
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 deemed necessary to protect participants' privacy and ensure the confidentiality of their study data and research participation. Once the CoC is in place, its protection is retroactive, offering protection for all study data collected from the start of the study through to the expiration of the Certificate.

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. Principal investigators 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. Principal investigators 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://www.yale.edu/hrpp/forms-templates/biomedical.html>.

Investigators applying to the FDA for a CoC should follow the instructions found at <http://www.yale.edu/hrpp/forms-templates/biomedical.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 his 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.

IRB Approval and CoCs

Initial Protocol Review

Investigators must state in the protocol, consent documents and during the consent process that a CoC will either be applied for or has been obtained. Consent documents must explain the protections offered by the CoC, and any conditions or limitations to these protections. 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.

The IRB may either determine that, (a) in the interests of protecting subjects, approval of the protocol cannot be granted until the CoC is obtained, or, (b) given the nature of the study and the IRB's assessment of potential risk, approval of the study may be granted prior to receipt of the CoC, with the understanding that subjects are informed during the consent process and in the consent or compound authorization form that the CoC is not yet in place and that its protections are not yet in effect.

If the IRB approves the protocol with the stipulation that a research study may begin to enroll subjects without the CoC in place, then it is imperative that investigators make immediate application to the appropriate agency to obtain the CoC. Investigators must also inform potential subjects that their research records will not be provided this level of protection until the CoC is acquired. Within two months after issuing IRB approval, the IRB will check with the PI on the status of the CoC, if the PI has not already provided the IRB with a copy of the CoC. If at that time no CoC application has been made, the Principal Investigator will be considered non-compliant with IRB requirements, and will be referred to the HRPP Compliance Manager for follow up.

Once the CoC has been obtained, the principal investigator must submit to the IRB (a) a copy of the Certificate and (b) an amendment request form with revised consent documents which have been modified to note that the CoC has been *obtained* rather than *applied for*. This is required for prospective subject enrollment.

Continuing Review

If, upon application for first re-approval of a protocol, the IRB discovers that the investigator has not obtained the CoC, then the IRB will decide whether to defer re-approval until the CoC is applied for and/or obtained, or renew approval for a limited time period sufficient for the CoC to be obtained. If the IRB defers re-approval, all study activity must stop and no new subjects may be enrolled until the CoC is obtained and the IRB re-approval has been granted.

If the IRB re-approves the study for a limited time period, the renewal period will be extended to the pre-existing annual anniversary date when the principal investigator submits the CoC to the IRB, along with the updated consent document(s) and protocol application for IRB validation.

If the IRB determines at re-approval that a CoC will expire within the course of the next year, the IRB will grant full approval of the protocol with a reminder to the investigator of the requirement to renew the CoC prior to its expiration.

Informing Subjects

Once the CoC is obtained, all subjects currently enrolled in the research must be informed 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. No notification need be made to subjects who are no longer actively participating in the project.

If a CoC expires before study interventions are complete, current subjects must be notified via consent addendum that the protections of the CoC are no longer in place. When the CoC extension has been issued, currently enrolled subjects must again be notified via an amended consent form.

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/HIV status]. We [will apply for/have obtained] a Certificate of Confidentiality (CoC) issued by the [DHHS/FDA/NIH]. Once granted, the CoC will protect the investigators from being forced, even under a court order or subpoena, to release information that could identify you. [If the CoC is not yet in place add: This protection will not apply until we have obtained the CoC, which may take a few months.]

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. 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 principal investigator 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 principal investigator 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.

Should a CoC lapse while a study is actively enrolling subjects, enrollment must stop. Subjects may not be enrolled until the PI has obtained the new CoC, or changed the protocol/consent form to reflect the current status of the CoC. Currently enrolled subjects must be informed that the CoC protections are no longer in effect.

If the IRB discovers at the time of a study's re-approval that the CoC has expired, the principal investigator will be required to submit a new consent form, amended with accurate information regarding the CoC. Subjects who are continuing in the study must be re-consented via a consent addendum informing them of the expired status of the CoC. When the new CoC has been issued by NIH, the principal investigator must submit a revised consent form reflecting the current CoC status. Both continuing and new subjects must be re-consented with the revised consent form. A statement explaining this procedure is communicated to the principal investigator by the IRB in the re-approval letter: