This guidance serves to summarize the National Institutes of Health (NIH) and other Department of Health & Human Service agency guidance on certificates of confidentiality (CoC).

Definitions:

Certificates of Confidentiality (CoC) protect the privacy of research participants enrolled in biomedical, behavioral, clinical or other research. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable information. The CoC prohibits disclosure in response to legal demands, such as a subpoena.

Identifiable, sensitive information is considered to be information about an individual, gathered or used during the course of biomedical, behavioral, clinical or other research, through which the individual is identified, or there is at least a very small risk that some combination of the information, a request for the information, and other available data sources could be used to determine the identity of an individual.

Scope: This guidance clarifies the issuing of CoC, the protections and limitations offered by CoC, and investigator responsibilities for research covered by a CoC.

Highlights of the NIH/DHHS Guidance

- NIH automatically issues a CoC to any research it funds that is collecting or using identifiable information. This automatic issuance is applicable to NIH funded research commenced or ongoing on or after December 13, 2016.
- The application process for research funded by other DHHS agencies as well as unfunded research remains the same. There is no automatic issuance of CoC from other agencies.
- As you’ll note from the definition of “identifiable, sensitive information” above, the new statute that governs CoC broadened the meaning of sensitive, identifiable information and focuses more directly on identifiability. Essentially any identifiable or possibly identifiable information is considered sensitive information and protected by a CoC.
- Investigator responsibilities include ensuring:
  - disclosure of information, physical documents, or biospecimens protected by a CoC only occurs when:
    - required by other Federal, State, or local laws, such as for reporting of communicable diseases;
    - made with consent of the subject; or
    - made for the purposes of scientific research that is compliant with human subjects regulations.
  - subjects are told about protections afforded by the CoC and any exceptions to those protections, when studies involve informed consent (see RSPP informed consent template for suggested language).
- The protection of the CoC lasts in perpetuity. However, data collected after a certificate expires, or funding ends, may not be protected. If the study continues after funding ends and you need continued protection for new information, you should apply for a CoC following the process for non-federally funded research. If a research project was issued a CoC and continues under a no-cost extension, the information is covered by the certificate for the duration of the no-cost extension.
- CoC offer additional protections beyond those afforded by the HIPAA Privacy Rule. The Privacy Rule would permit use or disclosure in response to certain judicial or administrative orders.

For additional information, see FAQ about Certificates of Confidentiality (CoC)