Certificates of Confidentiality

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Q: What is a Certificate of Confidentiality?

A federal law allows the NIH and other federal agencies to issue Certificates of Confidentiality (CoCs) to persons engaged in sensitive biomedical, behavioral, clinical or other research, for the purpose of protecting the privacy of research subjects. The authorizing federal law states that anyone who receives a CoC may not be compelled in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings to identify the subjects of research covered by the CoC. Thus, the CoC help minimize risks to subjects by adding an additional level of protection for maintaining confidentiality of private information.

Q: Are CoCs limited to federally-funded studies?

No, this protection is not limited to federally funded research. CoCs may be issued to cover any study that the issuing federal agency deems to be appropriate. Generally, research will be considered "sensitive" and eligible for CoC protection if the study involves the collection of identifiable information (including enrollment) which, if revealed, could harm the financial standing, employability, insurability, or reputation of a research subject. Such information includes, without limitation:

- Genetic information;
- Psychological well-being of the subjects;
- Subjects’ sexual attitudes, preferences, or practices;
- Substance abuse or other illegal conduct; or
- Data involving subjects who may be involved in litigation related to exposures under study (i.e. breast implants, environmental or occupational exposures).

Q: Are there any exceptions to the protections offered under a CoC?

Yes. CoCs do not protect research subjects against the voluntary disclosure by the investigator of identifying information. For example, disclosure of matters such as suspected child abuse, reportable communicable diseases, or subjects’ threatened violence to self or others are not protected under a CoC.

Also, certain NIH institutes insist that federal agency rights to audit research records are not eliminated by CoCs. The consent form for a research study must inform study subjects that even when a CoC has been obtained, the investigator will make certain disclosures (see language in the template informed consent form) [link to language].
Finally, if a subject requests in writing that his or her information be disclosed, the researcher cannot refuse to release the information.

Q: What should I do if I receive a subpoena or other demands for research information if I have a COC?

If you receive a subpoena or other demand for information, contact the Office of Vice President and General Counsel, Health Affairs Office for assistance.

Q: When should an investigator seek a CoC for a study?

Before submitting a new application to the IRB, investigators should consider whether a CoC would be an added protection for study data. If the PI seeks to obtain identifying information of a sensitive nature from research participants, and the disclosure of such information could harm the participants as described above, the PI may wish to apply to the government for a CoC. The investigator should state in the application to the IRB that he or she will seek a CoC after the IRB has reviewed the application.

Q: Will an IRB require an investigator to obtain a CoC?

The IRB may also request that an investigator apply for a CoC if the IRB determines that the data collected from participants should have the additional protections. For instance, studies targeting UAA Collegiate Athletes [link to guidance] require a CoC.

Q: Will a federal funding agency stipulate when a CoC is required for a project?

There are funding agencies that mandate use of a CoC during the conduct of a project. Frequently, cooperative group projects require CoCs.

Q: How does an investigator apply for a CoC?


Once the Assurance Document is signed, email the document, the protocol, and the consent to the Director of Research Operations and Services (Michael Mahoney, mmahoney@ufl.edu) for review and submission to the VP for Research for institutional sign-off. Please provide a date within the email by which the signed document is needed.

Q: What is the IRB process for the consent form when an investigator is applying for a CoC?

The consent form should have the IRB standard Certificate of Confidentiality language. This is provided in the UF IRB Informed Consent Template.
To help us protect your privacy, we have requested a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

When the study is approved, the IRB will release a non-stamped document to the investigator. The investigator must use this approved consent form as part of the application to the granting agency for the Certificate.

You will need to provide the signed Assurance Document (described above), the IRB approval letter, and the IRB approved consent form with the application.

**Q: Does the consent need to be revised once a CoC has been obtained?**

Yes. When the investigator receives the Certificate of Confidentiality, a revision must be submitted to the UF IRB that includes a copy of the Certificate of Confidentiality. The above template language should be revised by changing the word “requested” to “obtained.” If the Certificate is in order, the UF IRB will provide a stamped consent form.
Q: What is the IRB process for the consent form when the sponsor of the research is the entity applying for the CoC?

Many of the protocols submitted to the IRB that include a Certificate of Confidentiality are studies with a federal, commercial or cooperative group sponsor where the sponsor has already applied for and received the Certificate of Confidentiality.

The UF IRB will accept the Certificate language in the consent form, since it has prior approval from the granting agency for that Certificate holder.

If the UF investigator has a copy of the sponsor’s Certificate of Confidentiality, it should be included in the application to IRB.

Q: What happens if the CoC is disapproved by the NIH?

A revision will need to be submitted to the UF IRB, removing the informed consent template language discussed above. If the study was approved to enroll subjects pending the CoC approval, any subjects enrolled will need to be reconsented with the new consent form, following IRB approval of the revision.

Q: Does an investigator still need a HIPAA compliant privacy authorization form if the investigator also has a CoC?

Yes. HIPAA and the federal CoC statute are two different laws. The HIPAA Privacy Rule applies to any health information collected or used by employees of UF, and requires that "authorization" (permission) of a specific form be obtained before a person's health information may be collected, used, or disclosed for research. Use of the combined consent/HIPAA authorization template is the mechanism to follow in obtaining written authorization.

Q: Is the CoC still valid if the original Principal Investigator is replaced by another investigator?

No. The CoC is issued to an individual PI or sponsor. If the PI of a study is replaced by another investigator, the Certificate must be amended to reflect that change.

Q: Does the CoC have an expiration date?

Yes. The CoC is issued for an explicit period of time. Once it expires, any study information collected after that expiration is not protected. The PI must renew the CoC, well in advance of its expiration, so that the entire period of data collection is protected.

Q: Should the PI notify the issuing federal agency of any changes made to the protocol?
Yes. Most CoCs specify that the holder must notify the issuing agency of any changes to the protocol.