

1.2. CoC Login screen

1.2.1. User Interface

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

Certificate of Confidentiality Request

Funding Source

1. Select Funding Source(s):

NIH

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

→ Next

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

1.3. Certification

1.3.1. User Interface

The screenshot shows the 'Certificate of Confidentiality Request' form in the ERA system. The header includes the U.S. Department of Health & Human Services, NIH, and Office of Extramural Research logos, along with a 'Help' and 'Contact Us' link. The ERA logo and name are also present. The form title is 'Certificate of Confidentiality Request'. In the top right corner, OMB #0925-0689, OMB Approval Date: 02/28/2023, and Burden Disclosure are listed. The form contains several sections: 'Funding Source' with two dropdown menus for 'Select Funding Source(s)' and 'Select DHHS Agency'; 'Certification' with six numbered questions, each with radio button options for 'Yes' and 'No'. Question 6 includes a sub-question about IRB approval. A 'Next' button is located at the bottom left. A footer contains copyright information, screen rendering details, and navigation links for Help, Contact Us, Privacy Notice, Manage User Preferences, Accessibility, and Disclaimer. It also lists the Office of Extramural Research, NIH, and U.S. Department of Health and Human Services, along with the NIH slogan 'NIH...Turning Discovery Into Health®'.

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ERA Electronic Research Administration
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Certificate of Confidentiality Request

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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](#)

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[Help](#) | [Contact Us](#) | [Privacy Notice](#) | [Manage User Preferences](#) | [Accessibility](#) | [Disclaimer](#)
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1.4. Research & Performance Site details

1.4.1. User Interface

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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
<input type="text"/>	<input type="text"/>	<input type="text"/>

[+ 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

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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

