

DEPARTMENT: Yale University Institutional Review Boards
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Yale University Policy Regarding Certificates of Confidentiality in Human Subject Research

I. Purpose

The purpose of this policy is to describe those circumstances in which an investigator or the Institutional Review Board (IRB) may require a Certificate of Confidentiality (CoC) be obtained to further protect the confidentiality of persons participating in research.

II. Policy

Any investigator engaged in research that will collect and/or retain personally identifiable sensitive information which has the potential to be sought under a judicial subpoena must consider the targeted research population and determine whether a CoC will further protect the data from being involuntarily disclosed for civil, criminal or other judicial proceedings. The IRB may require an investigator to apply for, or obtain, a CoC prior to approving the enrollment of subjects into the research protocol.

Researchers must obtain a CoC promptly when an approved protocol indicates that a CoC will be used to enhance the confidentiality of subjects. Failure to obtain a CoC in a timely manner may result in the temporary suspension of enrollment. When a significant change in the research project is proposed after a CoC is issued, the Principal Investigator must obtain IRB approval for the change and inform the Certificate Coordinator of the Institute issuing the CoC.

III. Background

A Certificate of Confidentiality constitutes an important tool in protecting the privacy of research study participants. A CoC protects in perpetuity information collected during a distinct period of time (the duration of the study). It allows 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. By protecting researchers and institutions from being compelled to disclose information under a court order or subpoena that would identify research subjects, a CoC helps to promote participation in studies by assuring confidentiality and privacy to participants. This protection is not limited to federally supported research.

While a CoC protects against involuntary disclosure, research subjects might voluntarily disclose their research data or information. Subjects may disclose information to physicians or other third parties. They may also authorize, in writing, the investigator to release the information to insurers, employers, or other third parties. In such cases, researchers may not use the CoC to refuse disclosure. Moreover, researchers are not prevented from the voluntary disclosure of matters such as child abuse, reportable communicable diseases, or a subject's threatened violence to self or others. If the researcher intends to make any voluntary disclosures, the consent form must specify that such disclosure will take place upon the investigator's discovery.

A CoC does not authorize researchers to refuse to disclose information about subjects if authorized Department of Health and Human Service (DHHS) personnel request such information for an audit or program evaluation. Neither can researchers refuse to disclose such information if it is required to be disclosed by the Federal Food, Drug, and Cosmetic Act.

National Institutes of Health (NIH) documents stress that a CoC does not take the place of good data security procedures, which are essential to the protection of research participants' participation and data. Researchers should take appropriate steps to safeguard research data and findings against access by unauthorized individuals.

IV. Definitions

Certificate of Confidentiality (CoC): Certificates of Confidentiality are issued by agencies within the DHHS such as the Centers for Disease Control and Prevention, the Food and Drug Administration (FDA), or the NIH to enhance subjects' privacy and ensure the confidentiality of study data and study participation. The CoC prevents researchers from compelled disclosure of names and other identifying information about any individual who participates as a research subject in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. This protection is afforded by the Public Health Service Act §301(d), 42 U.S.C. §241(d). It does not protect against voluntary disclosures by the researcher, but anticipated disclosures must be specified in the informed consent and HIPAA research authorization forms. A researcher may not rely on the CoC to withhold data if the participant consents in writing to the disclosure.

Sensitive Information at Risk of Subpoena: Sensitive information at risk of subpoena includes any information which could be of interest to the court in civil, criminal or other judicial proceedings. Most commonly this includes the use of alcohol, illegal drugs or addictive products and illegal behavior. Other examples which may in some instances be of interest to the court include information regarding HIV, AIDS, and other STDs; sexual practices or preferences; the subject's psychological state or mental health; information that can be destructive

to a subject's financial standing, employability or reputation within the community or that might lead to social disgrace or prejudice; genetic information or identifiable biological samples and corresponding data that may be used to demonstrate predisposition to disease or disputes in paternity; or information regarding behavioral interventions.

Significant Change: Per NIH definition, any major change in the scope or aim of the research protocol, change in personnel having major responsibilities in the project, or change in the drugs being administered (if any) and the persons who will administer them is considered significant.

Guidance

Investigators are encouraged to consider whether a CoC is necessary to further protect the confidentiality of subjects when designing their research studies. Specifically, investigators should consider whether the populations targeted for enrollment may be particularly vulnerable to subpoenas by judicial authorities in an effort to gain access to the sensitive research information for use in legal proceedings. Furthermore, not all studies that include sensitive information require a CoC. The IRB decision about whether or not to require a CoC will depend on the type, amount and frequency of the sensitive information being collected (for example, a single urine drug screen for research eligibility vs. a protocol studying substance abuse), the population targeted for research, and the ability of the researcher to safeguard the data.

The Office of Human Research Protections (OHRP) recommends that a CoC be obtained to protect confidentiality of human cell repository specimens and data.

Investigators are reminded that research best practices and the HIPAA Privacy Rule require investigators to obtain only that information considered necessary to accomplish the research aim. In some instances it may not be necessary to collect identifiers or sensitive information that may be available outside the auspices of the research. For example, eligibility may be evaluated through hospital admission procedures such as a urinalysis screen to determine illicit or illegal drug use. Investigators can also consider sound data security methods to protect the sensitive information gathered during the research. Minimizing or avoiding the retention of identifiable sensitive data by stripping personal identifiers from the data sets as soon as feasible can help protect the records from involuntary disclosure.

The IRB may determine that a study can commence concurrent with the investigator applying to the appropriate federal agency for the CoC. Alternatively, the IRB may require that no subjects be enrolled until the investigator has obtained a CoC. The IRB's determination is dependent upon the need for the protection offered by the CoC in relation to the type of sensitive information being collected.

V. Procedures

A. NIH and the FDA require IRB approval of all aspects of the protocol other than the receipt of the CoC prior to an investigator applying for a CoC. Investigators must state in the protocol, consent documents and during the consent process that a CoC has either been applied for or obtained. Consent documents must explain the protections offered by the CoC, and any conditions or limitations to these protections. If the IRB stipulates that a research study may begin to enroll subjects without the CoC, then it is imperative to inform potential subjects that their records will not be protected until such time that the CoC is acquired.

The following language should be included, as applicable, in the informed consent document:

If you decide to take part in this research study, you will be required to give us information about your [substance use/genetic information/criminal behavior]. Any of your identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission, with the following exceptions: We will disclose to appropriate authorities reportable diseases, known or suspected abuse of a child or elderly person, or if you become a danger to yourself or others.

We have [applied for/obtained] a Certificate of Confidentiality (CoC) issued by the [DHHS/FDA/NIH]. The CoC will protect investigators from being forced, even under a court order or subpoena, to release research information that could identify you. This protection will not be in effect until we have obtained the CoC, which may take a few months. We will inform you when the CoC has been obtained.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

For federally sponsored studies, use the following paragraph:

Because this research is sponsored by the Department of Health and Human Services through [name of sponsor], staff from that and other DHHS agencies may review records that identify you only for audit or program evaluation. They cannot report anything that would harm you or other research subjects.

For non-federally sponsored research, use the following paragraph:

Because the CoC is issued by the Department of Health and Human Services (or an agency within DHHS), staff from that and other DHHS agencies may review

records that identify you only for audit or program evaluation. They cannot report anything that would harm you or other research subjects. The Certificate of Confidentiality is not an endorsement of this research by the Department of Health and Human Services, or by the National Institutes of Health.

Even when a CoC is in place, you and your family members must still continue to actively protect your own privacy. If you voluntarily give your written consent for anyone to receive information about your participation in the research, then we may not use the CoC to withhold this information.

B. Researchers should apply to the particular DHHS agency, if any, involved in the funding or regulation of the study. For studies which are not funded by DHHS, investigators should select the DHHS agency that most closely relates to the research area of the study. CoCs are issued by agencies within the DHHS (such as the Centers for Disease Control and Prevention, the FDA, or the NIH). The FDA issues CoCs for studies that obtain an Investigational New Drug (IND) authorization or other FDA authorization. Researchers should note that the CoC application and approval process may take up to three months. See http://grants.nih.gov/grants/policy/coc/appl_extramural.htm

C. Investigators applying to the NIH for a CoC should follow the instructions found at <http://grants.nih.gov/grants/policy/coc/>. In addition, they should consult the “Certificate of Confidentiality: Detailed Application Instructions” at <http://info.med.yale.edu/hic/forms/index.html>

D. Investigators applying to the FDA for a CoC should follow the instructions found at <http://info.med.yale.edu/hic/forms/index.html>, “FDA Certificate of Confidentiality Application Instructions”.

E. A CoC application must be signed by the Principal Investigator of the study and an authorized Institutional Official at Yale. The designated Institutional Official for the Faculty of Arts and Sciences is the Associate Director, Office of Grant and Contract Administration; for the School of Medicine, the Deputy Director of Grant and Contract Administration is the designated Institutional Official. The completed application, including all attachments, must be sent to and signed by the appropriate Institutional Official before submission to the NIH or FDA. Once approved, the Principal Investigator is responsible for sending CoC application materials to the NIH or FDA.

F. Per NIH instruction, the lead site of a multi-site research study should apply for a single CoC to protect participants enrolled at all sites. However, multi-site applicants must list each participating unit, its address, and project director. If any new sites are added to the research study after the CoC is issued, the lead investigator should provide the NIH with an updated list of participating sites along with a cover letter that includes a statement that IRB approval has been issued for the new site and that the lead site maintains a copy of that approval.

The lead investigator must ensure that consent forms used at all participating sites include appropriate language regarding the CoC.

G. Once the CoC is obtained, the researcher must submit a copy to the IRB and inform all subjects already enrolled that the protection offered by the CoC is now in effect. Currently enrolled subjects may be informed verbally at the time of their next research visit. Research records must be updated to note that subjects were informed. Subjects who are no longer actively participating in the research may be informed by letter. A copy of the letter should be retained in the research record. For prospective subject enrollment, the PI must also submit an amendment request form (available at <http://info.med.yale.edu/hic/forms/index.html>) to the IRB and the revised consent documents which have been modified to note that the CoC is obtained rather than applied for.

H. If a significant change to the protocol takes place, the Principal Investigator must submit an amended CoC application to the Yale IRB and to the Certificate Coordinator at the Agency which issued the CoC. Instructions and forms for filing an amended CoC application are the same as the original CoC application.

I. It is the responsibility of the researcher to ensure that the CoC remains valid. FDA CoCs for IND studies remain valid as long as the IND is in effect. Other CoCs specify an expiration date. If a study's duration needs to be extended, and data collection will continue past the expiration date of the CoC, the researcher must submit a written request to the appropriate agency for an extension of the CoC expiration date. NIH and other agencies request that this proposal be submitted at least 3 months prior to the expiration date. Extension applications should include a rationale for the extension request, a revised estimate of the study duration, the most recent IRB approval of the study, and a copy of the approved consent form which states a CoC has been obtained.

VII. References

Certificate of Confidentiality Kiosk at <http://grants.nih.gov/grants/policy/coc/>
March 15, 2002

Frequently asked Questions at <http://grants.nih.gov/grants/policy/coc/faqs.htm>

Contact information for Certificate of Confidentiality applications is available at:
<http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm>

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