

## 1.2. CoC Login screen

### 1.2.1. User Interface

The screenshot shows the eRA (Electronic Research Administration) interface for a Certificate of Confidentiality Request. The header includes navigation links for the U.S. Department of Health & Human Services, National Institutes of Health, and Office of Extramural Research, along with Help and Contact Us links. The eRA logo and name are prominently displayed. The main heading is "Certificate of Confidentiality Request". On the right, OMB information is provided: OMB #0925-0689, OMB Approval Date: 02/26/2023, and Burden Disclosure. The "Funding Source" section prompts the user to "1. Select Funding Source(s):". A dropdown menu is open, showing "NIH" as the selected option, with other options including "Other DHHS Agency", "Other Federal Agency", and "Non-Federal". A "Next" button is located below the dropdown.

U.S. Department of Health & Human Services | NIH | National Institutes of Health | Office of Extramural Research | Help | Contact Us

**eRA** Electronic Research Administration  
A program of the National Institutes of Health

### Certificate of Confidentiality Request

OMB #0925-0689  
OMB Approval Date: 02/26/2023  
Burden Disclosure

**Funding Source**  
1. Select Funding Source(s):

NIH

- NIH
- Other DHHS Agency
- Other Federal Agency
- Non-Federal

Next

## 1.3. Certification

### 1.3.1. User Interface

U.S. Department of Health & Human Services

NIH

National Institutes of Health

Office of Extramural Research

Help

Contact Us

ERA

Electronic Research Administration

A program of the National Institutes of Health

Certificate of Confidentiality Request

OMB #0925-0689

OMB Approval Date: 02/26/2023

Burden Disclosure

Funding Source

1. Select Funding Source(s):

Other DHHS agency

Select DHHS Agency:

Other

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

Next

© 2020 NIH. All Rights Reserved. | Screen Rendered: 01/16/2020 04:54:57 EST | COC0001@9835 | Version: 1.00.00

[Help](#) | [Contact Us](#) | [Privacy Notice](#) | [Manage User Preferences](#) | [Accessibility](#) | [Disclaimer](#)

[Office of Extramural Research](#) | [National Institutes of Health](#) | [U.S. Department of Health and Human Services](#) |

NIH...Turning Discovery Into Health®

## 1.4. Research & Performance Site details


### 1.4.1. User Interface

U.S. Department of Health & Human Services

NIH National Institutes of Health

Office of Extramural Research

Help Contact Us

 **Electronic Research Administration**  
A program of the National Institutes of Health

Certificate of Confidentiality Request

OMB #0925-0689  
OMB Approval Date: 02/28/2023  
Burden Disclosure

7. Research Project Title

8. Project Start Date

9. Project End Date

10. Project Description

Institution and Performance Site Details

11. Name of Institution

12. Institution Address

Street Address

City

State

Zip Code

13. Name of Institutional Official

14. Email Address of Institutional Official

15. Phone Number of Institutional Official

16. Performance Site Name

17. Performance Site Address

Street Address

City

State

Zip Code

Principal Investigator and Other Key Personnel

18. Name of Principal Investigator (PI)

First Name

Middle Name

Last Name

19. PI Phone

20. PI Email

21. PI Degree

22. PI Current Position

23. Other Key Personnel Name

First Name

Middle Name

Last Name

Other Key Personnel Degree

Other Key Personnel Current Position

Add Key Personnel

Administration of Drugs

24. List any drugs that will be administered in this study, including method of administration and dosage (e.g. Phenobarbital 50 mg 2 times daily)

Name of Drug

Method of Administration

Dosage

Add Drug

25. Are all individuals administering drugs authorized to do so by Federal and State law? ☐ Yes ☐ No

Verify

## **1.5. For instructional purposes only**

### **1.5.1. User Interface**

#### **Instructions Only**

After the user completes questions 1 – 26 and add the BND Form 223 then they will click on the Verify for button. This will send an email to the institutional official email address that was entered on the form and will contain an encrypted link. When the institutional official clicks on the link they will be re-directed to the CoC form to review and complete the Assurance Statement questions at which time they will have a button to submit.

Once the CoC request form is submitted a success screen will be displayed with a CoC Request ID #. There should be onscreen language instructing user to keep the request ID # for their reference.

After submission an automatic email should be generated and sent to the PI, Institutional Official. This email should include a PDF copy of the application.

## 1.6. Assurance

### 1.6.1. User Interface

OMB #0925-0689  
OMB Approval Date: 02/28/2023  
Burden Disclosure: 0

#### Assurance Statement

Check the box next to the statement below if the statement is true:

- ☐ 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.
- ☐ 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 and 42 CFR § 2a. 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 and 42 CFR § 2a.
- ☐ 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 institution and personnel involved in the conduct of the research will comply with the informed consent requirements of the applicable Federal regulations, including 45 CFR Part 46.
- ☐ 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 that are 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.

Submit

## 1.7. Burden Disclosure

When the Burden Disclosure link is selected on any system screen, the Burden Disclosure pop-up shown in 1.7.1 will appear on the screen.

### 1.7.1. User Interface

Burden Disclosure Statement

Public reporting burden for this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

**An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.**

Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0689).

Do not return the completed form to this address.

OK