

## HOW TO APPLY FOR A CERTIFICATE OF CONFIDENTIALITY (COC)

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**Please refer to the National Institutes of Health (NIH) "Certificates of Confidentiality Kiosk" for instructions on applying for a CoC.**

**The CoC Kiosk is available online at:  
<http://grants.nih.gov/grants/policy/coc/index.htm>**

### **Background Information**<sup>1</sup>

Certificates of Confidentiality are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. A Certificate of Confidentiality is usually employed in studies where investigators collect sensitive information, such as that which, "... if disclosed could have adverse consequences for subjects or damage their financial standing, employability, insurability, or reputation."

**The statutory basis for protection:** "Under section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)) the Secretary of Health and Human Services may authorize persons engaged in biomedical, behavioral, clinical, or other research to protect the privacy of individuals who are the subjects of that research. This authority has been delegated to the National Institutes of Health (NIH). Persons authorized by the NIH to protect the privacy of research subjects may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify them by name or other identifying characteristic."

### **Contacts for Information on Certificates of Confidentiality**

Please contact the appropriate NIH Certificate Coordinator (by funding agency) if you have any questions about the CoC application process.

Coordinators are listed on the NIH website at:  
<http://grants.nih.gov/grants/policy/coc/contacts.htm>.

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<sup>1</sup> Excerpted from: <http://grants1.nih.gov/grants/policy/coc/background.htm>

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### **Required signatures for CoC application**

The NIH requires that both the Principal Investigator and the Institutional Official sign the assurances requested in the application for a Certificate of Confidentiality.

**In order to obtain the UCLA Institutional Official's signature, please forward your completed application to OPRS, attention to either:**

**OPRS Assistant Director Alison Orkin (NGIRB or SGIRB) or  
OPRS Assistant Director Eric Mah (MIRB1, MIRB2, or MIRB3).**

- *Please note that the application must be signed by the Principal Investigator prior to forwarding the application to OPRS to obtain the Institutional Official's signature.*
- *The signed application will be returned to the investigator upon issuance of the UCLA IRB approval notice for the research.*
- *It is the investigator's responsibility to submit the completed application and required accompanying materials to the NIH Certificate Coordinator.*

### **CoC Issued To Student Investigator**

In cases where a Certificate of Confidentiality is sought for a student research project, the NIH requires that both the student investigator, the student's faculty sponsor, and the Institutional Official sign the assurances requested in the application for a Certificate of Confidentiality.<sup>2</sup> *Please ensure that the letter of application is on institutional stationery and has been signed by the student and the student's advisor or other appropriate faculty member prior to submission to OPRS.*

### **Once you receive the CoC**

Once received, please forward a copy of your Certificate of Confidentiality to the UCLA IRB.

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<sup>2</sup> Please note that in accordance with NIH requirements, for research projects submitted by student investigators, the UCLA IRB approval notice for this study will be issued jointly to the student and the student's faculty sponsor.

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### **Language to describe the CoC in the consent form**

The NIH Certificates of Confidentiality Kiosk<sup>3</sup> provides the following guidance regarding informing subjects about the protection afforded by a Certificate of Confidentiality (CoC):

*When a researcher obtains a Certificate of Confidentiality, the research subjects must be told about the protections afforded by the certificate and any exceptions to that protection. That information should be included in the informed consent form. Examples of appropriate language follow. Researchers may adapt the language to the needs of the research participants and to the subject matter of the study. However, the language used must cover the basic points.*

*Researchers should also review the language about confidentiality and data security that is routinely included in consent forms to be certain that it is consistent with the protections of the Certificate of Confidentiality.*

*Example:*

*To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, 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 United States Government that is used for auditing 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).*

*You should understand that a Certificate of Confidentiality 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.*

*[The researchers should include language such as the following if they intend to make voluntary disclosure about things such as child abuse, intent to hurt self or others, or other voluntary disclosures.] The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. [The researchers should state here the conditions under which voluntary disclosure would be made. If no voluntary disclosures will be made, the researchers should so state.]*

**PLEASE NOTE:** The NIH Certificate Coordinator will communicate with the UCLA investigator regarding acceptable language on a study-by-study basis.

All changes to the language in the consent form required by the NIH Certificate Coordinator must be submitted to the UCLA IRB for review and approval as an addendum to the approved protocol.

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<sup>3</sup> “Detailed Application Instructions For Certificate Of Confidentiality: Extramural Research Projects” (available online at: [http://grants.nih.gov/grants/policy/coc/appl\\_extramural.htm](http://grants.nih.gov/grants/policy/coc/appl_extramural.htm))