Certificate of Confidentiality

Certificates of Confidentiality (COCs) are documents issued by the National Institutes of Health (NIH) and other federal agencies (such as DOJ, FDA, CDC) to protect against forced disclosure of identifiable research information.

Certificates of Confidentiality are automatically provided to NIH funded studies of identifiable sensitive information. Additionally, NIH will issue a COC by request, for a study that fits the NIH mission regardless if the study has federal funding or not.

COCs allow investigators 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. COCs may be granted for studies collecting sensitive information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation.

Examples of sensitive information that may require a COC include:

- Genetic susceptibility or family pedigree
- Mental illness
- High risk sexual attitudes, preferences, and practices
- Substance abuse or other illegal behaviors
- Participation in exposure effects studies that later become litigious, such as breast implants or environmental or occupational exposures

How to Obtain a Certificate of Confidentiality

Use the Online Certificate of Confidentiality System

You can use this system to:

- Request new Certificates of Confidentiality (CoC)

To request a CoC, you need to provide the following information:

1. Project details, including research title, start date, projected end date, and description.
2. Institution and performance site (if applicable) details, including institution and performance site(s) names and addresses, and institutional official name, email address, and phone number.
3. Principal Investigator name, phone number, email address, degree, position.
4. Key personnel names, degrees, and positions
5. Name(s) of drugs that will be administered, route of administration, and dosage
6. The following document to upload, if applicable:
   1. a copy of the DEA certificate(s)/registration for studies in which a controlled drug will be administered

Note: An email will be sent to the Institutional Official (IO) listed on the CoC request. Please list RoseAnn Fleming (rfleming@usc.edu) as the IO on the CoC request. The IO will need to review the CoC request information for accuracy and affirm the online Institutional Assurance Statement by checking each box and then submitting the CoC request.

Resources

- NIH Guidance on Certificates of Confidentiality
- How to Get a Certificate of Confidentiality
- eRA Service Desk (If you have technical difficulties with the CoC system)