**

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POLICY:

- I. The term “confidentiality” refers to the PI’s agreement as to how a subject’s identifiable private information will be handled, managed, and disseminated.
- II. In contrast, “privacy” refers to the individual’s desire to control the access of others to them or to private information about them. (Refer to UIC HSPP policy [Approval Criteria: Privacy](#)).

PROCEDURE:

- I. The IRB strives to ensure that research subjects have adequate confidentiality protections. The IRB may request that the PI obtain a Certificate of Confidentiality as part of its review. In such cases, the PI must submit proof that a Certificate of Confidentiality was issued through an amendment. (Refer to UIC HSPP policy [Amendments](#)).
- II. The PI is responsible for accurately and adequately documenting in the appropriate application all circumstances under which identifiable private information may possibly be disclosed for purposes of the research.
- III. The PI must clearly disclose in the informed consent the circumstances under which confidential information may possibly be disclosed, and accurately discuss the possibility of voluntary disclosures in the context of confidentiality, which are not protected by a Certificate of Confidentiality or the HIPAA Privacy Rule. (Refer to Item IV(B) below for more information).
- IV. Certificates of Confidentiality.
 - A. Certificates of Confidentiality are issued by the NIH and other HHS agencies, such as the CDC and the FDA, as well as other federal agencies. The PI is the person responsible for submitting a request for a Certificate of Confidentiality from the NIH, other HHS agency, and/or other federal agency.
 - B. Depending on the terms that the investigator is able to negotiate, Certificates of Confidentiality generally allow the PI and the subjects protection against compelled disclosure of identifying information about subjects in various types of human subjects research trials (biomedical and social and behavioral) that is of a identifiable and of a sensitive nature. In this way, PIs cannot be

- compelled by subpoena, including any federal, state, local, criminal, administrative, legislative, or other proceeding to identify the subjects in the research study or certain information about the subjects. Regardless of funding source, an investigator conducting research that gathers personally identifiable information that is sensitive in nature is eligible to apply for a Certificate of Confidentiality. Again, the terms that the investigator negotiates govern, and therefore, the investigator should refer to these terms for the most complete information.
- C. Research qualifies as sensitive in nature if it involves the gathering of the following information:
1. Information related to the use of alcohol, drugs, or other addictive products;
 2. Information pertaining to illegal conduct;
 3. Information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community;
 4. Information that, if released, might lead to social stigmatization or discrimination;
 5. Information pertaining to an individual's psychological well-being or mental health;
 6. Genetic information;
 7. Tissue samples; and/or
 8. Information that, if released, might affect the subject's insurability (for VA Research). (NIH, Office of Extramural Research, *Frequently Asked Questions: Certificates of Confidentiality*, March 14, 2002; Refer to *Local Research Context* and *International Research*, as this definition may vary with the subject population and culture).
- D. If applicable, the consent form should clearly indicate that the Certificate of Confidentiality only applies to compelled disclosures, not the voluntary disclosure of information. (Refer to template language below as well as on the UIC OPRS Tip Sheet *Certificate of Confidentiality Language for Informed Consent*). Therefore, a PI 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 her self or others. (Refer to UIC HSPP 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.
- E. Informed Consent Form Template Language for Studies with Certificates of Confidentiality.
- F. If the investigator has obtained a Certificate of Confidentiality from DHHS or other federal agency for this research: (1) delete any template language that refers to releasing data or subject information "required by law" and (2) 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.”

REFERENCES:

[21 CFR 56.111\(a\)\(7\)](#)

[38 CFR 16.111\(a\)\(7\)](#)

[45 CFR 46.111\(a\)\(7\)](#)

[VHA Handbook 1200.05](#)

UIC Social and Behavioral Sciences Informed Consent Template

UIC Biomedical Informed Consent Template

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 06/26/09	1.0, 10/15/08	Expanded agencies issuing certificates of confidentiality and inserted updated certificate of confidentiality language.