

## Applying for a Certificate of Confidentiality at USC

Certificates of Confidentiality (CofCs) are documents issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. Certificates of Confidentiality may be granted for studies collecting information that, if disclosed, could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation. NIH Certificates of Confidentiality may be authorized for studies not funded by NIH (e.g., NIH funding is not a condition for receiving a Certificate of Confidentiality).

Examples of sensitive research activities include but are not limited to collecting identifiable information on:

- genetic susceptibility or family pedigree
- mental illness
- high risk sexual attitudes, preferences and practices
- substance abuse or other illegal behaviors
- involvement in litigation related to exposure effects (e.g., breast implants, environmental or occupational exposures)

By protecting investigators and institutions from being compelled to disclose information that would identify research participants, Certificates of Confidentiality help the investigator achieve research objectives and promote participation in studies by assuring confidentiality and privacy to participants.

Certificates of Confidentiality are effective on the date of issuance or upon commencement of the research project if that occurs after the date of issuance. The certificate will state the date upon which it becomes effective and the date upon which it expires. A Certificate of Confidentiality protects all information identifiable to any individual research participant (i.e., about whom the investigator maintains identifying information) during the time certificate is in effect.

An extension of coverage must be requested if the research extends beyond the expiration date of the original certificate. However, **the protection afforded by the certificate is permanent**. All personally identifiable information maintained about subjects in the project while the certificate is in effect is protected in perpetuity.

While certificates protect against **involuntary** disclosure, investigators should note that research subjects might themselves voluntarily disclose research data or information.

Subjects may disclose information to physicians or other third parties, and/or may authorize (in writing) the investigator to release information to insurers, employers, or other third parties. In such cases, researchers may not use the certificate to refuse disclosure. Moreover, researchers are not prevented from mandatory disclosure of matters such as child or elder abuse, reportable communicable diseases or subject's threatened violence to self or others. However, if the investigator intends to make any voluntary disclosures or is required to make mandatory disclosures, the Informed Consent Form must specify such disclosure.

In the Informed Consent Form, investigators should inform research subjects that a certificate is in effect. Subjects should be given a fair and clear explanation of the protection that it affords, including the limitations and exceptions noted above.

Investigators may choose to apply for a Certificate of Confidentiality, or the IRB may require an investigator to obtain a certificate prior to conducting the research. Investigators who intend to apply for a Certificate of Confidentiality should submit a CofC Investigator Packet to the IRB Office (see below).

### **CofC Investigator Packet for IRB Submission**

To request a Certificate of Confidentiality, PIs will submit a CofC Investigator Packet (see below) to the IRB. After the IRB reviews the packet, it is forwarded to the designated Institutional Official (Vice Provost for Research Advancement or VPRA).

The steps required at USC for all CofC submissions are as follows:

- Complete packets must be submitted to the IRB which will forward the packet and IRB approval to the attention of the Office for the Protection of Research Subjects (OPRS)
- OPRS will verify packet completion and approved for IO signature and forward packet for IO signature
- OPRS will keep a record of CofC request and documentation of VPRA signature
- Once the necessary signatures are in place, VPRA staff will send the signed packet back to PI and inform OPRS that transaction has been completed.

A complete CofC packet will contain these items in the prescribed order:

1. Memorandum signed by IRB Chair or Director
2. A letter from the PI requesting the CofC
3. IRB Study Approval\* Notice
4. Any additional documents submitted by PI

**Neither the USC IRB nor the VPRA/IO will evaluate the content of the Certificate of Confidentiality application. However, the study must be approved\* by the IRB before the VPRA/IO can sign the Certificate of Confidentiality application letter.**

**\*Note: until the CofC is received from NIH, the IRB approval will be conditional. Once it is received by the PI and uploaded into iStar, approved documents will be released and approval will no longer be conditional.**

For additional Certificate of Confidentiality information see links below:

DHHS Certificate of Confidentiality Kiosk

<http://grants.nih.gov/grants/policy/coc/index.htm>

DHHS Frequently Asked Questions on Certificates of Confidentiality

<http://grants.nih.gov/grants/policy/coc/faqs.htm>