University of Kentucky
Certificate of Confidentiality
Frequently Asked Questions (FAQs)

- **What is a Certificate of Confidentiality (CoC)?**

  A CoC protects the privacy of research participants enrolled in biomedical, behavioral, clinical, or other types of health-related research that collect or use identifiable, sensitive information. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The CoC prohibits disclosure in response to legal demands, such as a subpoena.

- **What is meant by identifiable sensitive information?**

  The statute that governs the CoC broadens the meaning of sensitive, identifiable information and focuses directly on identifiability. Identifiable, sensitive information is information about an individual, gathered or used during biomedical, behavioral, clinical or other research, through which the individual may be identified.

  This includes the risk that a combination of the information, could be used to determine the identity of an individual through a request for the information and combination with other available data sources. Identifiable, sensitive information includes but is not limited to name, address, social security, or other identifying number; and fingerprints, voiceprints, photographs, genetic information, tissue samples, or data fields that when used in combination with other information may lead to identification of an individual.

- **What are the researcher's responsibilities under a CoC?**

  Investigators or an institution issued a CoC shall NOT:
  - Disclose or provide information covered by the CoC, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding; or
  - Disclose or provide CoC covered information to any person not connected with the research for which the CoC is issued.

- **In what situations may CoC covered information be disclosed?**

  Disclosure of information, physical documents, or biospecimens protected by a CoC is permitted only when:
  - Required by other Federal, State, or local laws, such as for public health reporting of communicable diseases, or child or elder abuse reporting;
  - Made with consent of the subject; *or*
  - Made for the purposes of scientific research that is compliant with human subjects' regulations.

- **Is the researcher responsible for informing research participants of a CoC?**

  When a researcher is issued a CoC and the researcher will be obtaining informed consent from participants, the National Institute of Health (NIH) expects that the subjects will be told about protections afforded by the CoC and any exceptions to those protections. The NIH Human Subjects website has suggested consent language that investigators may refer to. See the University of Kentucky's (UK) consent template in E-IRB [under All Templates] for suggested

verbiage required by UK's Institutional Review Board (IRB).

- **If the study is funded by NIH, do I need to request a CoC?**

  No, eligible research studies that are funded by NIH are automatically issued a CoC under the NIH CoC Policy. To determine if your study is eligible, see next question.

- **Are all NIH funded-research protocols issued a CoC?**

  Effective October 1, 2017, CoCs have been automatically issued by NIH for all research covered by the policy that was commenced or ongoing on or after December 13, 2016. To determine if this policy applies to their NIH funded research investigators will need to answer the following question:

  - Is the activity biomedical, behavioral, clinical, or other research?

  If the answer to this question is **NO**, the activity is not automatically issued a CoC, and the investigator will need to apply for a CoC. (See **How does the CoC application process work at UK?**)

  If the answer is **YES**, investigators will need to answer the following questions:

  - Does the research involve Human Subjects as defined by 45 CFR Part 46?
  - Are you collecting or using biospecimens that are identifiable to an individual as part of the research?
  - If collecting or using biospecimens as part of the research, is there a small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual?
  - Does the research involve the generation of individual level, human genomic data?

  If the answer to **ANY** one of these questions is **YES**, then this Policy will apply and a CoC is automatically issued.

- **Does NIH issue CoCs for research involving identifiable, sensitive information funded by other HHS operating divisions?**

  Several non-NIH HHS agencies, including Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), and Indian Health Service (HIS), issue CoCs. If your research is funded by one of these agencies or is operating under the authority of the FDA, please contact the CoC Coordinator at the applicable funding agency (Certificates of Confidentiality (CoC) | grants.nih.gov) to determine how to obtain a CoC.

  The Agency for Healthcare Research and Quality (AHRQ) has its own privacy regulations which may apply; NIH will not issue a CoC for projects covered by AHRQ's regulations. Please contact AHRQ for further information about their privacy regulations.

  If your health-related research is funded by an HHS agency other than NIH, AHRQ, CDC, FDA, HRSA SAMHSA, or IHS, you may request a CoC for your research projects that collects or uses identifiable, sensitive information, through the NIH online CoC system. (Certificates of Confidentiality (CoC) | grants.nih.gov)

- **How does the CoC application process work at UK?**

  For **NIH funded studies** the project is automatically issued a CoC assuming it meets the criteria listed above. Follow the instructions in the NIH application to receive a copy of the CoC.

  For **Non-NIH funded studies** (It is the investigator's responsibility to ensure that the CoC is obtained before enrolling a subject.):

  i. Submit a research proposal to the IRB that contains CoC information in the General Information Sheet and consent form. Recommended consent language for CoC is available on ORI's model consent form and on the NIH Office of Extramural Research web page: https://grants.nih.gov/policy/humansubjects/coc/helpful-resources/suggested-consent.htm.

  ii. Obtain IRB approval before submitting paperwork for a CoC.

  iii. Submit the CoC application on-line. Please note: The on-line application will request that you list UK's Institutional Official, the Vice President for Research (VPR). Please use this email address in the CoC application: vpr@uky.edu.

  iv. The VPR will review the request and complete her review. The VPR may contact ORI if he/she has any questions regarding your study.

  v. If applicable, submit consent changes to the IRB to comply with NIH (or other agency) CoC consent requirements.

  vi. Submit documentation to the IRB once the CoC is obtained.

- **How do I apply for a CoC?**

  Information for applying for a CoC can be found at the following web page:Certificates of Confidentiality (CoC) | grants.nih.gov.

- **Who can I contact at NIH if I have CoC questions?**

  Inquires may be sent to NIH-CoC-Coordinator@mail.nih.gov.

All information within this document, with the exception of the CoC process at UK, is directly from NIH's CoC webpage.

For additional information on CoC, please go to NIH's FAQ page at https://grants.nih.gov/faqs#/s-of-confidentiality.htm?anchor=question55508. Additional info on CoC can be found at Certificates of Confidentiality (CoC) | grants.nih.gov. This page includes the CoC user guide, CoC podcast, NIH CoC policy, and suggested consent verbiage.

If you have a non-funded study and you have questions regarding the CoC process, please contact Joe Brown at Joe.Brown@uky.edu or Jenny Smith at Jenny@uky.edu.