

GUIDANCE: Certificates of Confidentiality (CoC) – NIH Process for Non-NIH Funded Studies NUMBER DATE PAGE HRP-910 9/22/2023 1 of 1

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The National Institutes of Health (NIH) has updated their website and process for non-NIH funded studies requesting CoCs.

- 1. If you would like to request a CoC for a non-NIH funded study, it must be first discussed with PPHS. Please email irb@mssm.edu to set up a request for discussion irb@mssm.edu to set up a request for discussion irb@mssm.edu to set up a request for discussion irb@mssm.edu to set up a request for discussion prior to completing any steps below but only after your RUTH application has been submitted
- 2. Once you have discussed with PPHS, researchers will be directed to request a CoC at the NIH's Online Certificate of Confidentiality System.
 - **a.** This new platform sends the Institutional Official (IO)/IO designee the assurance and verification directly.
 - **b.** The IO designee, who will sign the CoC assurance and verification, is Dr. Glenn Martin. On the CoC Request, under Institutional Official, list:
 - i. Institutional Official: Glenn Martin, MD, CIP
 - ii. Institutional Official email: glenn.martin@mssm.edu
 - iii. Institutional Official phone number: (212) 824-8200
 - **c.** The IO/IO designee will need to review the CoC request information for accuracy and affirm the online <u>Institutional Assurance Statement</u> by checking each box and then submitting the CoC request.
- 3. Researchers should follow the guidelines for what is needed when requesting a CoC located on the NIH website. If you should have any questions about the NIH process, please contact the NIH Coordinator at NIH-CoC-Coordinator@mail.nih.gov.
- 4. As a part of the application, there are regulatory questions that will be asked. If you would like to see the regulations being referenced, please see here.
- 5. Once your CoC has been issued, provide a copy of the certificate to the IRB along with a consent form that has been updated with CoC language.