IRB EQUIP TIPS
Certificate of Confidentiality Guidance –
What is a CoC and how do I obtain one?
V 2.1 September 2022

1. **What is a Certificate of Confidentiality (CoC)?**

   - CoCs are issued by the NIH to provide additional privacy protections to of research participants enrolled in biomedical, behavioral, clinical or other types of health-related research by protecting investigators and institutions from being compelled to release identifiable, sensitive information related to a participant.
   - CoC’s protect the privacy of research participants by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the participant consents or in a few other specific situations.
   - The Certificate prohibits disclosure in response to legal demands, such as a subpoena.
   - In What Situations May Covered Information Be Disclosed?
   - Investigator and Institutional CoC Responsibilities

2. **What research is automatically deemed to have a CoC?**

   - Effective October 1, 2017, all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH that was commenced or ongoing on or after December 13, 2016 is deemed to be issued a Certificate through this Policy and is therefore required to protect the privacy of individuals who are subjects of such research.

3. **How do I obtain a CoC if my study is not NIH funded?**

   - Any research on a sensitive health-related topic that collects names or other identifiable, sensitive information pertaining to subjects, that has been approved by an IRB, and that is in compliance with the Federal Policy for the Protection of Human Subjects at 45 CFR 46 (the Common Rule) or follows relevant provisions of the Common Rule relating to consent, may be eligible for a Certificate. The study topic (e.g., purpose, objectives, aims) must fall within a mission area of the National Institutes of Health or the Department of Health and Human Services. NIH issuance of Certificates is discretionary.

   - Examples of research that would be ineligible to receive a Certificate include:
     - not research based,
     - not collecting or using identifiable, sensitive information pertaining to research participants,
     - not involving a topic that is within a mission area of the NIH or the Department of Health and Human Services.

   - If the research is not federally funded, the Secretary may issue a Certificate to an investigator or institution engaged in such research, upon application.

   - See the CoC user guide for details about the application process.

   - **How to complete your Certificate of Confidentiality Request:**
     - Q 1-6: Please see the Details on Certificate of Confidentiality Eligibility Questions
     - Q 7 and 10: Enter the Project Title and description as it appears on your NIH Grant / IRB Application.
     - Q 8-9: Enter the Project start and end dates (NOTE: Dates for project must be in the future)
     - Q 11: Name of Institution: University of California Irvine
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- Q 12: Institutional Address: 160 Aldrich Hall, Irvine California, 92697
- Q 13: Name of Institutional Official (IO): Dr. Pramod P. Khargonekar
- Q 14: Email Address of Institutional Official: pramod.khargonekar@uci.edu
- Q 15: Phone Number of Institutional Official: (949) 824-5796
- Q 16 (optional): Add any Performance sites where UCI will be the IRB of record for the study
- Q 18-22: Add Principal Investigator(PI) / Lead Researcher detailed information
- Q 23: “Other Person to Receive CoC Communications and Certificate”: Add Beverley Alberola (beverley.alberola@uci.edu)
- Q 24 (optional): Add any key study personnel
- Q 25 (optional): List any drugs that will be administered in this study

Once all information has been entered, click “Submit for Verification”
Both the IO and the PI will receive a confirmation email which includes a PDF of all submitted information. The email will be from NIH-CoC-Coordinator@mail.nih.gov with a Subject of: Verification and submission of COC Application.
The institutional official (IO) will then need to verify and submit the CoC request to NIH.
The NIH CoC Coordinator can then view and process the request.
If NIH has questions about the request, the NIH CoC Coordinator will contact the PI and IO via email.
Typically, NIH processes CoC requests within one week after receiving the request. After submission, if you don't receive NIH communications regarding the CoC request within a week, contact the NIH CoC Coordinator to request a status update.
When the request is approved, the IO and PI will receive an email from the NIH CoC Coordinator with a PDF copy of the Certificate.

4. My research is covered by / will be issued a CoC. What changes do I need to make to my IRB Protocol?

➢ Ensure the UCI Consent includes the “Certificate of Confidentiality” section of the UCI Informed Consent Template is included on the Consent Form.

➢ If identifiable, sensitive information protected by a Certificate will be placed in a participant’s medical record, researchers must utilize the Health Information Management (HIM) safeguards for restricting the release of this information. The protections of the Certificate and prohibitions on further disclosure of the information apply to information included in the medical record.

➢ Within the IRB Protocol in the “Risk Assessment” – “Certificate of Confidentiality” section

- select “Yes” under the question “Is the research partially or wholly funded by NIH (including NIH Institutes and Centers), or does the research involve identifiable sensitive information that require CoC protections?”.
- Provide responses for all CoC related questions:
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