1.0 CoC Screens

1.1 CoC User Interface, Question 1

Note: You must complete the CoC request in one session, as you will not be able to save and return at a later time.

Certificate of Confidentiality Request ⓘ

• Required Field

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

🖶 Print

Funding Source

1. Select Funding Source(s):

National Institutes of Health ⬦
National Institutes of Health
Other DHHS agency
Other federal agency
Non-federal

➜ Next

ⓘ Help   🛡 Privacy Notice   NIH - Office of Extramural Research   Screen Rendered: 12/06/2021 10:26:53 AM EST |
📞 Contact Us   ♿ Accessibility   ⚓ U.S. Department of Health and Human Services   COC0001@6242
                  ⚠ Disclaimer

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1.2 Burden Statement

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

1.3 User Interface: Certification, Questions 2-6

eRA Electronic Research Administration | **NIH** National Institutes of Health
Office of Extramural Research

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Certificate of Confidentiality Request ❓

* Required Field

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

🖨 Print

Funding Source

1. Select Funding Source(s):

| Non-federal | ⇕ |

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 with 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

➜ Next

❓ Help
📞 Contact Us

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1.3 User Interface, Certification Questions 7-16, Research, Institution, and Performance Sites

Project Details

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*

Country*

Zip Code

13. Name of Institutional Official*

14. Email Address of Institutional Official*

15. Phone Number of Institutional Official

Peformance Site and Addresses

16.   Performance Site Name*

17. **Performance Site Address***

Street Address line 2

Street address line 3

City*

Country*

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 Person to Receive CoC Communications and Certificate: (New)

First Name   Last Name   Email Address of Other Person

24.   **Other Key Personnel**

First Name   Middle Name   Last Name

Other Key Personnel Degree

Other Key Personnel Current Position

Administration of Drugs

25. 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

26. Are all individuals administering drugs authorized to do so by Federal and State Law?

○ **Yes**　　　　○ **No**

1.4 For Instructional Purposes Only

1.41 User Interface

Instructions Only

After the user completes questions 1-26, she/he will submit the CoC request.

- The user will click on the Submit for Verification button. Once the button is clicked, a message appears: Confirmation Needed. The user will click Yes.
- If any of the drugs being administered are a controlled substance, the user will click on the Upload and Submit for Verification button. The screen displays the following instructions: Please submit all documents as a single PDF. If more than one Drug Enforcement Certification of Registration will be submitted, please merge documents into a single file prior to submission. Once the button is clicked, a message appears: Confirmation Needed. The user will click: Yes Proceed with Upload and will then browse to select the upload the BND form 223.

The browser will display a success message:

> ☑ **Success:** request submitted for verification successfully

If there are errors on the form, the form is not submitted and the user can scroll through the form to see the errors in red and correct:

> ▼ 🌐 Institution and Performance Site Details
>
> ❌ There are errors in this Section
>
> 11. Name of Institution*
>
> [|]
>
> This field is required

Once corrected, the user will repeat the steps above to submit the CoC request.

The request will trigger the system to send an email to the Institutional Official (IO) email addresses with a PDF copy of the CoC request. The email will contain an encrypted link, with the following information: Verification and submission is needed for the following CoC application. When the Institutional Official clicks on the link, she/he will be redirected to the CoC form to review and verify the information is correct. The IO will make corrections if necessary. At the bottom of the request is a section titled Assurance Statement

1.42 User Interface

Instructions Only

IO Assurance Statement questions

Assurance Statement

☐ *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 Sect. 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 whom the information pertains or as otherwise permitted in accordance with 42 U.S.C 241 and 42 CFR Sect. 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.

The IO will read each institutional assurance statement and mark each checkbox if she/he agrees that the statement is true. When all checkboxes are marked, the IO will click on the submit button.
The IO, PI, and other person will receive a confirmation email from the system, which includes a PDF attachment of all submitted information.   NEW

1.5 Burden Disclosure

When the Burden Disclosure link is selected on any system screen, the Burden Disclsoure pop-up shown in section 1.5.1 will appear on the screen.

1.5.1 User Interface

Burden Disclosure Statement   ✕

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OK