Certificates of Confidentiality (CoC) External User Guide

January 2, 2025

NOTE: This user guide is an identical PDF version of the online help.

Contact Us

Additional Help Needed? Please contact the eRA Service Desk (https://www.era.nih.gov/need-help).

Toll-free: 1-866-504-9552; **Phone:** 301-402-7469

Hours: Mon-Fri, 7:00 a.m. to 8:00 p.m. Eastern Time

Feedback on the user guide? Please email the eRA Communications Office (era-communications@mail.nih.gov).

Disclaimer STATEMENT

No data shown in illustrations represents any real account, project, or individual. Any resemblance to actual accounts, projects, or individuals is purely coincidental.

Table of Contents

Latest Updates

Updates and new features in Certificates of Confidentiality:

December 12, 2024

The CoC online help has been updated with improved organization and streamlined information on all topics.

October 10, 2024

Updated Sections When Reviewing CoC Request

The Certificate Management and CoC Request screens display updated sections and enhanced functionality. See the associated help topics for more information.

December 4, 2023

New Look and Feel for Online Help and User Guide

- The online help and user guide have been updated to the new look and feel, consistent with the new look and feel of eRA Modules. There are no changes to the organization or function of the help topics.
- New Confirmation dialog box during verification process.

Welcome to Certificates of Confidentiality (CoC) for External Users Online Help

This help system provides online information about the functionality of the Certificates of Confidentiality (CoC) for External Users module. This topic illustrates the use of this online help system.

Help Icon in Module Leads to Online Help

Access online help by clicking the Help icon, which is a blue circle containing a white question mark, from any screen within the Certificates of Confidentiality (CoC) for External Users module.

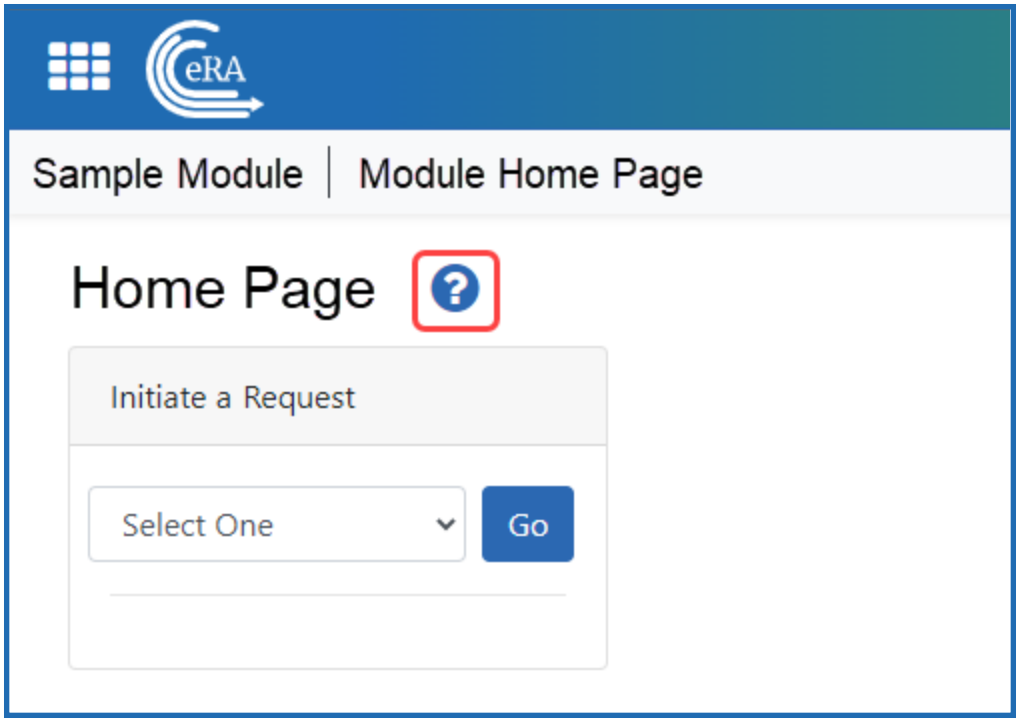
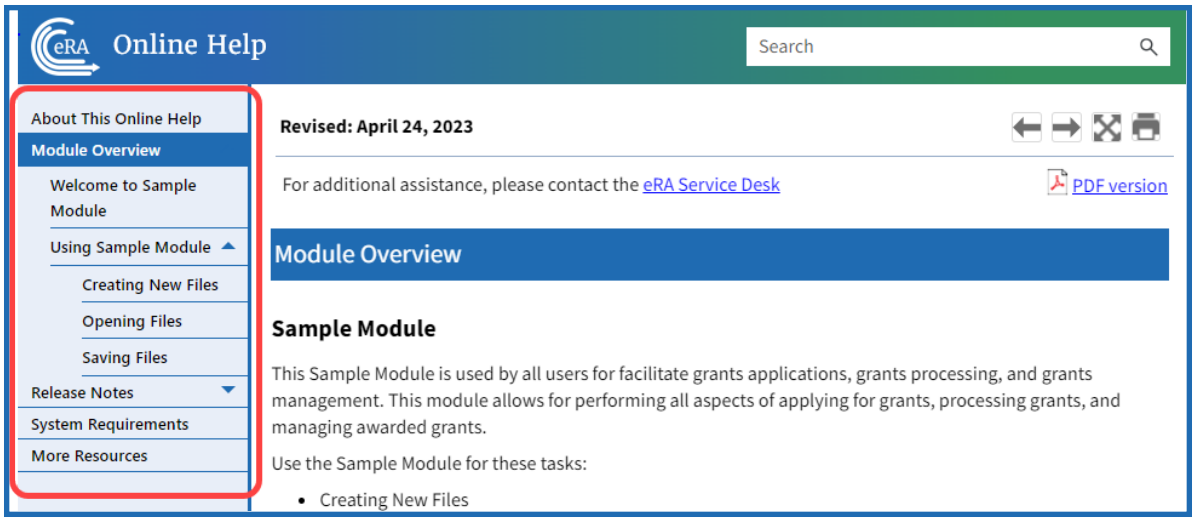
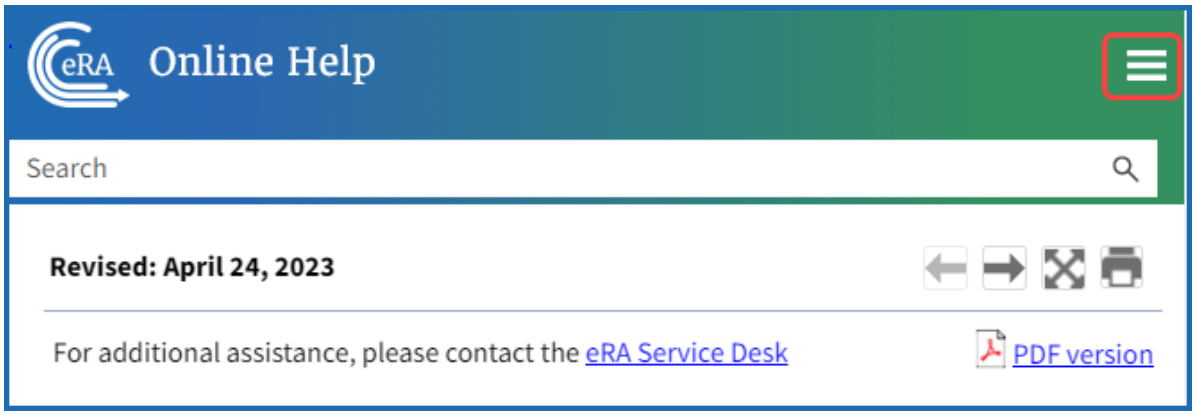


Table of Contents Pane

Use the table of contents pane at the left of a help system to navigate through topics. If a topic name has a down arrow next to it, click it to reveal subheadings.

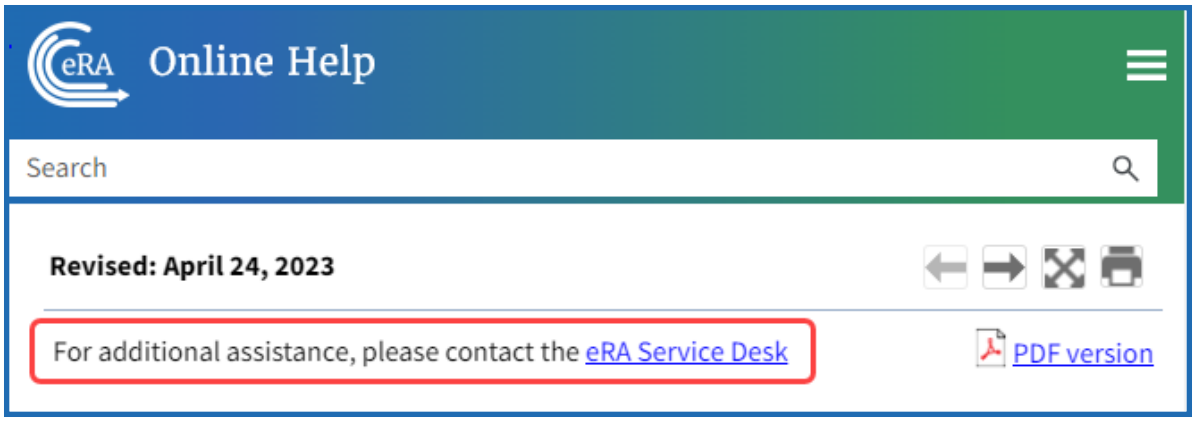


When the browser window is narrow, the table of contents pane is hidden. To view a hidden table of contents, click the three-horizontal-line icon at right top to toggle the table of contents between onscreen and hidden.



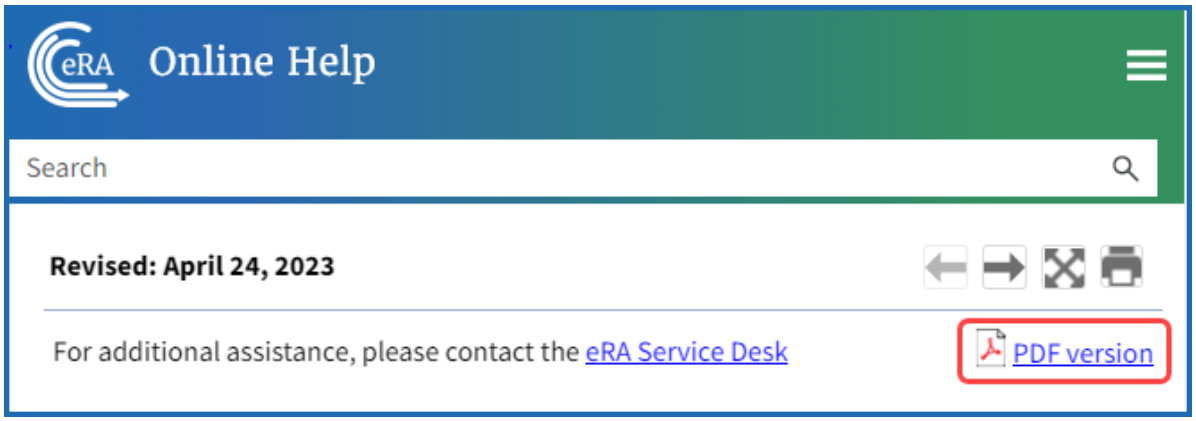
Contacting the eRA Service Desk

Online help pages contain a link to the eRA Service Desk at top. Contact the service desk for help with error messages, system questions, and help solving problems in eRA modules. The link is located above the page title on all online help pages.



Viewing all Online Help in a PDF Version

All online help is available in PDF format. The PDF contains identical information as the online help. The PDF is linked at the top right of every online help page with a link named PDF Version.



Showing Hidden Text or Images

You might encounter dropdown text or toggled images in online help. Sometimes, to save screen space and let you focus on the information important to you, online help hides text or images behind linked text.

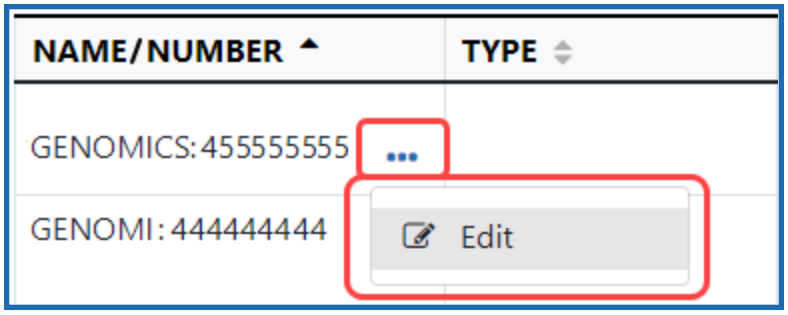
For instance, click the following heading to see the hidden dropdown text showing steps of a procedure:

Creating a New File

1. Click the New button.

2. Enter a name for the file.
3. Click the Save button.

Images can also be toggled. In the example below, click the words "Access the Edit action by clicking the three-dot ellipsis icon" to see the hidden image.



Tools for Navigating Topics, Showing Hidden Material, and Printing

Click the left and right arrow icons at top right to go to the previous or next topic in the table of contents:

Click the print icon, below, to print:

Click the expand icon, below, to expand all material that is hidden in a topic.

Click the collapse icon, below, to collapse all material. The collapse icon appears only after clicking the expand icon.

Search Field

Type text into the search field to find all topics that contain matching text. Then either press the Enter key or click the magnifying glass icon to search.

If you type multiple words in the search field, the search assumes an 'AND' between each word. For example, if you search for ***system requirements***, the search does this: Find all topics that contain both ***system*** **AND** ***requirements***, not necessarily adjacent to each other in text. It counts variations of words as a match; for example; ***require*** or ***required*** are deemed to be matches for ***requirements***.

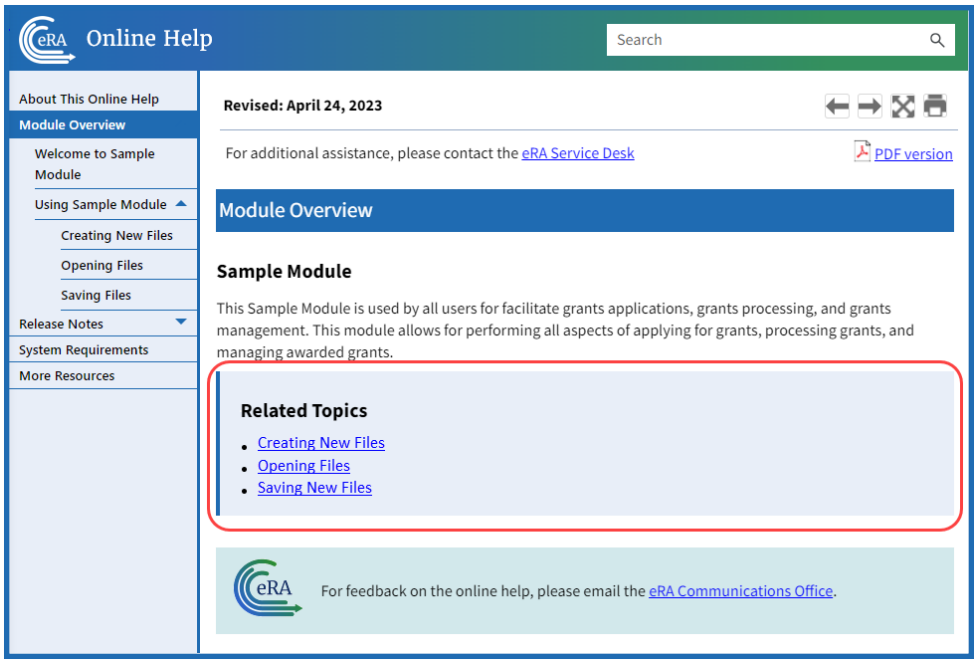
If you want only topics that contain an exact phrase, enclose it in double quotation marks like this:

"system requirements"

The search field searches ONLY the current help system for the Certificates of Confidentiality (CoC) for External Users module. To search all help systems, go to the eRA website and use the search field at the top of the page.

Finding Related Topics

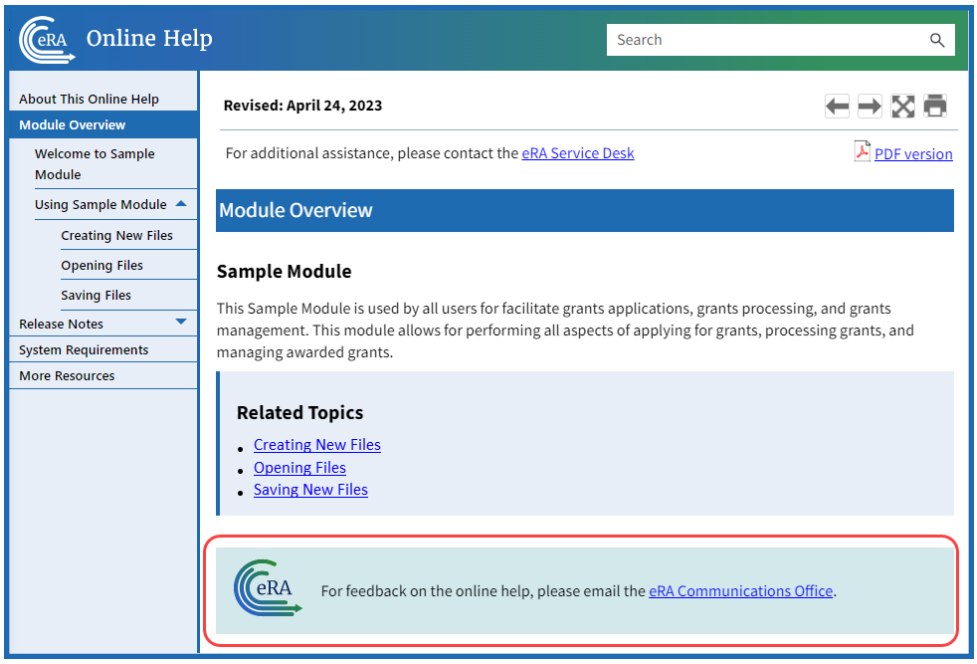
Most topics contain a Related Topics section, which show links to a list of topics that are related to the one you are viewing.



Providing Feedback on the Online Help or PDF

All topics contain a green feedback footer with an email link to the eRA Communications Office, which creates and updates online help and PDFs. The eRA Communication Office does not provide technical support but is happy to accept feedback on how we might make the online help better meet your needs.

For tech support, contact the eRA Service Desk instead of the Communication Office.


Online Help
Search
About This Online Help
Module Overview
Welcome to Sample Module
Using Sample Module
Creating New Files
Opening Files
Saving Files
Release Notes
System Requirements
More Resources
Revised: April 24, 2023
For additional assistance, please contact the eRA Service Desk
PDF version
Module Overview
Sample Module
This Sample Module is used by all users for facilitate grants applications, grants processing, and grants management. This module allows for performing all aspects of applying for grants, processing grants, and managing awarded grants.
Related Topics
Creating New Files
Opening Files
Saving New Files
For feedback on the online help, please email the eRA Communications Office.

Certificates of Confidentiality Frequently Asked Questions (FAQs)

Researchers working on eligible human subjects research projects can use the Online Certificate of Confidentiality System to request a Certificate of Confidentiality (CoC) from NIH. A series of questions at the start of the system determines initial eligibility. To learn about Certificates of Confidentiality, see the NIH Certificates of Confidentiality website, CoCs for Research Not Funded by NIH, including the section, Limitations on Issuance of CoCs for Non-NIH Funded Research, and FAQs, and the information below.

Below is an abbreviated FAQ on Certificates of Confidentiality. For a *comprehensive* policy FAQ, see https://grants.nih.gov/faqs#/certificates-of-confidentiality.htm.

What is a Certificate of Confidentiality?

A Certificate of Confidentiality (Certificate) protects the privacy of research participants enrolled in biomedical, behavioral, clinical or other types of health-related research that collect or use identifiable, sensitive information. With limited exceptions, researchers may not disclose names or any information, documents or biospecimens containing identifiable, sensitive information. The Certificate prohibits disclosure in response to legal demands, such as a subpoena.

How do I start a Certificate of Confidentiality request?

See *Starting a Certificate of Confidentiality Request*.

IMPORTANT: You must know your funding source to determine if and how you obtain a CoC.

Where do I access the Online Certificate of Confidentiality System?

- Go to https://public.era.nih.gov/commonsplus/public/coc/request/init.era

  OR

- Click the **Access NIH Certificate of Confidentiality System** link from the Requesting a Certificate of Confidentiality for non-NIH Funded Research page.

Where can I get help on the eligibility questions?

See *Details on Certificate of Confidentiality Eligibility Questions*.

How do I know my request was submitted?

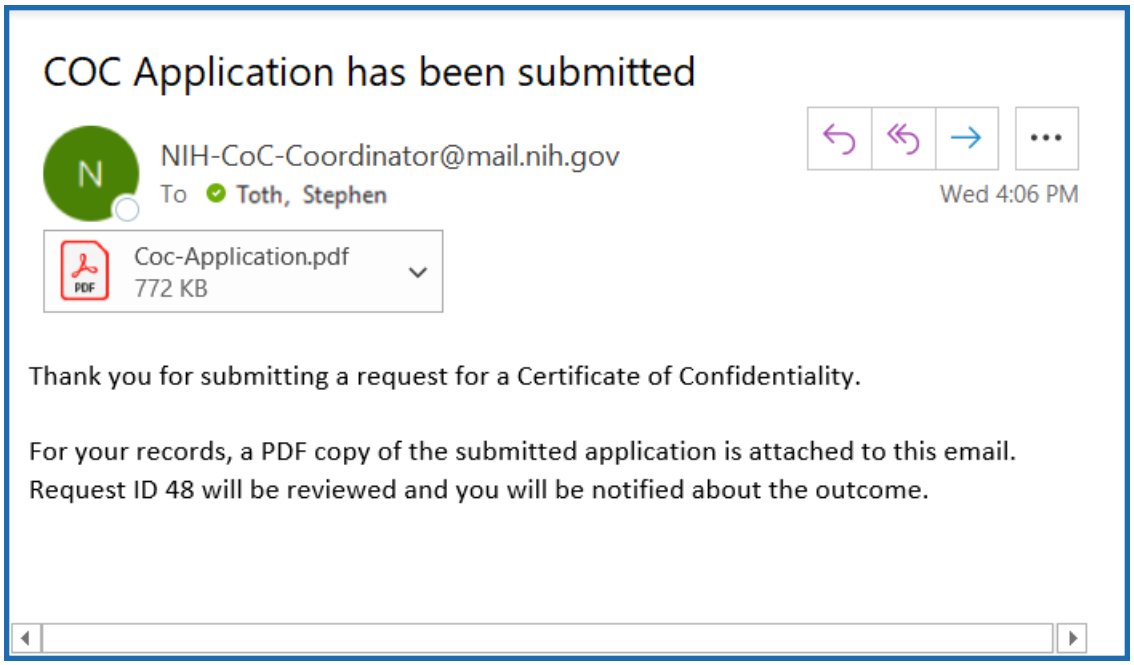
When you first submit the request, you see a message in the browser that it was submitted for verification:

Figure 1: Successful submission message

After the initial CoC request is submitted for verification, the institutional official (IO) receives an email titled "Verification and submission..." from *NIH-CoC-Coordinator@mail.nih.gov* with a link. The IO needs to click the link in the email, which opens a browser page to the submitted request. The IO needs to review the CoC request, correct any data fields as needed, and then affirm the institutional assurance statements. Once the IO affirms these statements and submits the request to NIH, the IO will receive a success message in the browser:

Figure 2: Successful IO submission message

In a few minutes, the IO, PI and the other person to receive CoC communications will receive a confirmation email:



Also see *Next Steps* for what happens after a request is received by NIH.

What if I Experience Problems?

If you have technical problems with the CoC system, contact the eRA Service Desk or email helpdesk@od.nih.gov.

If you have process or policy-related questions about a CoC request, contact NIH-CoC-Coordinator@mail.nih.gov.

TIP: eRA recommends using Internet Explorer, Mozilla Firefox, or Google Chrome browsers (Windows) or Safari (Mac).

What Are My Responsibilities if I have a CoC?

To learn about investigator and institutional responsibilities associated with a CoC, go to Investigator and Institutional CoC Responsibilities. Additional information can also be found in the CoC FAQs. Scroll to the following questions under *A. General Information about Certificates*:

- What are the recipient's responsibilities under a Certificate?
- What is the researcher's responsibility to inform participants of a Certificate?

- Is it possible to share information protected by a Certificate with other researchers? Can such information be shared openly (e.g., on a public website without any requirements for download)?

Also, see NIH's policy for Issuing Certificates of Confidentiality.

Other Sources of Information

- Certificates of Confidentiality (CoC) - Human Subjects
- Definition of Human Subjects Research

Overview of Requesting a Certificate of Confidentiality

This section provides a very general overview of steps to use the Online Certificate of Confidentiality (CoC) System to request a CoC for non-NIH funded research. To learn more about CoCs and this system, see *Certificates of Confidentiality Frequently Asked Questions (FAQs)* on page 13.

General steps to use the Online Certificate of Confidentiality System to request a CoC (for detailed steps, click the linked topics below):

1. First, specify the funding source for your research. Some federal agencies have their own CoC processes and indicating one of those agencies as a source of funding directs you to more information for CoCs for those agencies. If the funding source is covered by the Online Certificate of Confidentiality System, continue to the eligibility questions.

   See *Starting a Certificate of Confidentiality Request* on page 19

2. Next, answer a set of eligibility questions. The eligibility questions are based on applicable U.S. law and regulations.

   See *Details on Certificate of Confidentiality Eligibility Questions* on page 23.

3. If the eligibility answers indicate your research is eligible for a CoC, you are shown the next screen, where you enter the details of your research such as research title, institution, institutional official, principal investigator, physical and email addresses, etc. You also specify drugs administered for the study and attach a DEA certificate for any controlled substances.

   See *Requesting a Certificate of Confidentiality* on page 27.

4. Then you submit the CoC request for verification, after which an email is automatically sent to the institutional official's email address with a link to verify the request. The email is from *NIH-CoC-Coordinator@mail.nih.gov*.

   See *Requesting a Certificate of Confidentiality* on page 27.

5. Finally, the institutional official clicks the link in the email, which opens all the data from the original request in a web page. The institutional official reviews the data, makes any necessary corrections, attests to the institutional assurance statements, and then submits the CoC request to NIH. Both the institutional official and principal investigator receive a confirmation email from NIH.

   See *Verifying a Certificate of Confidentiality* on page 42.

NOTE: Using the Online Certificate of Confidentiality System is NOT necessary for NIH-funded projects, as applicable NIH-funded research studies are automatically deemed issued a CoC. See CoCs for NIH-funded Research.

Starting a Certificate of Confidentiality Request

Use the Online Certificate of Confidentiality System to request a Certificate of Confidentiality (CoC), issued by NIH. First, determine your eligibility by answering questions. Then, if the answers indicate eligibility, enter information about your research and your institution to complete the request.

A Certificate of Confidentiality request must be completed in its entirety in one Internet browser session; you cannot save and finish or revise it later. Because of this, you might want to review the information listed under CoCs for Research Not Funded by NIH and Limitations on Issuance of CoCs for Non-NIH Funded Research before you begin.

NOTE: At any time during the CoC request process, click the **Print** button at the right of the page to display a printer-friendly form with all questions and answers entered thus far. The browser's print dialog also opens.

To start the CoC request:

1. Go to the Requesting a Certificate of Confidentiality for Non-NIH Funded Research page.
2. Under the **To Request Non-NIH Funded CoCs** heading, click the **Access NIH Certificate of Confidentiality System** link to open the Certificate of Confidentiality Request system.

Figure 3: CoC Request screen showing Funding Source question

3. Select the source of funding from **Select Funding Source** dropdown and click the **Next** button.

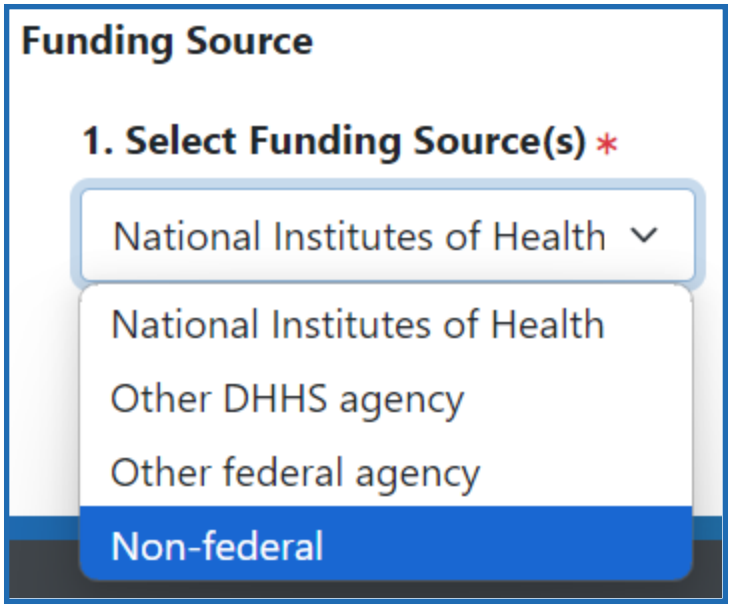


Figure 4: Select Funding Source dropdown options

4. If you select this option:

   - **National Institutes of Health**: Your CoC request stops. Research funded by NIH that collects or uses identifiable, sensitive information and was ongoing on or after December 13, 2016 is covered by the NIH CoC Policy and is automatically deemed issued a Certificate of Confidentiality. Do not submit a CoC request through this system. See CoCs for NIH-funded Research for additional information.
   - **Other DHHS agency**: Select an option from the **Select DHHS Agency** that appears, which lists some Department of Health and Human Services agencies.
     - For all selections listed, except **Other**, your CoC request stops. You will see a window on NIH's website that directs you to agency-specific

directions.

- Choose **Other** if your funding agency is within HHS and is not listed in the drop-down list. Choosing **Other** continues to eligibility questions.

- **Other federal agency**: Select an option from the **Select Federal Agency** that appears, which lists **DOJ** (Department of Justice) and **Other**.
  - If your funding agency is DOJ, your request stops. You will see a window that directs you to agency-specific directions on NIH's website.
  - Choose **Other** if your funding agency is a non-HHS federal agency other than DOJ. Choosing **Other** continues to eligibility questions.
- **Non-federal**: Indicates you are doing research not funded by any federal department or agency.
  - Choosing **Non-federal** continues to eligibility questions. Requestors who have applied but not received funding from NIH may designate their request as non-Federal.

NOTE: You do not need to apply for a CoC if your research project will not begin until after award.

5. Answer all eligibility questions. These appear only if you choose one of the following:
   - **Other DHHS agency --> Other**
   - **Other federal agency --> Other**
   - **Non-federal**

   For specific details on these questions, see *Details on Certificate of Confidentiality Questions*.
6. Click the **Next** button, which takes you to the intake form, where you enter information about your research. See *Requesting a Certificate of Confidentiality* for details on the next screen.

NOTE: Answering **No** on question 2, 3, 4, or 5 disqualifies the research project from proceeding with the CoC request. Answering **Yes** on question 6, and **No** on the subsequent question that appears under question 6 also disqualifies. Contact NIH-CoC-Coordinator@mail.nih.gov with questions related to eligibility for a CoC.

Details on Certificate of Confidentiality Eligibility Questions

The Online Certificate of Confidentiality System includes questions to determine if a research project may be eligible to receive a Certificate of Confidentiality (CoC) issued by NIH. The questions asked are partly derived from United States Code (laws) or the Code of Federal Regulations (explanations of how agencies carry out laws).

NOTE:
- Non-federally-funded research might also qualify to receive a CoC from NIH.
- The NIH Guide Notice for NIH Policy for Issuing Certificates of Confidentiality discusses identifiable, sensitive information, as well as human subject research, in detail.

After selecting a funding source and clicking **Next**, the Certification questions display.

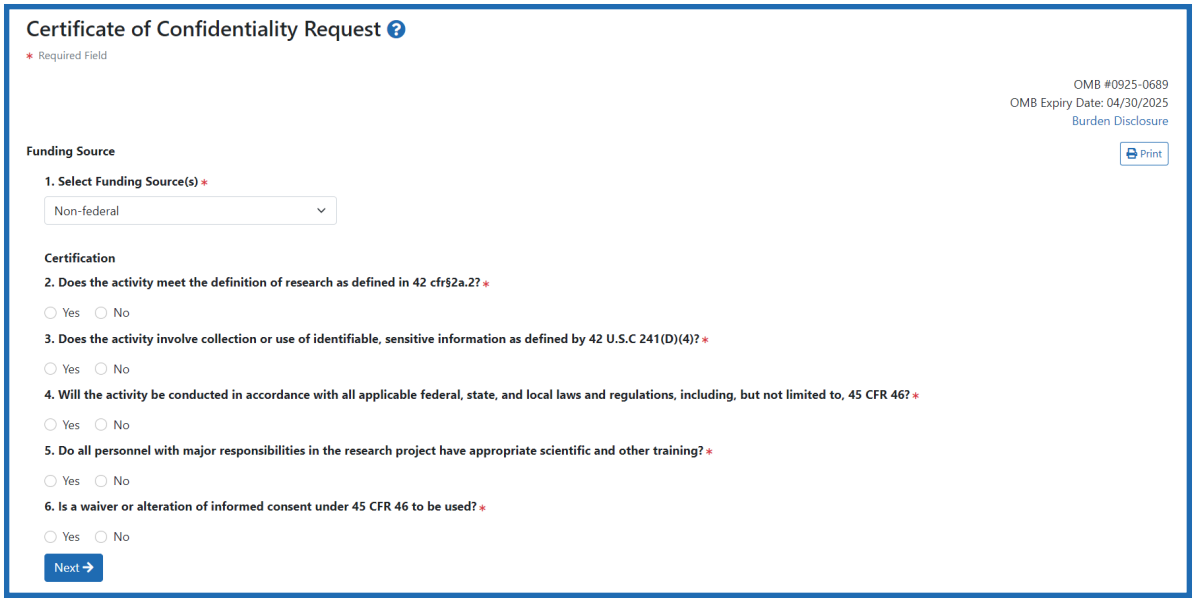


Figure 5: Certification questions screen

See the questions below to find out more about each question:

1. Select Funding Source(s) / Select Federal Agency

The only answers to this question that will continue the Online CoC request are **Other DHHS agency --> Other**, **Other federal agency --> Other**, or **Non-federal**.

DO NOT use the Online Certificate of Confidentiality System if your research is funded by the NIH. NIH-funded research studies that are within the scope of the NIH CoC Policy are automatically deemed issued a CoC

In addition, the Online Certificate of Confidentiality System is not the method used to request a CoC for all federal agencies. If your research is funded by any of the following, the Online Certificate of Confidentiality System will display an alert message that directs you to CoC information for the respective agency.

HHS agencies and federal departments that have their own process for issuing a Certificate of Confidentiality:

- AHRQ - Agency for Healthcare Research & Quality
- CDC - Centers for Disease Control and Prevention
- FDA - Food and Drug Administration
- HRSA - Health Resources and Services Administration
- IHS - Indian Health Service
- SAMHSA - Substance Abuse and Mental Health Services Administration
- BARDA – Biomedical Advanced Research and Development Authority
- DOJ - Department of Justice

For research funded by agencies listed above, see the non-NIH HHS Agencies CoC Coordinators and Contact information on the NIH website for CoC Coordinator contact information at the applicable funding agency.

NOTE: BARDA funded research studies with awards issued prior to July 17, 2023, are eligible to request a CoC from NIH.

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

Clicking **Yes** on this question is consistent with eligibility for a CoC.

This refers to the Title 42 of the Code of Federal Regulations (Public Health).

The relevant definition from the code is:

Research means systematic study directed toward new or fuller knowledge and understanding of the subject studied. The term includes, but is not limited to, behavioral science studies, surveys, evaluations, and clinical investigations.

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

Clicking **Yes** on this question is consistent with eligibility for a CoC.

This refers to Title 42 of the United States Code (Public Health and Welfare).

The relevant definition from the code is:

> (A) An individual is identified; or
>
> (B) There is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, the request, and other available data sources could be used to deduce the identity of an individual

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?

Clicking **Yes** on this question is consistent with eligibility for a CoC.

This question asks you to verify that the research activity complies with all federal, state, and local laws and regulations, including Title 45 (Public Welfare) Part 46 (Protection of Human Subjects) of the Code of Federal Regulations, located at the following website:

https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46

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

Clicking **Yes** on this question is consistent with eligibility for a CoC.

This question ascertains if personnel who have major research responsibilities also possess the training necessary to perform the research.

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

Clicking **No** on this question is consistent with eligibility for a CoC. However, clicking **Yes** results in a follow up question to further determine eligibility.

This question asks if the IRB waived or altered the requirement to obtain the informed consent (i.e., you are not obtaining informed consent or parental permission), as

described in Title 45 (Public Welfare) Part 46 (Protection of Human Subjects) of the Code of Federal Regulations. If you are obtaining written or oral informed consent from participants or their legally authorized representatives, answer **No** to this question.

See section §46.116 for a description of informed consent.

NOTE: Do not answer YES to this question if the IRB approved the plan for the investigator to obtain information or specimens for the purpose of screening, recruiting, or determining eligibility of prospective participants without informed consent of the participant or participants legally authorized representative under 45 CFR 46.116(g) OR if the IRB waived the requirement to obtain a signed informed consent form under 45 CFR 46.117(c) (i.e., the IRB waived documentation of informed consent).

If you *are* using a waiver or alteration, answer **Yes** and another question appears.

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

Clicking **Yes** on this question is consistent with eligibility for a CoC. Clicking **Yes** means the waiver or alteration of informed consent has been approved by the reviewing Institutional Review Board (IRB).

This question appears only if you answered **Yes** to question 6. Details on obtaining a waiver or alteration of consent are contained in Title 45 (Public Welfare) Part 46 (Protection of Human Subjects) of the Code of Federal Regulations, section §46.116.

US Code §46.116, sections (e) and (f), titled, *Waiver or alteration of consent in research involving public benefit and service programs conducted by or subject to the approval of state or local officials*, and *General waiver or alteration of consent*, provide details on waiving the requirement to obtain informed consent or altering or omitting some or all of the elements of informed consent, including IRB findings and approval.

See section §46.116 section (e) and section §46.116 section (f):

After answering all questions, click the **Next** button to continue.

Requesting a Certificate of Confidentiality

If your answers to eligibility questions determine that your research is eligible for a Certificate of Confidentiality (CoC), you will see a data entry screen after answering eligibility questions and clicking the Next button. Here, you enter the details of your research project, contact info, and drug administration details.

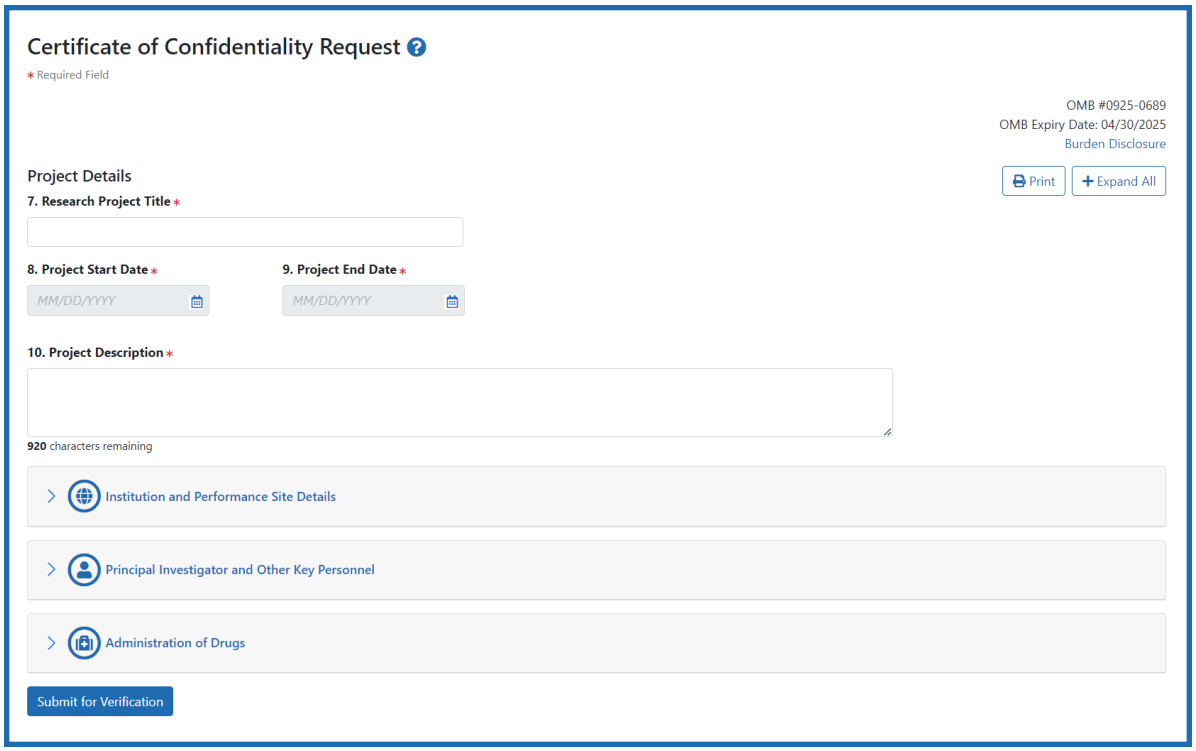


Figure 6: CoC Request screen for an eligible project, showing Project Details fields with the other sections collapsed

All fields with a red asterisk are required. Toggle the sections on the page to expand or collapse by clicking the **View All** / **Hide All** toggle button at the right. Click the **Print** button at the right of the page to display a printer-friendly form with all questions and answers entered thus far.

There are four main sections to the Certificate of Confidentiality Request screen, and two ways to submit:

Project Details

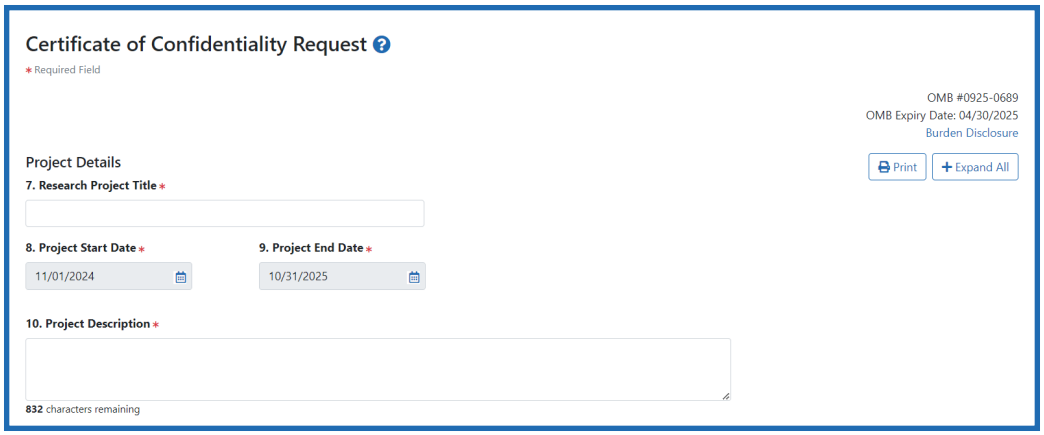


Figure 7: Certificate of Confidentiality Project Details screen

You must complete the required fields in the Project Details section before completing the other sections; otherwise you won't be able to save performance sites, key personnel, or drugs later in the form:

- **7. Research Project Title.**
- **8. Project Start Date.** This date must be in the future. If the research has already begun, enter today's date plus one business day. If the research has not yet begun, enter the expected future start date.
- **9. Project End Date.**
- **10. Project Description.** Include enough detail to show that the research project falls within the health-related mission of NIH or HHS and provides details about the research project being conducted. This field is limited to 1000 characters.

Institution and Performance Site Details

If the requesting institution is not in the United States, then at least one of the performance sites must be in the United States to proceed. If you have questions about this requirement, contact the NIH CoC Coordinator at NIH-CoC-Coordinator@mail.nih.gov.

A warning displays if the institutional official (IO) and the principal investigator (PI) are the same person or share the same email address. Go to the Institutional Official definition question in the FAQ . If this information is accurate, you may proceed through this warning.

In the Institution and Performance Site Details section, complete the following fields:

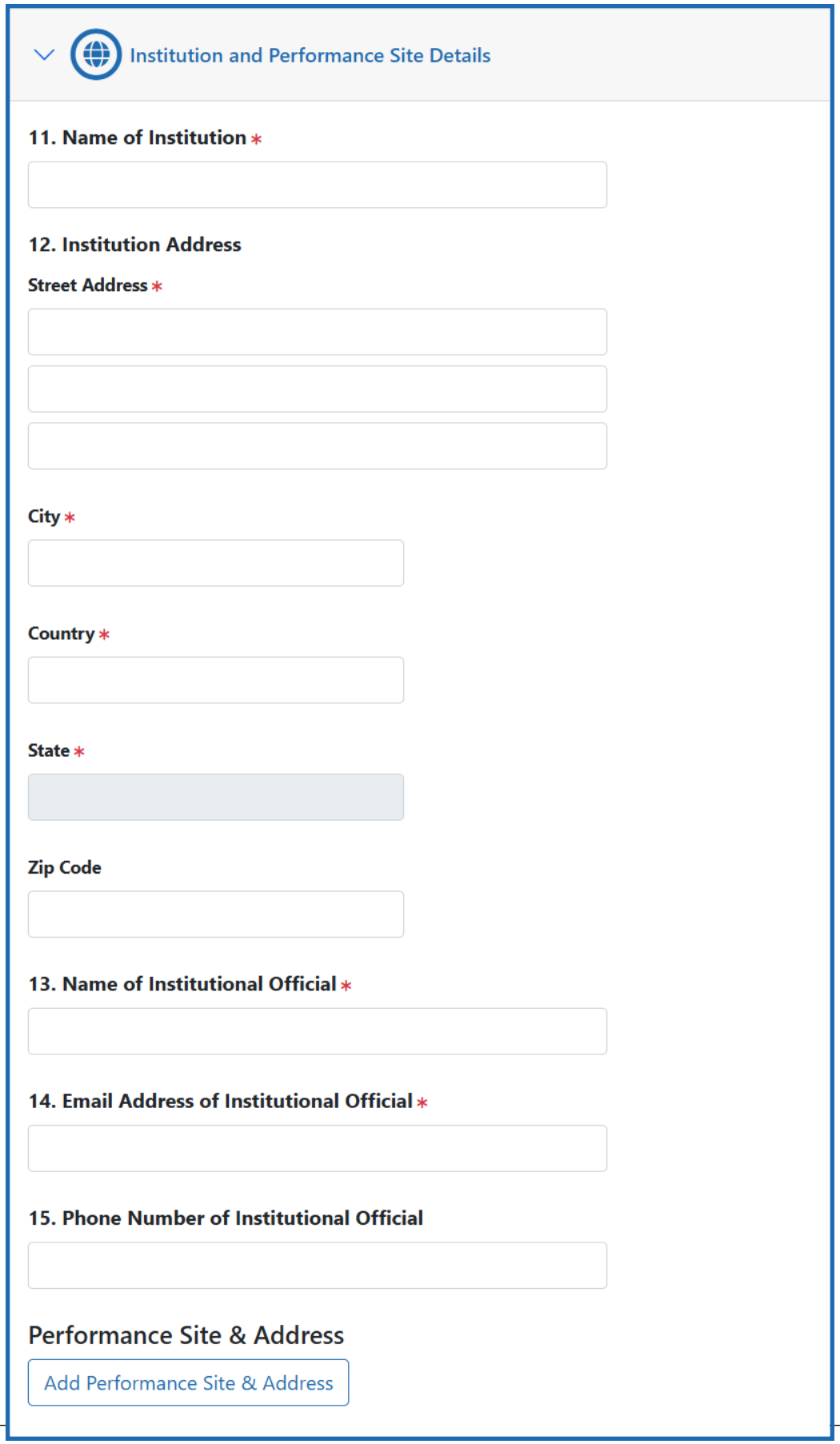

Institution and Performance Site Details
11. Name of Institution *
12. Institution Address
Street Address *
City *
Country *
State *
Zip Code
13. Name of Institutional Official *
14. Email Address of Institutional Official *
15. Phone Number of Institutional Official
Performance Site & Address
Add Performance Site & Address

Figure 8: Certificate of Confidentiality Institute and Performance Site Details section

11. Name of Institution — The institution that will be responsible for overseeing the research project and will support and defend the authority of the Certificate against legal challenges. For multisite projects in which the coordinating center or lead site is requesting a Certificate on behalf of all member institutions (e.g., participating sites), enter the requesting institution name.

- **12. Institution Address**

TIP: The State field is disabled unless "UNITED STATES" or other applicable country is entered as the country. Also, you must use the drop-down menu to specify **State** and **Country** rather than typing the state or country. Not doing so can result in a submission error.

- **13. Name of Institutional Official** — The authorized institutional official (IO) is the individual named by the requesting institution who is authorized to act for that institution and assumes on behalf of the institution the obligations imposed by the Certificate of Confidentiality as well as obligations imposed by the Federal laws, regulations, and other requirements. The IO must have signature or other authority to submit the request. In general, the IO is not the investigator or member of the research team.

IMPORTANT: The IO must have signature or other authority to submit the request. Before you complete the CoC request, you should confirm that you are listing the appropriate person as the IO.

- **14. Email Address of Institutional Official** — After you submit the CoC request, the email address you enter for the IO will receive a system-generated email with a link to the original request. The IO clicks the link, reviews the request, and agrees to a set of legal obligations imposed by the CoC. This email address will receive all further communications on this CoC, so be sure that this email address is correct and routinely monitored.

- **15. Phone Number of Institutional Official** — Optional.

If you are the coordinating center or lead institution and if you would like to request for and receive a Certificate on behalf of all U.S. performance site(s), list the additional performance site(s). If there is only one performance site, and it is the same as the institution requesting the CoC, then you can skip entering information in this field. Click the **Add Performance Site & Address** button to display fields for entering performance site data. Then enter the following:

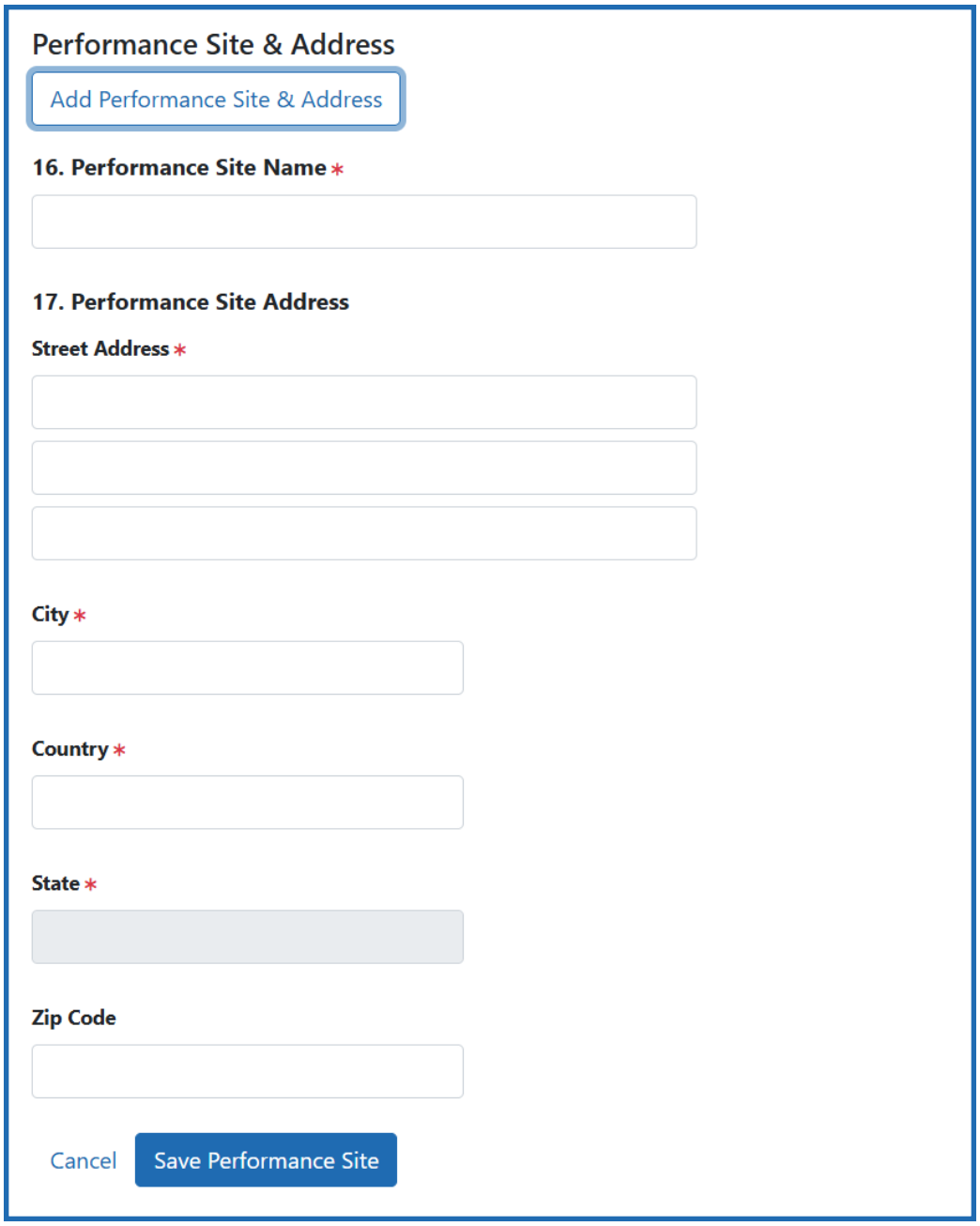


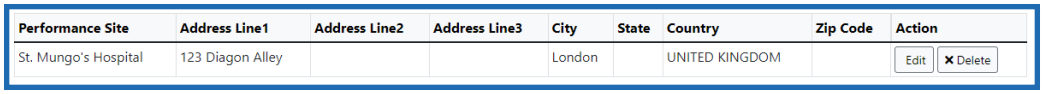
Figure 9: Performance Site & Address section

- **16. Performance Site Name** — Name of institution or other identifier where the research will mainly take place. For multisite projects, enter the name(s) of all member institution(s) (e.g., participating sites).

- **17. Performance Site Address** — Physical address where research will mainly take place. For multisite projects, enter the physical address(es) of all member institution(s) (e.g., participating sites).

NOTE: The State field is disabled unless "UNITED STATES" or other applicable country is entered as the country. Also, you must use the dropdown menu to specify **State** and **Country** rather than typing the state or country. Not doing so might result in a submittal error.

Click the **Save Performance Site** button when finished. For multisite projects, click the **Add Performance Site & Address** repeatedly to enter the name(s) of all member institution(s) (e.g., participating sites). A table displays, listing the performance sites that you have added. You can edit or delete individual performance site information by clicking the **Edit** and **Delete** buttons in the Action column of the table:



Performance Site	Address Line1	Address Line2	Address Line3	City	State	Country	Zip Code	Action
St. Mungo's Hospital	123 Diagon Alley			London		UNITED KINGDOM		Edit ✖ Delete

Figure 10: Table of Performance Sites

Principal Investigator and Other Key Personnel

In the Principal Investigator and Other Key Personnel section, complete the following fields:

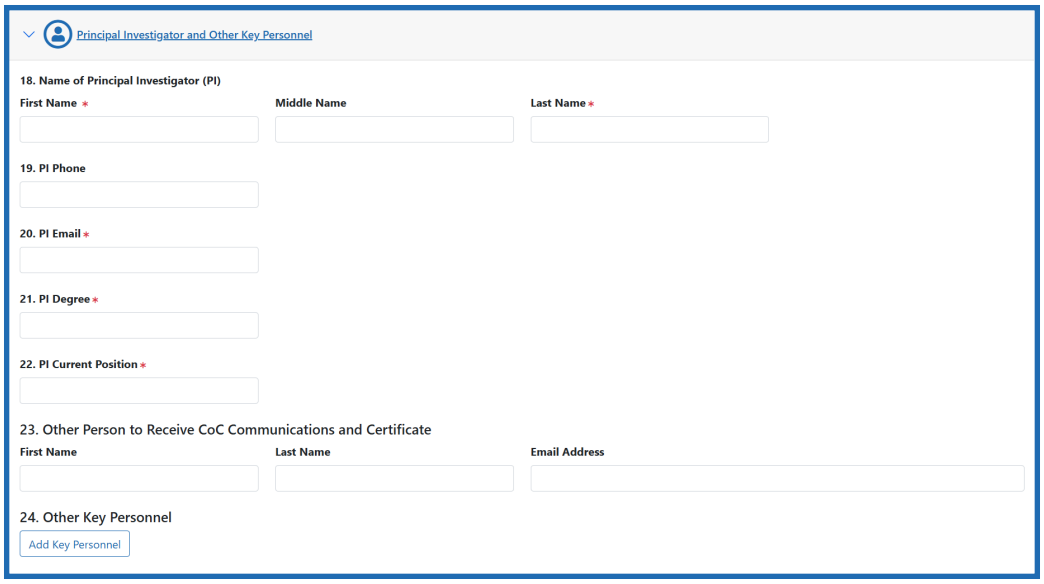


Figure 11: Certificate of Confidentiality Principal Investigator and Key Personnel section

- **18. Name of Principal Investigator (PI)** — The person leading the research team.
- **19. PI Phone** — This optional field can be used to supply the phone number of the PI.
- **20. PI Email** — The PI will receive a system-generated notification when the IO submits the CoC request to NIH. See *Verifying a Certificate of Confidentiality* on page 42.
- **21. PI Degree** — Enter the terminal degree of the PI.
- **22. PI Current Position** — List the PI's title at the institution.
- **23. Other Person to Receive CoC Communications and Certificate**— List another individual who should receive CoC information related to your research project. The purpose of this item is to designate a person in addition to the IO and PI to receive CoC notifications and correspondence.

  If the "Other Person to Receive CoC Communications and Certificate" has the **same name** or **same email address** as either the IO or the PI, a same-name warning or same-email warning appears.

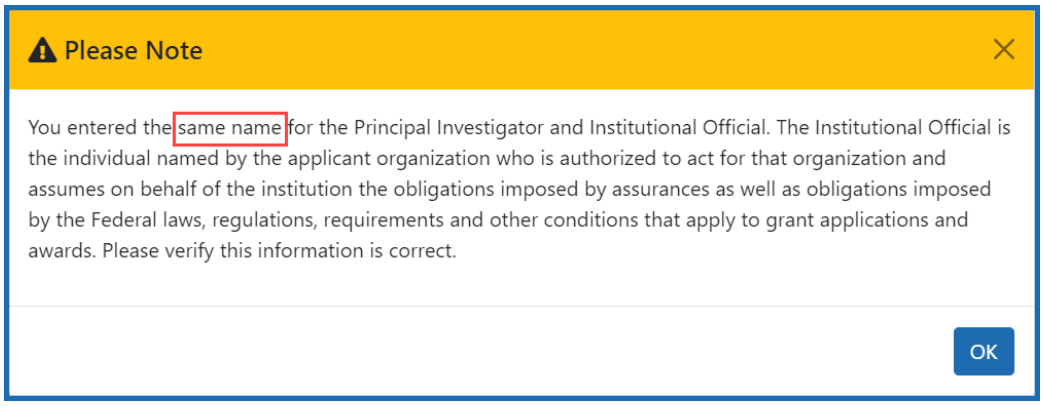


Figure 12: IO/PI and Other Person to Receive CoC Communication Same-Name Warning

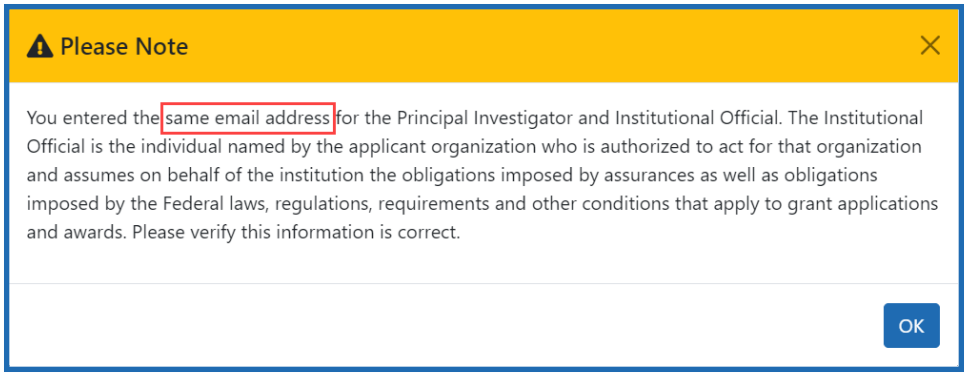


Figure 13: IO/PI and Other Person to Receive CoC Communications same-email warning

If this information is accurate, you may proceed through this warning.

NOTE: Item 23 is optional, but if you choose to list another person, you must complete all three fields (**First Name, Last Name, Email Address**).

- **24. Other Key Personnel**
    - Click the **Add Key Personnel** button to display fields where you can record key personnel name, degree, and position. Key Personnel are *individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation.*

- Click the **Save Key Personnel** button when finished. Click **Add Key Personnel** again to add additional individuals, when relevant. A table displays, listing key personnel you have added. You can edit or delete individual key personnel information by clicking the **Edit** or **Delete** buttons in the Action column of the table:

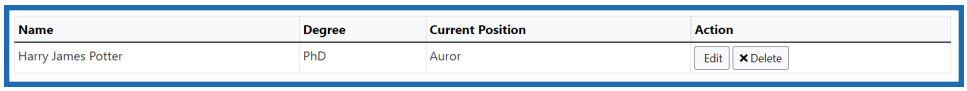


Figure 14: Other Key Personnel table

Administration of Drugs

If drugs will be administered as part of the research, complete the following questions in the Administration of Drugs section:

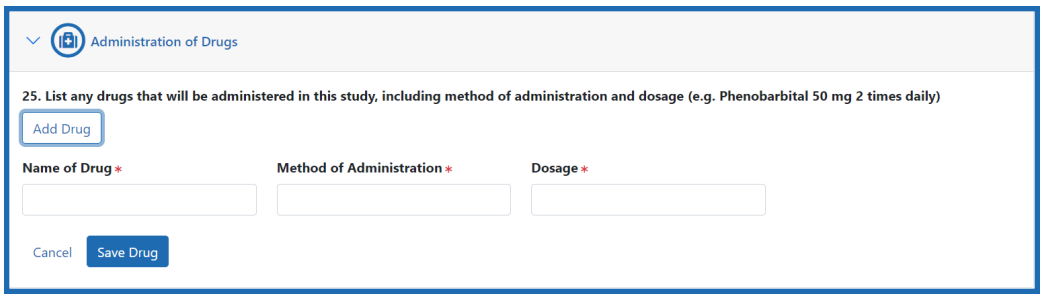


Figure 15: Administration of Drugs section showing the Add Drug button and initial questions

TIP: Do not enter drugs/study agents that will be administered under standard of care processes and not administered as part of the research.

1. Click the **Add Drug** button and enter the following:
   - **Name of Drug** — Example: ibuprofen
   - **Method of Administration** — Example: oral administration
   - **Dosage** — Example: 600 mg 2x/day
2. After entering a drug, click the **Save Drug** button.

- Click **Add Drug** additional times to enter each drug that will be administered in the study. A table appears, listing all drugs that you have added.
- Modify individual drug information by clicking the **Edit** or **Delete** buttons in the Action column of the table.

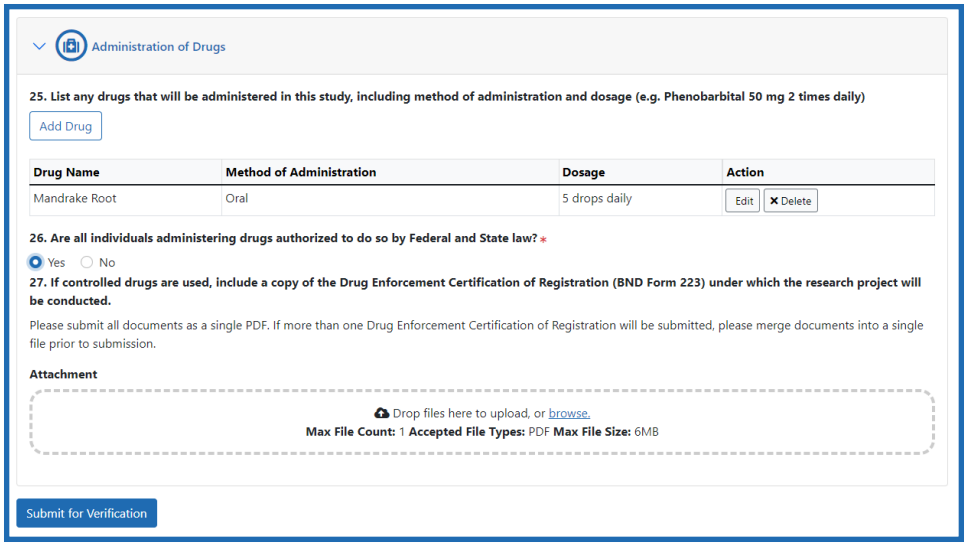


Figure 16: Certificate of Confidentiality Project Details screen

3. **Are all individuals administering drugs authorized to do so by Federal and State law?**
   - After you are done adding drug(s), answer **Yes** or **No** to item 26. Answering **No** will result in a message indicating ineligibility for a CoC.
4. **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.**

   You must include a PDF copy of the Drug Enforcement Certification of Registration (BND Form 223) for item 27 if one or more drugs being administered as part of the research are a controlled drug.

NOTE: Do not enter drugs/study agents that will be administered under standard of care processes and not administered as part of the research.

If you need to include multiple certification forms, merge them into one PDF file. This file must be under 6 MB in size. You can use Adobe Acrobat to merge and compress files, if needed. Do not upload until you are ready to submit the request; see *Requesting a Certificate of Confidentiality* on page 27.

Submit the CoC Request

1. Before you click on a **Submit for Verification** button, carefully check the information you have entered and make corrections, if needed.
2. Click the **Print** button at the top right of the web page if you wish to print the CoC request for your records.
3. Click the **Submit**button:

Figure 17: Submit for Verification button

   - In the *Confirmation Needed* dialog, click the **Submit** button.

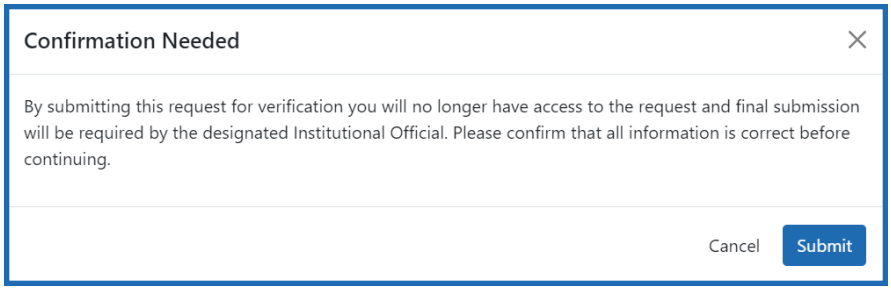


Figure 18: Confirmation message for submission

NOTE: If you need to upload a Certification, do so under the *Administration of Drugs* section before submitting the request.

A success message displays:

Figure 19: Success message

If there are errors on the form, the success message does not display and the form remains unsubmitted. Scroll through the form to see the errors in red and correct:

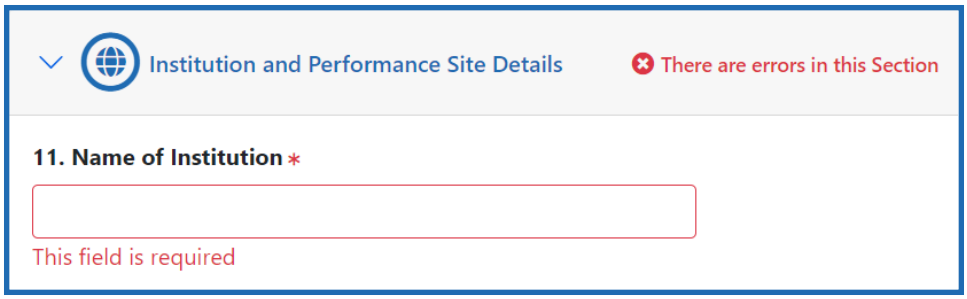


Figure 20: Example of errors on form

IMPORTANT:
After submitting for verification, the CoC request is NOT final. The individual identified as the institutional official will receive an email with a link to the requestor's submitted data and must verify the data and confirm legal obligations imposed by the CoC. Once this is done, the institutional official must click the button to submit the CoC request to NIH.
See *Verifying a Certificate of Confidentiality* on page 42 for details on the institutional official verification process.

NOTE: The PI and other person to receive CoC communications and Certificate will not receive the system generated email that the CoC was submitted at this time. Once the IO completes the verification and submission process, the IO, PI, and other person to receive CoC communication and

Certificate will receive an email from the CoC system that the CoC request has been submitted.

Verifying a Certificate of Confidentiality

After the initial request is submitted, there is a verification process.

Verification Email

Once the request to apply for a Certificate of Confidentiality (CoC) has been completed by clicking a **Submit for Verification** button, the CoC system sends an automated message to the email address entered for the institutional official. (See sample email.) The email is from NIH-CoC-Coordinator@mail.nih.gov with a subject of: *Verification and submission of COC Application*.


Verification and submission of COC Application

N

NIH-CoC-Coordinator@mail.nih.gov

To Wood, Oliver (NIH/OD) [E]

9:56 AM

A request for a Certificate of Confidentiality (CoC) was submitted to NIH for the following study:

Principal Investigator: Rubeus Hagrid
Project Title: COVID

You are listed as the Institutional Official on this request. Please verify and submit the request using the following link:
https://public.test.era.nih.gov/commonsplus/public/coc/request/editCocRequest.era?cocRequestId=.(v2)ATMsDgAAAZJX0I7CABRBRVMvQ0JDL1BLQ1M1UGFkZGluZwCAABAAEDzdr70JsvBlZBnspDWjJMAAAAQtr6Z9tdcrZnxKH0bQogH7QAUx-I4Ucp9gIDfjROTBv-14fmFfUw

Please contact the investigator listed above or the NIH CoC Coordinator at NIH-CoC-Coordinator@mail.nih.gov if you have any questions.

Figure 21: CoC verification email

IMPORTANT:
1. The NIH CoC Coordinator is not able to access or view your request until after the institutional official verifies and submits the request.
2. If you have questions about the status of your CoC request and have not received an

email from the CoC system that the CoC request has been submitted (i.e., the institutional official has not yet verified and submitted the CoC request), contact the IO to confirm that the request was received.
3. If the IO did not receive the CoC request via email, contact the NIH Certificates of Confidentiality Coordinator.

1. At this point, the institutional official (IO) must take the following steps to verify and submit the CoC request to NIH:
2. Click the link in the *Verification and submission* email.
   The browser opens to a page that contains the original CoC request.
3. Review the information in the request and verify it is correct. Edit and make corrections if necessary.
   See *Requesting a Certificate of Confidentiality* on page 27 for details on fields.
4. At the bottom of the request, a section titled *Assurance Statement* appears.

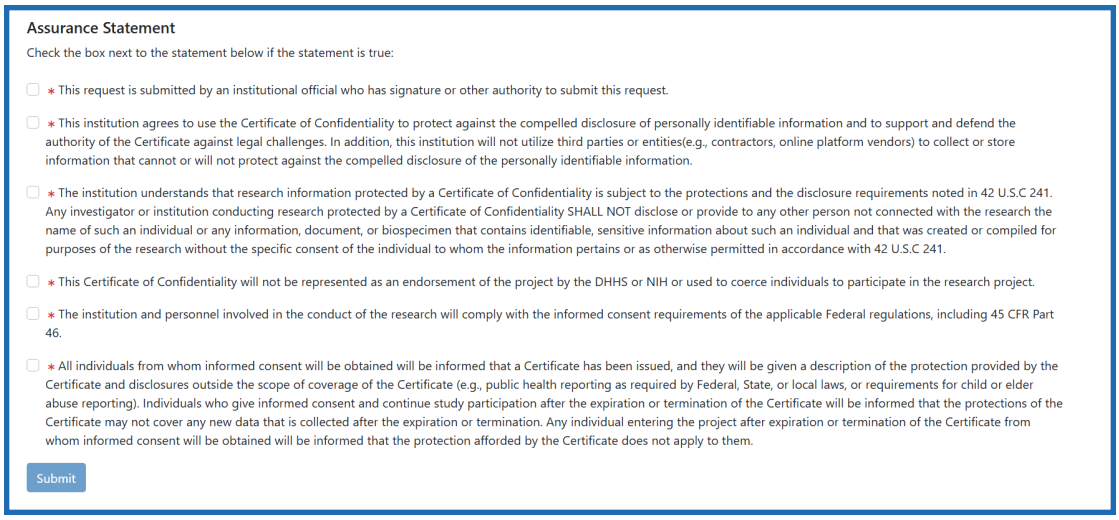


Figure 22: Verification Assurance Statement showing checkboxes for each statement that need to be verified

5. Carefully read each institutional assurance statement and mark each checkbox if you agree that the statement is true.
6. After selecting all checkboxes, click **Submit**.

7. A pop-up confirmation message appears. Click **I Certify** to verify that the statements are true and complete the submission.

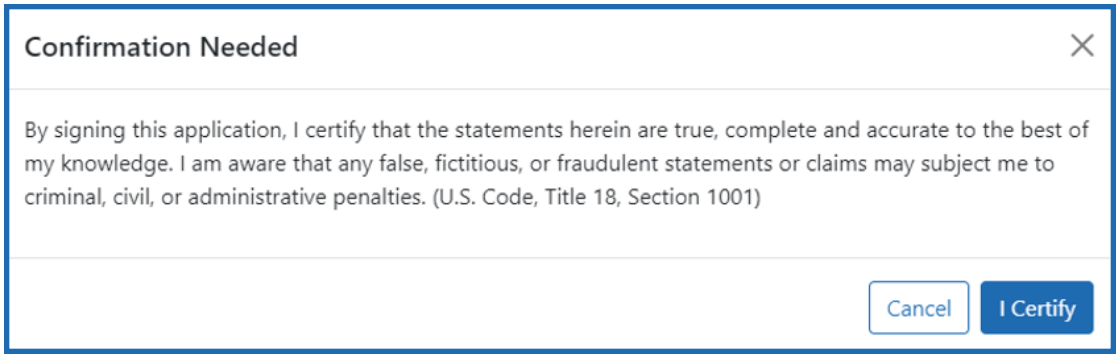


Figure 23: Confirmation message for assurance statements with "I Certify" button

Confirmation Email

The IO, PI and the other person to receive CoC communications will receive a confirmation email such as this, which includes a PDF of all submitted information:

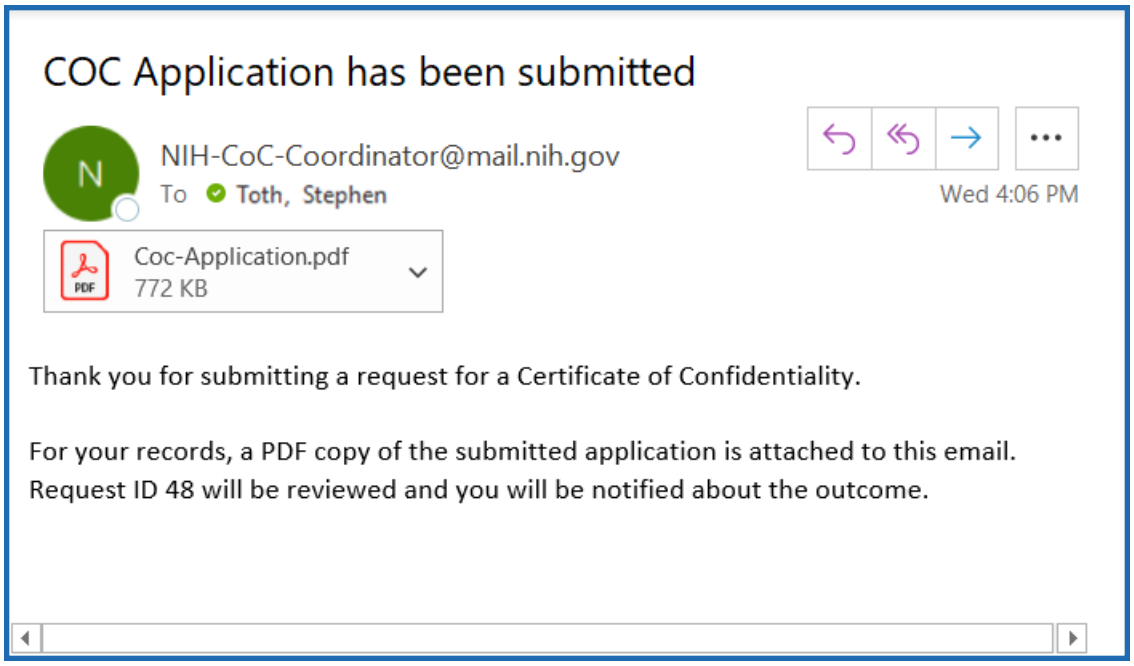


Figure 24: Success submit email

This email serves as confirmation that NIH received your request. Reference the Request ID number if you need to contact the eRA service desk regarding this request. Contact NIH-CoC-Coordinator@mail.nih.gov if you have CoC policy questions.

Next Steps...

Once the IO verifies and submits the CoC request, the NIH CoC Coordinator can view and process the request. If NIH has questions about the request, the NIH CoC Coordinator will contact the PI and IO via email. Typically, NIH processes CoC requests within three business days after receiving the request. After submission, if you don't receive NIH communications regarding the CoC request within a week, contact NIH-CoC-Coordinator@mail.nih.gov to request a status update. When the request is approved, the IO, PI and the other person to receive CoC communications will receive an email from the NIH CoC Coordinator with a PDF copy of the Certificate.