

# UK/ORI's Summary Sheet on Certificate of Confidentiality

## **What is a Certificate of Confidentiality?**

A Certificate of Confidentiality 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.

## **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. NIH or 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>

## **When should I apply for a Certificate?**

Generally, 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 form should include language describing the Certificate and any voluntary disclosures specified by the investigator, the Applicant could 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 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.

### **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.

### **Should researchers apply for a Certificate of Confidentiality for all HIV studies?**

ORI contacted NIH with the above mentioned question in May 2005. According to NIH, Certificates of Confidentiality should not be sought when HIV testing is done for research and clinical purposes, as the clinician is required to report the disease (although a Certificate might be sought to cover other aspects of the research). Researchers may request a Certificate of Confidentiality when HIV testing is done solely for research purposes which may be granted particularly if the referring or treating physician has or will report the disease as required by state law; however, the IRB evaluates research proposals on a case by case basis and may determine that a Certificate of Confidentiality is not needed for a study. For additional information on NIH's policy on reporting communicable diseases, see [http://grants.nih.gov/grants/policy/coc/cd\\_policy.htm](http://grants.nih.gov/grants/policy/coc/cd_policy.htm)

### **Does a Certificate of Confidentiality preclude the need to notify public health authorities regarding Kentucky reportable diseases and conditions?**

ORI has contacted NIH several times to clarify its position on Certificates of Confidentiality and required reporting of communicable diseases. According to NIH, it generally requires that state reporting requirements be followed, and that Certificates of Confidentiality generally will not exempt reporting in accordance with state law. Researchers should notify public health authorities regarding all reportable diseases and conditions listed in 902 KAR 2:020. For additional information on NIH's policy on reporting communicable diseases, see [http://grants.nih.gov/grants/policy/coc/cd\\_policy.htm](http://grants.nih.gov/grants/policy/coc/cd_policy.htm)

## **Does a Certificate of Confidentiality preclude the need to report elder abuse, child abuse, or spouse abuse, as required by state laws?**

As a policy matter, NIH generally is unwilling to issue a Certificate of Confidentiality that exempts reporting of child abuse. 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 abuse which has not already been reported, contact UK's Office of Legal Counsel for additional directions.

## **How does the Certificate of Confidentiality process work at UK?**

The IRB recommends the following steps to obtain a Certificate of Confidentiality at UK:

1. Submit a research proposal to the IRB that contains Certificate of Confidentiality information in the General Information Sheet 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](http://grants2.nih.gov/grants/policy/coc/appl_extramural.htm))
2. Obtain IRB approval before submitting paperwork for a Certificate of Confidentiality.
3. Obtain signature from UK's Institutional Official, James W. Tracy, PhD, Vice President for Research, before submitting the Certificate of Confidentiality request to the appropriate agency. Investigators should contact the University of Kentucky's Office of Research Integrity for assistance in obtaining Dr. Tracy's signature.
4. If applicable, submit consent changes to the IRB in order to comply with NIH (or other agency) Certificate of Confidentiality's consent requirements.
5. Submit documentation to the IRB once the investigator obtains a Certificate of Confidentiality.
6. It is the investigator's responsibility to ensure that the Certificate of Confidentiality is obtained before enrolling any subject.

Compiled by Joe Brown from the University of Kentucky. Revised 3/04/08.  
Information came from NIH's Frequently Asked Questions on Certificates of Confidentiality web page: <http://grants.nih.gov/grants/policy/coc/faqs.htm>, conference call with NIH on 5/5/05, and subsequent emails in 2006.