V1 effective December 1, 2024

Columbia University
Human Research Protection Office
Standard Operating Procedure (SOP) for reviewing and submitting
Requests for a Certificate of Confidentiality

Background:

A Certificate of Confidentiality (CoC) from the National Institutes of Health (NIH) is required for certain federally funded research involving identifiable, sensitive data and may be requested for specific projects that are not funded by NIH, including projects for which NIH funding has ended.

NIH-funded research:

Effective October 1, 2017, CoCs are automatically deemed to be issued for any NIH-funded research that collects or uses identifiable, sensitive information that was on-going on or after December 13, 2016. For these projects, the CoC is issued as a term and condition of the award and the NIH does not issue a physical certificate.

Identifiable, sensitive information is defined by the NIH CoC Policy as information that is about an individual and that is gathered or used during the course of research where the following may occur:

- Through which an individual is identified; or
- For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identify of an individual.

If the NIH funding ends, the study will no longer be deemed to be issued a CoC. While CoC protections remain in perpetuity for already collected or used information, a new CoC will need to be obtained in order to cover any new data collected from already enrolled participants or any new participants.

Non-NIH funded/unfunded research:

Investigators whose research **is funded by the federal agencies listed below**, **is not federally funded or does not have external funding** may request a Certificate of Confidentiality for specific research projects that collect or use identifiable, sensitive information through the online NIH CoC system.

Research funded by these federal agencies:

- **a HHS agency other than** NIH, excluding the Agency for Healthcare Research & Quality (AHRQ), the *Biomedical Advanced Research and Development Authority (BARDA**), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration

(FDA), Health Resources and Services Administration (HRSA), the Indian Health Service (HIS), and the Substance Abuse and Mental Health Services Administration (AMHSA)
- **a non-HHS federal department or agency**, other than the Department of Justice (DOJ)

The HHS and non-HHS federal departments and agencies excluded above have their own privacy or CoC requirements.

**Investigators whose research is funded or sponsored by BARDA through an award that was issued prior to July 17, 2023, may continue to request a CoC for specific research projects that collect or use identifiable, sensitive information through the NIH portal.*

Per information included on the NIH webpage (FAQs), "*NIH is authorized to issue Certificates only for research within the **NIH or HHS mission areas***." In addition, CoC requests for research not funded by the NIH are issued at the discretion of the NIH and will not be issued for a research program (i.e., research that involves multiple projects, studies or protocols.).

CoC Expiration date:

- NIH-issued CoCs for **non-NIH funded research** activities issued on or after January 12, 2021 **do not have an expiration date**.
- NIH-funded research: When NIH funding ends, the study will no longer be deemed issued a CoC. While CoC protections remain in perpetuity for already collected or used information, a new CoC will need to be obtained to cover any **new data collected from already enrolled participants or any new participants**.

Process

Step 1: Request for a CoC

The request for a CoC can be submitted by the Principal Investigator or other research personnel (Researcher). All requests are submitted through the NIH portal: Certificate of Confidentiality Request (nih.gov).

The request should be submitted only when the protocol has been approved by the IRB and, if the approved protocol includes a consent form or information sheet, the consent form submitted in Rascal includes language about the CoC.

Information to be provided by the Researcher through the NIH portal when requesting the CoC:

- Project details, including research title, start date, projected end date, and description.
- Question about informed consent or waiver or alteration of informed consent under 45 CFR 46 to be used
- Institution and performance site details, including institution and performance site(s) names and addresses, and institutional official* name, email address, and phone number.
- Principal Investigator name, phone number, email address, degree, position.

- Key personnel names, degrees, and positions.
- Name(s) of drugs that will be administered, route of administration, and dosage.
- If applicable, a copy of the DEA certificate(s)/registration for studies in which a controlled substance will be administered.

*For the purpose of this SOP, Institutional Officials are defined as the signatories on the Federalwide Assurance (FWA). They are authorized to act for that institution and assume on behalf of the institution the obligations imposed by the Certificate of Confidentiality as well as obligations imposed by Federal laws, regulations, and other requirements. At Columbia University, the Institutional Officials have delegated the signatory authority for CoC requests to the Associate Vice President for Human Research Protection and the Assistant Directors for IRB Management in the Human Research Protection Office (each, a HRPO designee). Contact information for each HRPO designee can be found in the HRPO Directory.

Step 2: NIH CoC system response

Following submission by the Researcher, an email will be sent to the HRPO designee's email address. The email is sent from nih-coc-coordinator@mail.nih.gov with the subject line: "Verification and submission of COC Application".

See below example:

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A request for a Certificate of Confidentiality (CoC) was submitted to NIH for the following study:

Principal Investigator: --------
Project Title: ---------

You are listed as the Institutional Official on this request. Please verify and submit the request using the following link:

_____
Please contact the investigator listed above or the NIH CoC Coordinator at NIH-CoC-Coordinator@mail.nih.gov if you have any questions.

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Step 3: HRPO confirmation process:

The following steps will be conducted by a HRPO designee:

- Upon receipt of the automated email from the NIH CoC system, an email will be sent to the PI and initiator of the request (if not initiated by the PI) to obtain the Rascal protocol number that is associated with the project title included in the verification email received from NIH.
- Following the link included in the NIH email, the information entered by the Researcher will be reviewed.

  - The name entered in the "Name of Institution" field will be confirmed or corrected: Trustees of Columbia University in the City of New York (The).
  - The information entered in the "Institution Address" field will be confirmed or corrected: Human Research Protection/IRB Office, 154 Haven Avenue, 2nd Floor, New York, NY 10032.
  - The Researcher's address as entered under the "Performance site" section will be confirmed or corrected.
  - The IRB-approved protocol will be reviewed to assess whether the information in the request is consistent with the information approved in Rascal: funding information, title, personnel, consent or waiver of consent, CoC language in the consent form or information sheet.
- If the application is accurate and there are no questions, the HRPO designee will:
  - save and forward a copy of the CoC request to the applicable Institutional Official or designee, confirming its concurrence with the IRB approved protocol and indicating that the CoC application will be submitted to the NIH. If it is not clear why the CoC is being obtained, the PI will be contacted to provide an explanation and this explanation will be included in the email sent to the applicable Institutional Official. The Vice President for Research Operations and Policy should be copied on the email if the CoC request is associated with a protocol originating from the Morningside campus.
  - confirm that the 6 assurance statements** are true and will submit the application through the NIH portal.
- If the application needs revision to be consistent with the IRB-approved protocol, the HRPO designee will:
  - edit the application accordingly
  - save and forward a copy of the CoC request to the PI and, if applicable, requestor
  - save and forward a copy of the CoC request to the applicable Institutional Official or designee, confirming its concurrence with the IRB approved protocol and indicating that the CoC application will be submitted to the NIH. If it is not clear why the CoC is being obtained, the PI will be contacted to provide an explanation and this explanation will be included in the email sent to the applicable Institutional Official. The Vice President for Research Operations and Policy should be copied on the email if the CoC request is associated with a protocol originating from the Morningside campus.
  - confirm that the 6 assurance statements** are true and will submit the application through the NIH portal
- The HRPO designee may request assistance from other HRPO staff in the congruency review but only the HRPO designee who will sign the application can edit it.

***Assurance Statements:*

- *This request is submitted by an institutional official who has signature or other authority to submit this request.*

- *This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally identifiable information and to support and defend the authority of the Certificate against legal challenges. In addition, this institution will not utilize third parties or entities (e.g., contractors, online platform vendors) to collect or store information that cannot or will not protect against the compelled disclosure of the personally identifiable information.*

- *The institution understands that research information protected by a Certificate of Confidentiality is subject to the protections and the disclosure requirements noted in 42 U.S.C 241. Any investigator or institution conducting research protected by a Certificate of Confidentiality SHALL NOT disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research without the specific consent of the individual to who the information pertains or as otherwise permitted in accordance with 42 U.S.C 241.*

- *This Certificate of Confidentiality will not be represented as an endorsement of the project by the DHHS or NIH or used to coerce individuals to participate in the research project.*

-*The research will be conducted in accordance with 45 CFR Part 46 and relevant Subparts (even if not specifically required by regulation), as well as all applicable federal, state, and local laws and regulations throughout the life of the study.*

- *All subjects will be informed that a Certificate has been issued, and they will be given a description of the protection provided by the Certificate and disclosures outside the scope of coverage of the Certificate (e.g., public health reporting as required by Federal, State, or local laws, or requirements for child or elder abuse reporting). Any research participant entering the project after expiration or termination of the Certificate will be informed that the protection afforded by the Certificate does not apply to them.*

Step 4: Response from NIH

- An email from NIH-CoC-Coordinator@email.nih.gov will confirm that the CoC application has been submitted. A copy of the request will be attached to the email.
- The request is usually approved within 1 week. An email including the pdf copy of the Certificate will be sent to the PI and HRPO designee.

Step 5: Storage of documents

- The HRPO designee will save the pdf Certificate on the HRPO network drive in the folder: P:\Certificate of Confidentiality.

- Information about the CoC will be added to the Excel spreadsheet of requested and approved certificates, filename “CoC requests submitted”, that is saved under the same folder.
- A copy of the CoC will also be attached in Rascal to the IRB protocol.

References:

https://grants.nih.gov/faqs#/certificates-of-confidentiality.htm

https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-2a

https://www.era.nih.gov/erahelp/CoC_Ext/Content/Latest_Updates.htm

https://www.era.nih.gov/erahelp/CoC_Ext/Content/External/Verify.htm