



1.0 CoC Screens




1.1 CoC User Interface, Question 1



Commons



NIH National Institutes of Health
Office of Extramural Research




Certificate of Confidentiality |

Certificate of Confidentiality Request

* Required Field

OMB #0925-0689
OMB Expiry Date: 04/30/2025
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



eRA - End-to-End Grants Management Solutions

NIH Grants and Funding
National Institutes of Health
HHS - U.S. Dept. of Health and Human Services

Resources

Privacy Notice | Accessibility | Disclaimer
HHS Vulnerability Disclosure
10/09/2024 10:25:26 AM EST

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



Certificate of Confidentiality Request ?

* Required Field

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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 →](#)

1.3 User Interface: Certification, Questions 7-10, Project Details


Project Details

7. Research Project Title *

8. Project Start Date *


9. Project End Date *

10. Project Description *

920 characters remaining

1.3 User Interface: Certification, Questions 11-15, Institution and performance Site Details

▼  Institution and Performance Site Details

11. Name of Institution *

12. Institution Address

Street Address *

City *

Country *

State *

Zip Code

13. Name of Institutional Official *

14. Email Address of Institutional Official *

15. Phone Number of Institutional Official

Performance Site & Address

[Add Performance Site & Address](#)

1.3 User Interface: Certification, Questions 18-24, Principal Investigator and Other Key Personnel



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

First Name

Last Name

Email Address

24. Other Key Personnel

Add Key Personnel

1.3 User Interface: Certification, Question 25-27, Administration of Drugs and Submit Button

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)

Add Drug

Drug Name	Method of Administration	Dosage	Action
Mandrake Root	Oral	5 drops daily	<input type="button" value="Edit"/> <input type="button" value="X Delete"/>

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

Yes No

27. If controlled drugs are used, include a copy of the Drug Enforcement Certification of Registration (BND Form 223) under which the research project will be conducted.

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.

Attachment

Drop files here to upload, or [browse](#).
Max File Count: 1 Accepted File Types: PDF Max File Size: 6MB

Submit for Verification

1.4 For Instructional Purposes Only: User Interface

After the user completes questions 1-25 and clicks the Submit for Verification button, the Confirmation Needed dialog pops up. The user will click Yes.

Confirmation Needed ✕


By submitting this request for verification you will no longer have access to the request and final submission will be required by the designated Institutional Official. Please confirm that all information is correct before continuing.

Cancel

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. Once the request to apply for a CoC has been completed and submitted, it will trigger the system to send an automated email to the email address entered for the Institutional Official (IO).

The IO will need to click the link in the Verification and Submission email, and the browser will open to a page that contains the original CoC request. The IO needs to review the information in the request and verify it is correct. At the bottom of the request, a section titled Assurance Statement appears. The IO needs to review and select all checkboxes and click the Submit button.

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. 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 whom 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 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 individuals from whom informed consent will be obtained 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). Individuals who give informed consent and continue study participation after the expiration or termination of the Certificate will be informed that the protections of the Certificate may not cover any new data that is collected after the expiration or termination. Any individual entering the project after expiration or termination of the Certificate from whom informed consent will be obtained will be informed that the protection afforded by the Certificate does not apply to them.

Submit

A pop-up confirmation message appears. The IO needs to click the I Certify button to verify that the statements are true and complete the submission. Once it is fully submitted, both the IO and the PI and other persons listed in the application will receive a confirmation email.

Confirmation Needed ✕

By signing this application, I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. (U.S. Code, Title 18, Section 1001)