CERTIFICATES OF CONFIDENTIALITY

Description

Certificates of Confidentiality (CoCs) are intended to protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive information to anyone not connected to the research except when the subject consents, or in a few other specific situations. CoCs are issued by the National Institutes of Health (NIH) and other Health and Human Services agencies. All ongoing or new research funded by NIH (as of December 13, 2016), that is collecting or using identifiable, sensitive information is automatically issued a Certificate of Confidentiality.

If your research meets any of the following criteria, then the research data or information is automatically protected by a CoC from NIH:

- Meets the definition of human subjects' research, including exempt research in which subjects can be identified
- Is collecting or using human biospecimens that are identifiable or that have a risk[1] of being identifiable
- Involves the generation of individual level human genomic data
- Involves any other information[2] that identify a person

Health-related research that is not federally funded in which identifiable, sensitive information is collected or used, may request a CoC but in such situations the COCis granted at the discretion of the issuing agency.

A CoC provides protection for the Investigator and the participants against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research. This means that Investigators may not be compelled in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings to identify their participants.

It should be noted that at University of Utah Health, information associated with clinical research may be included within the medical record of the research participant. Investigators may request an exception to this general rule (see IRB SOP 505: Research Materials in Participants' Medical Records). As part of the informed consent process, research participants consent to the inclusion of research-related data within their medical record. To the extent research information is included in the medical record of a research participant, the CoC will not operate with respect to such information.

CoCs 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. Unauthorized individuals must not access the research data or learn the identity of research participants.

[1] At least a very small risk that some combination of the biospecimen, a request for the biospecimens, and other available data sources could be used to deduce the identity of an individual.

[2] Information about an individual for which there is at least a very small risk, as determined by current scientific practice or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of the individual.

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A CoC does not protect information voluntarily disclosed or information that must be disclosed under particular mandatory reporting laws. Examples include voluntary disclosures by the participant themselves or disclosures to which the participant has consented. Mandatory disclosures include disclosures on matters such as child abuse, reportable communicable diseases, or possible threat to self or others.

Points to Address

New Study Application:	1. **Data Monitoring Page, Confidentiality Precautions**: Please select "A Certificate of Confidentiality (from the NIH) will be used"
Consent Document:	1. **Confidentiality**: If a Certificate of Confidentiality is valid for your study, briefly provide participants with a clear explanation of the protection that the Certificate of Confidentiality affords, **including the limitations and exceptions**. Also, ensure that an explanation of how identifiable information will be used or disclosed is provided.

References & Links

How to Get a Certificate of Confidentiality	https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm
What is a Certificate of Confidentiality	https://grants.nih.gov/policy/humansubjects/coc/what-is.htm
Who Can Get a Certificate of Confidentiality	https://grants.nih.gov/policy/humansubjects/coc/who-can.htm

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

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Applying for the Certificate of Confidentiality ¶
Applications for a Certificate of Confidentiality should be submitted to the NIH at least three (3) months prior to the date on which enrollment is expected to begin. If the Investigator has not already applied for a Certificate of Confidentiality, upon its review of ... [9]
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Data collection about sensitive issues (such as illegal behavior, alcohol or drug use, or sexual practices or preferences) requires the protection of confidentiality beyond preventing accidental disclosures. Under Federal law, Investigators can obtain an advance grant of confidentiality, known as a Certificate of Confidentiality that will provide protection against compulsory disclosure, such as a subpoena, for research data.

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Which research projects are eligible for Certificates of Confidentiality?

Certificates of confidentiality are only issued for research projects that are:

Collecting personally identifiable (subject names or other identifying characteristics) on a sensitive research topic
Approved by an IRB operating under a Federalwide assurance (FWA) issued by the Office of Human Research Protections or the approval of the FDA
On a topic that is within the HHS health related research mission
Storing research data in the United States
Allowable under federal regulations

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(Public Health Service Act '301(d), 42 U.S.C. '241(d)). Under this Act, the Secretary of Health and Human Services (HHS) may authorize persons engaged in research to protect the privacy of participants by withholding from all persons not connected with the conduct of the research the names or other identifying characteristics of the participant.

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, research records are not separated from medical records unless the i

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the Certificate of Confidentiality may become invalid. The Certificate of Confidentiality may only be valid to those studies that do not include research information in medical records.

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The protection is available only when the research is of a sensitive nature where the protection is judged necessary to achieve the research objectives. Examples of studies that would **not** qualify for a certificate of confidentiality are:

Projects that are not research based;

Projects that are not approved by an IRB in accordance with the NIH guidelines governing Certificates of Confidentiality;

Projects that do not collect sensitive information or information that might harm the research participants; or

Projects that do not collect personally identifiable information.

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An investigator should consider applying for a Certificate of Confidentiality when the results of research participation could yield information in one or more of the following categories:

HIV status, AIDS related complications, or other sexually transmitted diseases;

Information relating to sexual attitudes, preferences, or practices;

Information relating to the use of alcohol, drugs or other addictive products;

Information pertaining to substance abuse, illegal conduct, or other risk behaviors;

Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community;

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;

Information where subjects may be involved in litigation related to exposures under study (e.g. breast implants, environmental or occupational exposures);

Information pertaining to an individual's psychological well-being or mental health;

Information collected that may be considered sensitive in connection with behavioral interventions and epidemiologic studies; and

Genetic information.

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More information can be found on the Certificates of Confidentiality FAQ page (see link at the end of document).

Applying for the Certificate of Confidentiality

Applications for a Certificate of Confidentiality should be submitted to the NIH at least three (3) months prior to the date on which enrollment is expected to begin. If the Investigator has not already applied for a Certificate of Confidentiality, upon its review of the research, the IRB may recommend that an Investigator apply for a Certificate of Confidentiality. NIH provides detailed instructions for investigators wishing to make an application. See below under References and Links.

It must be noted that the issuance of this certificate is up to the discretion of the NIH. If granted, the Certificate provides indefinite protection from compulsory disclosure, such as subpoena for research data.

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State whether the certificate has been requested or has been obtained and is in effect for the study.

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http://grants.nih.gov/grants/policy/coc/background.htm