NOTE: This is an introduction to COCs and not everything an investigator could possibly want to know about them. Also, new information may come along. Potential applicants for COCs should check federal website to be sure they have the latest information.

What is a Certificate of Confidentiality (COC) and What Does it Do?

A COC is a document that helps researchers protect the privacy of participants in sensitive research studies. It protects the investigator and participants against compulsory legal demands (forced disclosure) such as court orders and subpoenas requesting release of identifying characteristics or information about participants. The Privacy Rule does not preclude the need for COCs. It provides protections for covered entities and disclosure of Protected Health Information, but it permits disclosure under certain judicial or administrative orders.

COCs often aid recruitment of persons who would not otherwise participate in a study or who, if recruited, might not provide valid data. Some worthy studies cannot be done without a COC.

Who May Apply for a COC?

Any investigator conducting research or planning to conduct research in which sensitive identifiable information is collected from human research participants and for which routine data security measures may be inadequate to protect privacy. The study must be research, it must be approved by an IRB, and it must collect personally identifiable information. Anonymous studies in which the investigator cannot identify participants, regardless of how sensitive the information is, would never need a COC.

What is Sensitive Information?

Sensitive information is Information that if released might be damaging to a person’s financial standing, employability, or reputation in the community or might lead to discrimination or stigmatization. Examples include information about sexual attitudes, preferences, or practices; use/abuse of drugs or alcohol; illegal behaviors; psychological well-being or mental health; and genetic information for tissue samples.
There may be other kinds of sensitive information for particular studies. Both PIs and IRBs can propose the use of a COC for other types of information with appropriate rationale.

**What is an “Identifying Characteristic”?**

- Name, address, social security or other identifying number
- Fingerprints, voiceprints, photographs
- Genetic information or tissue samples
- ANY COMBINATIONS OF DATA (above or otherwise) that may make it possible to identify research participants. This is a BROAD definition.
- It is essential for both the PI and the IRB to look at the details of studies to analyze sensitivity of information, presence of identifying characteristics, and combinations of information that may add up to more than the sum of the parts and thus mean potential harm for subjects if confidentiality is breached.

**What Are Examples of Studies That Used COCs?**

- Interview study of pastors with HIV/AIDS—release of knowledge of their health status would have profound social and economic effects on them and reluctance to participate might otherwise be great.
- Study of company officials' use of substances to “get high”—potential damage to reputation and employability
- Studies of illegal behavior by university students in the Greek system—might affect student status
- Studies of genetic basis for alcoholism among American Indians—lead to stigma or discrimination
- Studies where participants may be involved in litigation related to exposures under the study—e.g., breast implants, environmental or occupational exposures

**When and How Should PIs Apply for a COC?**

PIs should apply for a COC well in advance, as soon as the need is apparent, and at least three months before enrollment of research participants is expected to begin.

The first step is to apply to IRB, describing the intent and rationale for requesting a COC, measures to protect privacy and confidentiality, and providing the consent language to be used when the COC is granted.

Upon receipt of the IRB approval letter, the next step is to apply to NIH, which is the unit that actually grants COCs. If the study is NIH-funded, apply for a COC through the funding institute. If the study is not NIH-funded, and you are not sure which institute or center to apply to, go to the NIH Certificates of Confidentiality Kiosk (URL and more information later.)
It generally takes NIH at least three months to reply, longer if NIH raises questions about the application.

NIH may or may not approve the COC request, even though the IRB did. If the request is refused, the study plan must be revised and resubmitted to IRB.

**How Long Does A COC Last?**

The protection of a COC lasts for the entire expected duration of the study and as long as the investigator keeps identifiable information about study participants. Effectively, this may be in perpetuity. Investigators should tell IRB how long they plan to keep identifiable data.

If the investigator sees that a study will last beyond the expiration date of the COC, file a written request for extension at least three months before expiration. Provide the reasons for extension, propose a new termination date, and include the most recent IRB approval and approved consent document.

**What if the Study Changes after a COC is Issued?**

Inform the Certificate Coordinator at NIH of a significant change and submit an amended application. NIH may approve and issue an amended COC or it may disapprove and terminate the original COC.

**What about COCs and Multiple Studies or Sites?**

If multiple studies are planned, collecting the same information from different populations, a separate COC must be sought for each study. COCs are not given for broad groups or classes of projects.

If multiple studies are done, using different protocols but the same sample, the investigator need file for only one COC. (The same group is being protected in each study.)

If a study is being done at several institutions, the coordinating center or lead institution can apply for a COC on behalf of all participating sites AFTER it receives copies of IRB approvals and approved consent forms from each site. Each site’s consent form must describe the protections and limitations of a COC.

**Can COCs Be Obtained for Foreign Studies?**

COCs can be obtained for data collected from persons in foreign countries IF the data are stored in the U.S.

**How Do Subjects Respond to COCs?**
Many subjects find them reassuring and respond by participating and providing valid data. However, COCs do not necessarily mean smooth sailing with all research prospects.

- The sample language provided by government sites on COCs is complex—it is best if investigators adapt it for their studies and preferably pilot their versions for participant comprehension.
- The consent form must explain both the assurances (protections) and limitations of confidentiality with a COC. For example, study records may have to be given to a government agency (for program evaluations, audits, or other legal requirements), and information legally required to be reported such as child or spouse abuse or sexually transmitted diseases must be disclosed. Describing both protections and limitations leaves some people unsure of just how confidential their information will be. The remark “So this really isn’t confidential after all” is not uncommon.
- Distrust of the government and research are common—Sentiments like “Who knows what the government might do with this information” and “I won’t put my name on anything connected with research” are sometimes expressed.

**Can COC-protected Information Ever Be Disclosed?**

Yes. Participants are free to voluntarily disclose information about themselves. Also, information may be released if participants have consented in writing to disclose certain information to insurers, employers, or other third parties.

**What about COCs, Legislation, and Legal Action?**

- The Patriot Act does NOT affect the provisions of a COC.
- Challenges to the legality of COCs have been very rare. In 1973 the New York Court of Appeals upheld the certificate’s authority and the US Supreme Court declined to hear the case.
- If legal action is brought against a PI to release information, inform the University Legal Counsel and the federal Certificate Coordinator who issued the certificate. The NIH legal advisor is also willing to discuss regulations with the university attorney.

**What is the Major Source of Information about COCs?**

Go to the NIH COC KIOSK for complete information: [http://grants.nih.gov/grants/policy/coc/](http://grants.nih.gov/grants/policy/coc/). The Kiosk gives background information and instructions, application information for investigators, a contact list for various institutes, the Reportable Communicable Disease Policy, and FAQs.