



| <b>GUIDANCE: Certificates of Confidentiality (CoC) – NIH Process for Non-NIH Funded Studies</b> |  |        |
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## **GUIDANCE: Certificates of Confidentiality (CoC) – NIH Process for Non-NIH Funded Studies**

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

1. **Once the RUTH application has been submitted and the initial review is complete, the assigned analyst will assess whether your study should request a COC. If the study is eligible for a COC, the analyst will reach out to you directly to schedule a time to review the requirements, address any outstanding questions, and outline the next steps in the process.**
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. Theodore Bania. On the CoC Request, under Institutional Official, list:
    - i. Institutional Official: Theodore Bania, MD, MSCR, CIP
    - ii. Institutional Official email: [theodore.bania@mssm.edu](mailto:theodore.bania@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 [Institutional Assurance Statement](#) 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](mailto: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.