



Campus Institutional Review Board
University of Missouri-Columbia


Certificates of Confidentiality

Policy Number 2876.25

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Effective Date: December 12, 2007

Board Review


Signed _____
IRB Chair

Date December 12, 2007

Administrative Review


Signed _____
Associate Vice-Chancellor for Research

Date December 12, 2007

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1.0 Policy

A researcher may obtain a Certificate of Confidentiality if a determination is made that the research is of a sensitive nature and additional protective mechanisms are necessary to reach the objectives of the research and comply with Campus IRB standards.

2.0 Purpose

Certificates of Confidentiality (COC) are issued by the National Institutes of Health (NIH) to protect the privacy of research subjects and can promote recruitment in studies requiring disclosures of sensitive personal information. The COC protects the holder from releasing information that could be used to identify subjects associated with a research project. The COC permits the investigator to refuse to disclose identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

3.0 Scope

The COC applies to human subject research whereby the disclosure of identifying information or other ascertainable characteristics could potentially have adverse consequences to participants or negatively impact their financial standing, employability, insurability, or reputation.

4.0 Standard Operating Procedure

Researchers may apply for COC for particular sensitive research projects. The Office of Human Research Protections (OHRP) finds research to be sensitive if it involves collecting any of the following types of information:

A. Categories qualifying for a Certificate of Confidentiality

1. Information relating to sexual attitudes, preferences, or practices.
2. Information relating to the use of alcohol, drugs, or other addictive products
3. Information pertaining to illegal conduct
4. Information that, if released, could reasonably be damaging to an individual's financial standing, employability, or reputation in the community.
5. Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.
6. Information pertaining to an individual's psychological well being or mental health.
7. Genetic information

NOTE: Other agencies may evaluate applications using different criteria.

B. Limitations on Certificates of Confidentiality

The COC will not apply to the following:

1. Voluntary disclosure of identifying information by either a subject or an investigator
2. The Certificate is not transferable from one project to another. This raises questions with Secondary Data studies, in that the confidential identity protection that exists in the Primary project will not transfer to the secondary project.

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3. All amendments to a project covered by a COC, must be submitted to the granting agency for consideration.
4. The COC is only valid for the period issued. If the study will not be completed by the expiration date of the COC, the investigator must request an extension.
5. Information requested by Department of Health and Human Services (DHHS) for the purposes of performing audits, carrying out investigations, or evaluation of DHHS funded research projects.

C. Applying for a Certificate of Confidentiality

1. The Investigator may access the Office of Human Research Protections (OHRP) website to identify agency contacts to obtain information about obtaining COC. The website is currently located at:

<http://ohrp.osops.dhhs.gov/jan2001bu/humansubjects/guidance/cert-con.htm>.

NOTE: The investigator should contact OHRP directly for current information regarding COC.

D. The Campus IRB Review Process

1. The Campus IRB shall review the proposed COC in conjunction with the informed consent process and data security measures.
2. The Campus IRB may request revisions to the COC to ensure the highest standard of protection of human subjects or to comply with State and Local Laws.
3. The Campus IRB shall require the investigator to provide information regarding the effectiveness of the COC.
4. The Campus IRB shall require the investigator to provide the subjects with a fair and clear explanation of the protection that the COC affords, including the limitations.
5. Investigators should inform the subject that researchers are not prevented from the voluntary disclosure of matters such as child abuse, reportable communicable diseases, or subject's threatened violence to self or others;
6. Investigators must provide information about subjects if it is required to be disclosed by the Federal Food, Drug, and Cosmetic Act; and
7. The COC does not take the place of data security plans and protection.

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