Summary Guidance on Certificates of Confidentiality

What is a Certificate of Confidentiality?
A Certificate of Confidentiality (CoC) helps researchers protect the privacy of human research participants enrolled in biomedical, behavioral, clinical and other forms of sensitive research. Certificates protect against compulsory legal demands, such as court orders and subpoenas, for identifying information or identifying characteristics of a research participant. It is most often issued by the National Institutes of Health (NIH) whether or not the project is funded by them (other sponsoring agencies within the Department of Health and Human Services and the National Institute of Justice may also issue CoCs).

What kind of research is eligible for a Certificate?
Any research project that collects personally identifiable, sensitive information and that has been approved by an IRB is eligible for a Certificate. Federal funding is not a prerequisite for a Certificate.

What is meant by sensitive information?
Sensitive information includes (but is not limited to):
- information relating to sexual attitudes, preferences, or practices;
- information relating to the use of alcohol, drugs, or other addictive products;
- information pertaining to illegal conduct;
- information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination;
- information pertaining to an individual's psychological well-being or mental health; and
- genetic information or tissue samples.

Who may apply for a Certificate of Confidentiality?
Any person engaged in research in which sensitive information is gathered from human research participants (or any person who intends to engage in such research) may apply for a Certificate of Confidentiality.

Is NIH required to give all who apply a Certificate of Confidentiality?
No. No project is entitled to a Certificate; its issuance is discretionary.

How long does a Certificate's protection last?
Individuals who participate as research subjects (i.e., about whom the investigator maintains identifying information) in the specified research project during any time the Certificate is in effect are protected permanently.

To whom should I apply for a Certificate of Confidentiality?
If NIH funds the research project for which you would like a Certificate, you may apply through the funding Institute. However, even if your research is not supported with NIH funding, you may apply for a Certificate through the NIH Institute or Center (IC) funding research in a scientific area similar to your project. Contact information is available on the NIH website: [http://grants.nih.gov/grants/policy/coc/index.htm](http://grants.nih.gov/grants/policy/coc/index.htm)
When should I apply for a Certificate?
An application for a Certificate of Confidentiality is submitted after the Institutional Review Board (IRB) responsible for its review approves the research project (because IRB approval or approval conditioned upon issuance of a Certificate of Confidentiality is a prerequisite for issuance of a Certificate). Since the informed consent document should include language describing the Certificate and any voluntary disclosures specified by the investigator, the Applicant should tell the IRB that they are applying for a Certificate of Confidentiality and have included appropriate language in the informed consent form. Applications for Certificates should be submitted at least three months prior to the date on which enrollment of research subjects is expected to begin.

What is the researcher's responsibility to participants regarding a Certificate of Confidentiality?
When a researcher obtains a Certificate of Confidentiality, 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 making an amendment of the informed consent 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 federal government or use it in a coercive manner when recruiting subjects.

Does the Privacy Rule preclude the need for Certificates of Confidentiality?
No. Certificates of Confidentiality offer an important protection for the privacy of research study participants by protecting identifiable health information from forced disclosure (e.g., by court order). While the Privacy Rule does establish protections for covered entities’ use and disclosure of PHI, it permits use or disclosure in response to certain judicial or administrative orders. Therefore, researchers/contractors may obtain Certificates of Confidentiality to protect them from being forced to disclose information that would have to be disclosed under the Privacy Rule.

Does a Certificate of Confidentiality preclude the need to report elder abuse, child abuse, or spouse abuse, as required by NY State laws?
As a policy matter, NIH generally is unwilling to issue a Certificate of Confidentiality that exempts reporting of child abuse. In addition, Section 413 of the New York State Social Services Law requires that suspected or actual instances of child abuse be reported to the appropriate authority. To date, it does not have similar policies on reporting of elder abuse or spouse abuse. Should you obtain a Certificate of Confidentiality for either spouse abuse or elder abuse, in the unlikely event you become aware of threatened or actual abuse which has not already been reported, contact NYU’s Office of General Counsel for additional directions. Instances or suspected instances of child abuse always need to be reported to the New York State Child Protective Services Office.

How does the Certificate of Confidentiality process work at NYU?
The IRB recommends the following steps to obtain a Certificate of Confidentiality:
1. Submit a research proposal to the UCAIHS that contains Certificate of Confidentiality
information in the application and consent form. Recommended consent language for Certificates of Confidentiality is available on the National Institutes of Health Office of Extramural Research web page:

http://grants2.nih.gov/grants/policy/coc/appl_extramural.htm

2. Obtain UCAIHS approval before submitting paperwork for a Certificate of Confidentiality.

3. The UCAIHS Office will obtain the signature from NYU’s Institutional Official before submitting the Certificate of Confidentiality request to the appropriate agency. Investigators should contact the UCAIHS Office at 212-998-4808 for assistance and review prior to submission.

4. If applicable, submit consent changes to the IRB in order to comply with NIH (or other agency) Certificate of Confidentiality’s consent requirements. Sample language is available on the NIH’s web site under the heading “Informed Consent” at:

http://grants.nih.gov/grants/policy/coc/appl_extramural.htm

5. Submit documentation to the UCAIHS once a Certificate of Confidentiality has been obtained.

6. It is the investigator’s responsibility to ensure that the Certificate of Confidentiality is obtained before enrolling any subject.