
Yale University Institutional Review Boards

400 PR.2 Certificate of Confidentiality

Overview

This procedure describes the process for obtaining a Certificate of Confidentiality (CoC) to further protect the confidentiality of persons participating in research. An investigator may pursue obtaining a CoC when he/she feels it necessary, or the IRB may require an investigator to apply for, or obtain, a CoC prior to approving the enrollment of participants into the research protocol.

Need for and Use of a CoC in Human Research

Federal agencies and institutes provide the CoC when it is necessary to protect participants' privacy and ensure the confidentiality of their study data and study participation. The issuing agencies generally require IRB approval of all aspects of the protocol other than the receipt of the CoC prior to approving a CoC application. 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. If the IRB discovers upon first reapproval of a protocol that the investigator has not obtained the CoC, the IRB will require an explanation from the PI. Depending on the reason, on a case-by-case basis, the IRB may (or may not) decide to implement a similar procedure as with expiring CoCs (see last section of this document).

Application to the US Department of Health and Human Services (DHHS)

Under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. 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

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>

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

Institutional Official Signature

A CoC application must be signed by the Principal Investigator of the study and an authorized Institutional Official at Yale. The designated Institutional Official is the Director of Grant and Contract Administration or their designee. 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.

Informing Subjects

Once the CoC is obtained, the researcher must submit a copy to the IRB and inform all subjects already enrolled in the research 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 can 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 to the IRB and the revised consent documents which have been modified to note that the CoC is obtained rather than applied for.

Consent Form Language

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]. We have [applied for/obtained] a Certificate of Confidentiality (CoC) issued by the [DHHS/FDA/NIH]. The CoC will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. The protection offered by the CoC does not stop us from voluntarily reporting information about suspected or known sexual, physical, or other abuse of a child or older person, or a subject's threats of violence to self or others. If any member of the research team is given such information, he or she will make a report to the appropriate authorities. This protection will not apply until we have obtained the CoC, which may take a few months. We will inform you when the CoC has been obtained.

For federally sponsored studies, insert 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, insert 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.

Continue with this language:

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.

Multi-Site Studies

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. A copy of the CoC should be distributed to the sites as appropriate.

Amending the CoC

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 or institute which issued the CoC. Instructions and forms for filing an amended CoC application are the same as the original CoC application.

Expiration of the CoC

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.

Investigators are advised that, should a CoC lapse while a study is actively enrolling subjects, enrollment must stop. Subjects should not be enrolled in such studies until the PI has taken steps to extend the CoC, or change the protocol/consent form to reflect the current status of the CoC. If the IRB discovers at the time of a study's reapproval that the CoC is lapsed or expiring, the IRB will limit the duration of the entire protocol's reapproval to 3 months to allow the PI to initiate extension or amend the protocol and consent form to remove mention of the CoC. In the latter case, reconsenting subjects who continue in the study should be done via a consent addendum.

A statement explaining this procedure is communicated by the IRB in the reapproval letter:

The IRB notes that the Certificate of Confidentiality (CoC) for this protocol ends on [date]. An extension of the CoC should be obtained to cover the duration of the study. For this reason, the protocol and consent form(s) will be valid for 3 months, expiring on [date]. When the CoC extension is received, a copy should be forwarded to the IRB, along with all materials necessary for reapproval. If the CoC expires and no extension is obtained, the protocol and consent form(s) must be amended to remove mention of the CoC, and a consent addendum must be prepared to notify subjects who continue in the study that the coverage of the CoC has ended.