HUMAN RESEARCH PROTECTIONS PROGRAM
UNIVERSITY OF MICHIGAN

CoC FAQs for U-M Researchers

This document highlights key aspects of Certificates of Confidentiality for U-M researchers. More detailed information can be found at the U-M HRPP CoC website, the NIH CoC kiosk or NIH FAQs. The information is for use by University of Michigan NIH-funded, other HHS-funded, or non-federally funded researchers. NIH-funded and specific other HHS agencies issue CoCs as a term and condition of funding. Other researchers may apply to the NIH for a CoC if the research falls within the mission of the NIH.

- **What is a Certificate of Confidentiality (CoC)**? It is an authorization from the Department of Health and Human Services (HHS) that helps researchers and their institutions safeguard the privacy of research participants enrolled in sensitive biomedical and behavioral research by protecting against compulsory legal demands such as subpoenas for identifying information.
- **What does a CoC do?** Research institutions can use a CoC to avoid forced disclosure of names and other identifying characteristics about research participants. It is used to oppose subpoenas and other compulsory demands.
- **Who is responsible for using the CoC to resist disclosures?** The research institution is expected to implement the privacy protections offered by the CoC. As part of the application process, an institutional official agrees to use the CoC and to defend its authority against legal challenges.

  Researchers who share identifiable data with other researchers may only do so as allowed by the CoC and as described in the consent document under which the data were collected. The CoC protections, and limitations on disclosure, follow the data. It is the U-M PI's responsibility to ensure that anyone with whom they share the data are informed about the CoC protections and limitations on disclosure (typically, this should be done as part of the data sharing agreement).
- **Are there circumstances where a CoC cannot be used to resist disclosure?**
  - When the disclosure is requested in writing by the research participant, their legal guardian, or their legal representative.
  - To HHS or FDA in certain situations such as research audits as required by law.
- **Are there circumstances where information about study participants may be voluntarily disclosed by the Investigator or Institution?** Investigators and their institutions may (and should be prepared to) make disclosures to prevent serious harm to the participant or to someone else. The consent form should explain when disclosures will be made because of legal requirements and any other circumstances of voluntary disclosure.
- **Is identifiable research information obtained before a CoC was issued protected?** A CoC protects identifiable information about research participants that is maintained by an investigator during any time the CoC is in effect, even if the participant was enrolled before a study obtained a CoC. Data collected under an active CoC are protected in perpetuity. However, participants enrolled after a CoC has expired, and if a new CoC is not obtained, are not protected.
- **What HHS agencies are authorized to issue CoCs?** NIH, CDC, HRSA, IHS, and SAMHSA can issue CoCs for research that they fund; HRSA and SAMHSA require a direct application for funded researchers; FDA is authorized to issue CoCs for studies with an IND/ IDE that do not have other HHS funding.

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- **Is research that is not funded by HHS eligible for a CoC?** NIH is authorized to issue CoCs for sensitive research that is not federally funded, at its discretion, if the research is related to the NIH/HHS health research mission. Additionally, the research must be approved by an IRB operating under an approved Federal-wide Assurance and must accurately reflect the protections and limitations of the CoC in the subject consent form.
- **What kinds of projects may not be eligible for a CoC?** Projects that are not within the NIH mission or are not considered research are not eligible.
- **Can Multi-site studies apply for a single CoC?** Although the NIH policy allows for a lead institution to obtain a CoC and have it cover all collaborators/sites in that project, the University of Michigan does not implement this option. **The U-M will only agree to and confirm CoC assurances for U-M researchers.**

  NOTE: If the U-M researcher is a sub-awardee or sub-contractor paid via NIH funding from the Lead institution then the CoC that the Lead holds by virtue of direct NIH funding also affords protections to the U-M researcher.
- **Can graduate or undergraduate students apply for a CoC?** Graduate students may serve as the PI on a research study and apply for a CoC under their name. Undergraduate students are not allowed to apply for a CoC. Therefore, if a CoC is required given the nature of the research, the undergraduate student may serve as a Co-I and the PI must be a current U-M faculty.
- **Where should researchers submit the NIH CoC application?** U-M researchers should not apply to the NIH until after first applying to the U-M HRPP office. Instructions for the application process can be found at the U-M HRPP CoC website.

Questions

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