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

V 3.1 December 2023

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

- CoCs are issued by the NIH or FDA to provide additional privacy protections 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 from the NIH 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 F*ederal 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 NIH 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
  - **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. How do I obtain a CoC from the FDA if my study is FDA regulated and not federally funded?

- Historically, FDA has accepted requests for CoCs from sponsors and researchers and issued CoCs on a discretionary, case-by-case basis.
- The FDA has recently issued guidance relating to changes for Certificates of Confidentiality (CoCs) brought about by the 21st Century Cures Act ("Cures Act")
- This guidance clarifies that, for FDA-regulated research that **is not federally funded studies with an IND / IDE**, **FDA will continue to consider applications for discretionary CoCs** and issue them as appropriate, depending on the nature of the case.
- If an IRB in reviewing research determines that particular data collected in a clinical trial are sufficiently sensitive to warrant requesting a CoC, then it is within the purview of an IRB to request that a CoC be obtained in order to secure IRB approval.
- **How to obtain a CoC from the FDA:**
  - Review the FDA's guidance on CoC before submitting a request.
  - FDA suggests such sponsors / sponsor - investigators ask themselves four questions **before submitting a request for a CoC**:
    - Does the human subject research collect **identifiable, sensitive information**?
    - Is the requestor a **sponsor or sponsor-investigator** or authorized representative (i.e., the individual who takes responsibility for or initiates the clinical investigation)?
    - Does the human subject research, for which a discretionary CoC is being requested, involve the **use or study of a product subject to FDA's jurisdiction** and subject to FDA's regulatory authority?

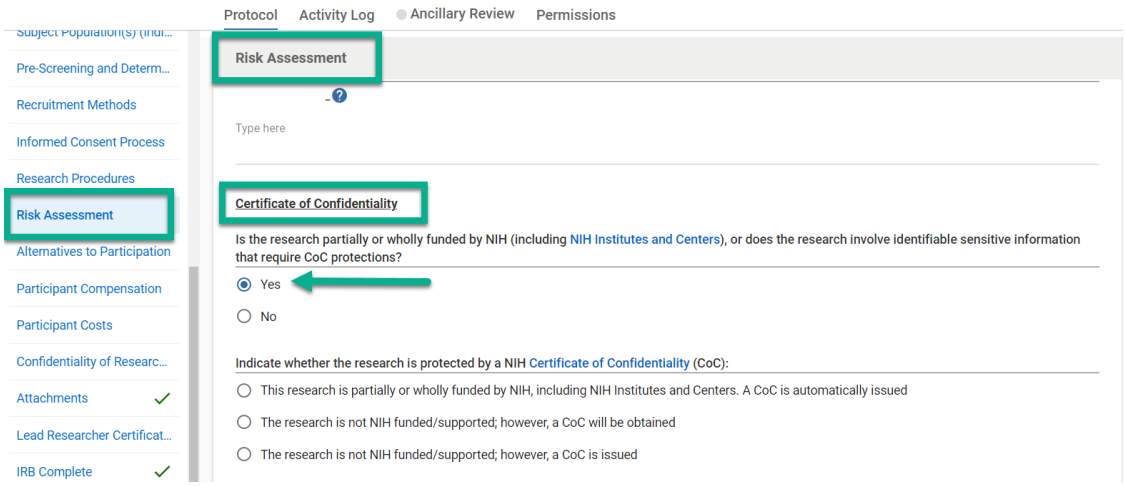
  - Are the requestor's research measures **sufficient to protect the confidentiality** of the identifiable, sensitive information?"[1]
- After determining your study qualifies for a CoC from the FDA, follow the steps outlined in Section IV of the guidance.
- After FDA completes its review of a request, the guidance says the agency will send **an electronic response letter** to the requestor indicating whether or not the CoC has been granted. If granted, that **letter will serve as the CoC**.

5. 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**.
  - **Both** the "**Certificate of Confidentiality" and "Medical Care" sections** of the UCI Informed Consent Template should be included on the Consent Form.
  - Please see the **UCI Health Tip Sheet related to CoC's and Medical Records** for more details.
  - *Note that a Certificate is not intended to limit the access of research participants to research information about themselves.*

- **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:



[1] The amendments to section 301(d) of the PHS Act, signal Congressional support for enhanced privacy protections for participants in research. FDA recommends that sponsors and investigators explore ways to further enhance their own privacy and confidentiality procedures.