CERTIFICATE OF CONFIDENTIALITY APPLICATION INSTRUCTIONS

Click on the Certificates of Confidentiality Kiosk. This webpage will provide background information and application instructions for either Extramural or Intramural Projects.

Please note: the site does not provide an ‘application form’ to complete. The application should be written on your department’s letterhead and include all of the information requested from the instruction pages found on the Kiosk site.

Per the instructions, you will be requested to provide the following:

- IRB Federal Wide Assurance Number: 00007961
- Signature of the OUHSC Institutional Official:
  Valorie Owens, MSW, CRA
  Director of Sponsored Programs
  Office of Research Administration
- IRB Approval Letter:
  The IRB will hold the official approval letter but will provide an approval memo that can be submitted along with your application.
  
  Upon receipt, the actual COC should be submitted to the IRB. The IRB will then release the approval letter and stamped informed consent(s) so you can begin enrollment.

Required Language for the Informed Consent Document

The following language must be included to the informed consent document under the “What About Confidentiality” section:

To help protect your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. This Certificate means that the researchers cannot be forced (for example by court subpoena) to share information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.
The Certificate cannot be used to resist a demand for information from personnel of the U.S. government that is used for checking or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The protection offered by the Certificate of Confidentiality does not prevent us from being required by applicable state law to report information about suspected or known sexual, physical or other abuse of a child or older person, or a subject’s threats of violence to self or others. If any member of the research team is given such information, he or she will be required to make a report to the appropriate authorities.

The Certificate, however, does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information. This means that you and your family should actively protect your own privacy.

(Delete the following statement if your research is funded by NIH): If you are enrolled in the study after the expiration or termination of the Certificate, the protection afforded by the Certificate as described above will not apply.