



Quick Guide: Certificate of Confidentiality (CoC) Applications for Non-Federally Funded Research

(NEW: June 29, 2020)

Overview

Effective February 28, 2020, the NIH updated its Certificate of Confidentiality (CoC) online system used to request an NIH-issued CoC **for non-NIH funded research**.

The notice of that change: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-075.html>

The key components of the change:

- The new system streamlines and simplifies the CoC request process by using self-certification statements and shortened text fields, rather than attachments; and
- The new CoC system **requires direct submission by the authorized institutional official, rather than by the investigator or another research team member.**

This document describes the process to apply for a CoC for non-federally funded research **that is NOT regulated by the FDA.**

Instructions to apply for a CoC for research that is FDA-regulated is here:
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/certificates-confidentiality>

Instructions for applying for a CoC for research that is funded by other federal agencies is outlined here: <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step2>

Frequently asked questions: <https://grants.nih.gov/faqs#/certificates-of-confidentiality.htm>

Coordination of IRB review and NIH CoC Online Application

- ✓ Please do not start your NIH CoC application until after you have submitted your webIRB application.
- ✓ Include your webIRB protocol ID in the “Project Details – Project Description” section of the NIH CoC application.
- ✓ If you have any questions about whether you should request a CoC application, please [contact OHRPP staff](#) at the time you are drafting your webIRB application.

How to Start the Online Application

Instructions: <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm#step2>

On this page: <https://grants.nih.gov/policy/humansubjects/coc/how-to-apply.htm>, select “Get your CoC”

POLICY & COMPLIANCE

Policy Topics

Human Subjects Research

Definition of Human Subjects Research

Pre and Post Award Process

How to Get a Certificate of Confidentiality?

How to Get a Certificate of Confidentiality?

Step 1: Identify the Funding Source for Your CoC Request

Step 2: Use the [Online Certificate of Confidentiality System](#) to provide the required information

Get your CoC

That will take you to the online application:

<https://public.era.nih.gov/commonsplus/public/coc/request/init.era>

Investigator Application Process

1. Identify your funding as “Non-federal”

Funding Source

1. Select Funding Source(s):

Non-federal

Next

2. Answer the questions about the regulatory status of the research. Note that the response to question 6 should be “yes” for research that has an approved waiver of documented consent or approved waiver of informed consent.

Certification

2. Does the activity meet the definition of research as defined in 42 cfr§2a.2?

Yes No

3. Does the activity involve collection or use of identifiable, sensitive information as defined by 42 U.S.C 241 (D)(4)?

Yes No

4. Will the activity be conducted in accordance with all applicable federal, state, and local laws and regulations, including, but not limited to, 45 CFR 46?

Yes No

5. Do all personnel have major responsibilities in the research project have appropriate scientific and other training?

Yes No

6. Is a waiver or alteration of informed consent under 45 CFR 46 to be used?

Yes No

If yes, has the waiver or alteration been approved by the IRB in accordance with 45 CFR 46?

Yes No

3. Provide Project Details (include webIRB protocol ID)

4. Provide Institution and Performance Site Details

5. Provide name and contact information for Institutional Official

13. Name of Institutional Official*

Alison Orkin

14. Email Address of Institutional Official*

aorkin@research.ucla.edu

15. Phone Number of Institutional Official

310-206-3969

6. Identify Principal Investigator and Other Key Personnel

7. Skip “Administration of Drugs” as it is not applicable to your research.
8. Select “Submit for Verification”

Submit for Verification

UCLA Institutional Official (OHRPP Designee)

Next steps: UCLA Institutional official will receive email from NIH to:

- review the CoC request information for accuracy,
- affirm the online Institutional Assurance Statement by checking each box, and
- submit the CoC request.

UCLA Institutional Official (OHRPP Designee)

The NIH CoC system will send an automated message to the Institution Official (“IO”), with instructions for the IO to verify and submit the CoC request.

UCLA IO will:

- open the link in the email,
- review the CoC request information for accuracy,
- make corrections if needed,
- certify that the Institutional Assurance Statement is true, complete and accurate, and
- submit the request.

CoC Issuance

The NIH typically processes the CoC request after submission within one business day of receiving the request.

The Certificate is sent via email to the IO and PI.

webIRB documentation

OHRPP staff will upload a copy of the Certificate to the “Other Regulatory Documents” tab in the protocol workspace in webIRB, where it will be available to both the study team and to IRB members and staff.