Certificates of Confidentiality: What are they? When should you apply for one?

Certificates of Confidentiality 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. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. 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 assuring confidentiality and privacy to participants.

What are Certificates of Confidentiality and under what circumstances would I apply for one?

Certificates of Confidentiality 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. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. 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 assuring confidentiality and privacy to participants.

Who may apply for a Certificate?

Any person engaged in research in which sensitive information is gathered from human research participants (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality.

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.

Who must sign the Certificate?

The Principal Investigator and the authorized “Institutional Official” must sign the document. For research approved by UB IRBs, the Institutional Official is the UB Vice President for Research, Dr. Jorge José. To obtain the signature of the VPR, PIs should sign the Certificate request and forward it to the attention of Edward Zablocki (zablocki@buffalo.edu) for processing.

Some Important Caveats

Certificates of Confidentiality 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. De-identification of records is the best way to ensure data confidentiality. When that is not possible, a Certificate of Confidentiality may afford legal protection of research records from subpoena.

An application for a Certificate of Confidentiality does not guarantee that one will be issued. The NIH is authorized to issue this privacy protection at its discretion and issuance is limited to important research that is “within its mission areas.”

Do I need IRB approval before I apply for a Certificate?

Generally, IRB approval or approval conditioned upon issuance of a Certificate of Confidentiality is a prerequisite for issuance of a Certificate. Since the informed consent document should include language describing the Certificate and any voluntary disclosures specified by the investigator, the Applicant could tell the IRB that they are applying for a Certificate of Confidentiality and have included appropriate language in the informed consent document. Applications for Certificates should be submitted at least three months prior to the date on which enrollment of research subjects is expected to begin.

Comments and suggestions for future “HRPP Topics” are welcome and may be submitted to:
Dorothy Wright at: dswright@buffalo.edu