Certificates of Confidentiality

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Certificates of Confidentiality are addressed in HRPP Policy #710, Privacy and Confidentiality in Research
What is a CoC?

- Protects against compulsory disclosure of personal identifiers in federal, state, or local civil, criminal, administrative, legislative, or other legal proceedings

- Protects the privacy of human subjects when they are a part of a research study that includes sensitive private information
Who is Eligible?

- Researchers engaged in biomedical, behavioral, clinical or other studies involving sensitive information:
  - Genetic
  - Psychological
  - Sexual
  - Etc.

- The IRB may require that an investigator obtain a CoC, especially for research involving vulnerable populations or research involving illegal substances.
Who Issues a COC?

- The National Institute of Health issues the COC through Certificate Coordinators at a variety of institutions, including NCI and FDA

- This authority has been delegated by the Secretary of Health and Human Services
How Does a COC Affect the Protocol?

- The COC does not affect the protocol; however the ICF must contain language that notifies the patient that a CoC exists.

- The modified ICF must be approved by the IRB before the CoC application is made.
Apply to the agency best suited for the research study being conducted
- FDA
- NCI
- CDC
- Etc., there are approximately 30 separate agencies to whom applications may be sent

Application instructions are available online at: http://grants.nih.gov/grants/policy/coc/
- Applications must include an end-date for the study
- Applications are available for both intramural and extramural research studies

There is no fee to apply
What are the Limitations?

- The individuals protected are not required to keep their own personal information private

- Communicable disease reporting is still required

- Standard disclosure to DHHS employees during the course of an audit are not exempted by the CoC
There are very few instances in which a CoC has been challenged.

In 1973, the New York State Court of Appeals upheld the protections provided by the CoC.

In 2006, the Kentucky Administrative Office of the Courts denied the Louisville branch of the NAACP access to identifiable data associated with a research project designed “to benefit the functioning of the Court of Justice,” based on the prior issuance of a CoC to those conducting the study.
Where Can I Find More Info?

- The Certificates of Confidentiality Kiosk:  
- 42 USC §241(d)
- WIRB  
  - http://www.wirb.com/content/foot_wirb_faq.aspx
- *Ethical Challenges in the Management of Health Information*  
  - http://books.google.com/books?id=QXTTPciur6EC&pg=PA283&lpg=PA283&dq=%22Certificate+of+Confidentiality%22+1973&source=web&ots=3-8DwGT5HC&sig=QY4T2_BXluRTNaBi8mh4H0m–mvc&hl=en
- *Current Medicolegal and Confidentiality Issues in Large, Multicenter Research Programs*  