• **What is a Certificate of Confidentiality (CoC)?** It is an authorization from the Department of Health and Human Services (HHS) that helps researchers and their institutions safeguard the privacy of research participants enrolled in sensitive biomedical and behavioral research by protecting against compulsory legal demands such as subpoenas for identifying information.

• **What does it do?** Research institutions can use a CoC to avoid forced disclosure of names and other identifying characteristics about research participants. It is used to oppose subpoenas and other compulsory demands.

• **Who is responsible for using the CoC to resist disclosures?** The research institution is expected to implement the privacy protections offered by the CoC. As part of the application process, an institutional official agrees to use the CoC and to defend its authority against legal challenges. You should be sure that these arrangements are in place at your institution.

• **Are there circumstances where a CoC cannot be used to resist disclosure?**
  - When the disclosure is requested in writing by the research participant, their legal guardian, or their legal representative.
  - To HHS or FDA in certain situations such as research audits as required by law.

• **Are there circumstances where information about study participants may be voluntarily disclosed by the Investigator or Institution?** Investigators and their institutions may (and should be prepared to) make disclosures to prevent serious harm to the participant or to someone else, including child abuse and to voluntarily comply with state and local reporting requirements for communicable diseases. The consent form should explain these and any other circumstances of voluntary disclosure.

• **Is identifiable research information obtained before a CoC was issued protected?** A CoC protects identifiable information about research participants that is maintained by an investigator during any time the CoC is in effect, even if the participant was enrolled before a study obtained a CoC. However, participants enrolled after a CoC has expired are not protected.

• **What HHS agencies are authorized to issue CoCs?** NIH, CDC, HRSA, IHS, and SAMSA can issue CoCs for research that they fund; FDA is authorized to issue CoCs for studies with an IND/IDE that do not have other HHS funding.

• **Is research that is not funded by HHS eligible for a CoC?** NIH is authorized to issue CoCs for sensitive research that is not federally funded, at its discretion, if the research is related to the NIH/HHS health research mission. Additionally, the research must be approved by an IRB operating under an approved Federal-wide Assurance and must accurately reflect the protections and limitations of the CoC in the subject consent form.

• **What kinds of projects may not be eligible for a CoC?** Projects that are not within the NIH mission or are not considered research are not eligible. For research that will gather information from existing records, the CoC will not protect information contained in the primary records.

• **Can Multi-site studies apply for a single CoC?** Multi-site studies should apply for a single CoC to avoid overlapping coverage and unintended gaps. A lead institution can apply for a CoC on behalf of all member institutions. Please see FAQ C6 for more details and lead site responsibilities ([http://grants.nih.gov/grants/policy/coc/faqs.htm](http://grants.nih.gov/grants/policy/coc/faqs.htm)).

• **Where at NIH should applications be submitted?** At NIH, CoCs are issued by the individual NIH Institutes or Centers (ICs). Thus, CoC application must be directed to the IC that is funding the research or that supports similar research. The Certificates of Confidentiality Kiosk web site has
Certificates of Confidentiality Summary

information to help you with your application (http://grants.nih.gov/grants/policy/coc/index.htm). If you are uncertain about which IC is appropriate, contact the NIH CoC Central Resource at NIH-COC_Coordinator@mail.nih.gov.

• What is the researcher’s responsibility to participants regarding a CoC?
When a researcher obtains a CoC the subjects must be told about protections afforded by the Certificate and any exceptions to those protections - i.e., the circumstances in which the investigators plan to disclose, voluntarily, identifying information about research participants (e.g., child abuse, harm to self or others, etc.). This information should be included in the informed consent form unless a research subject is no longer actively participating in the project so amendment of the informed consent would be impractical. The researchers should eliminate provisions in consent form templates that may be inconsistent with the Certificate protections (such as references to disclosures required by law, since the Certificate enables researchers to resist disclosures that would otherwise be compelled by law). In addition, researchers may not represent the Certificate as an endorsement of the research project by the DHHS or use it in a coercive manner when recruiting subjects.

• How does the CoC process work at UK?

• For NIH funded studies
If NIH funds the research project, the project is automatically issued a CoC assuming it meets the criteria above. Follow the instructions in the application to receive the CoC.

• For non-NIH funded studies ….
  o Submit a research proposal to the IRB that contains CoC information in the General Information Sheet and consent form.
  o Recommended consent language for CoC is available on ORI’s model consent form and on the National Institutes of Health Office of Extramural Research web page: https://humansubjects.nih.gov/coc/suggested-consent-language.
  o Obtain IRB approval before submitting paperwork for a CoC.
  o Obtain signature from UK’s Institutional Official (Vice President for Research (VPR)), before submitting the CoC request to the appropriate agency. Investigators should contact the University of Kentucky’s Office of Research Integrity for assistance in obtaining the VPR’s signature.
  o If applicable, submit consent changes to the IRB in order to comply with NIH (or other agency) Certificate of Confidentiality’s consent requirements.
  o Submit documentation to the IRB once the investigator obtains a CoC.
  o It is the investigator’s responsibility to ensure that the CoC is obtained before enrolling any subject.

• How to apply for a CoC. Information for applying for a CoC can be found at the following web page: https://humansubjects.nih.gov/coc/how-apply

All the information above came (with the exception of the CoC process at UK) came directly from NIH’s Certificate of Confidentiality webpage. The information in this document was copied verbatim from NIH to prevent any error of interpretation regarding Certificates of Confidentiality. For additional information, please go to NIH’s CoC Kiosk at https://humansubjects.nih.gov/coc/index

If you have a non-funded study and you have questions regarding the CoC process, please contact Joe Brown @ 859-257-9084 or email him at Joe.Brown@uky.edu

J:\Master Outreach Documents\Survival Handbook\D - Guidance-Policy-Educational\56-ORI_Summary_on_COC.doc