Online Certificate of Confidentiality System User Guide

June 20, 2023

TABLE OF CONTENTS

Latest Updates

August 11, 2022

Added introduction and screen captures to the *Principal Investigator and Other Key Personnel* section in the *Requesting a Certificate of Confidentiality* topic with information on a new item, Other Person to Receive CoC Communications and Certificate.

January 12, 2021

Updated the introduction to the *Institution and Performance Site Details* section in the *Requesting a Certificate of Confidentiality* topic with information on institutional officials and the performance sites for institutions outside the US.

Overview of Requesting a Certificate of Confidentiality

This topic is a very general overview of steps to use the Online Certificate of Confidentiality (CoC) System to request a CoC. To learn more about Certificates of Confidentiality and this system, see *About Certificates of Confidentiality*.

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*
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*.
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*.
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 *Methods to Submit the CoC Request*.
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 corrections if necessary, confirms 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*.

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.

About Certificates of Confidentiality

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 and FAQs, and read below.

Frequently Asked Questions (FAQs)

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 **Get your CoC** button from the How to Get a Certificate of Confidentiality? page.

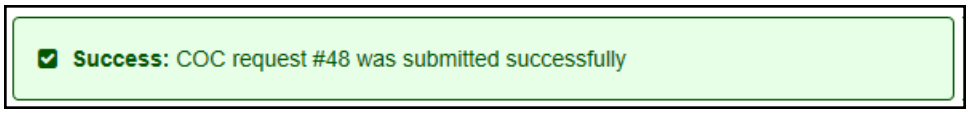
Where can I get help on the eligibility questions?

See *Details on Certificate of Confidentiality Eligibility Questions*.

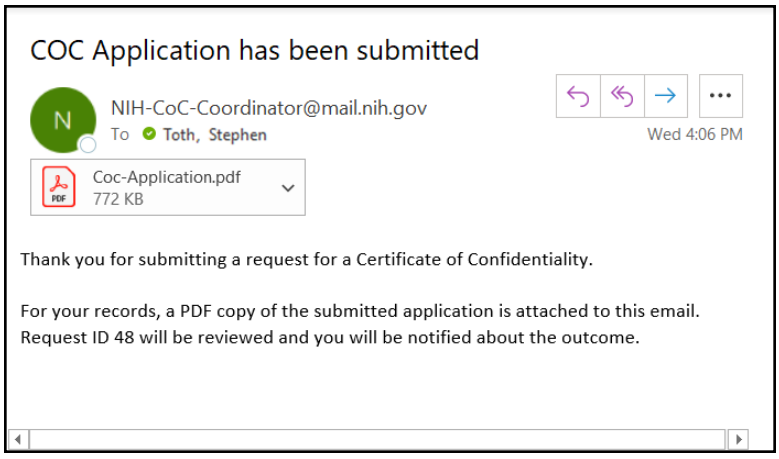
How do I know my request was submitted?

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

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:



In a few minutes, the IO and the PI 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. **Note:** eRA recommends using Internet Explorer, Mozilla Firefox, or Google Chrome browsers (Windows) or Safari (Mac).

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

What Are My Responsibilities if I have a CoC?

To learn about your legal responsibilities and rights regarding data from a research project covered by a CoC, go to CoC FAQs and 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, located here: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html

Other Sources of Information

Certificates of Confidentiality (CoC) - Human Subjects

Definition of Human Subjects Research

NIH's policy for Issuing Certificates of Confidentiality

Starting a Certificate of Confidentiality Request

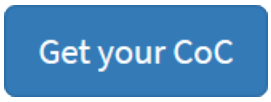
Use the Online Certificate of Confidentiality System to request a Certificate of Confidentiality (CoC), issued by NIH. First, determine your eligibility by answering questions. Then, if the answers indicate eligibility, enter information about your research and your institution to complete the request.

A Certificate of Confidentiality request must be completed in its entirety in one Internet browser session; you cannot save and finish it later. Because of this, you might want to review the information that you will be asked to provide in the online Certificate of Confidentiality (CoC) system 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 How to Get a Certificate of Confidentiality? page.
2. Click the **Get your CoC** button to open the Online Certificate of Confidentiality System.



3. Select the source of funding from **Select Funding Source** and click the **Next** button. If you select this option:
   - **National Institutes of Health**, your CoC request stops. Research covered by the NIH CoC Policy is automatically deemed issued a Certificate of Confidentiality. You do not need to use this system to request a CoC.
   - **Other DHHS agency**, then 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 that directs you to agency-specific directions on NIH's website. 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**, then 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 funding 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**, this 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.

4. 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 Eligibility Questions*.
5. 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.

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.

Agencies 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
- DOJ - Department of Justice

For research funded by agencies listed above, see the How to Get a Certificate of Confidentiality page on the NIH website for CoC Coordinator contact information at the applicable funding agency.

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), located here:

https://www.ecfr.gov/cgi-bin/text-idx?SID=90791b67270aeed31a19094a24309963&mc=true&node=pt42.1.2a&rgn=div5#se42.1.2a_12

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) and is located here:

https://www.govinfo.gov/content/pkg/USCODE-2018-title42/pdf/USCODE-2018-title42-chap6A-subchapII-partA-sec241.pdf

The relevant definition from the code is:

(4) For purposes of this subsection, the term "identifiable, sensitive information" means information that is about an individual and that is gathered or used during the course of research described in paragraph (1)(A) and-

> *(A) through which an individual is identified; or*
> *(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, 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 here:

https://www.ecfr.gov/cgi-bin/text-idx?SID=57fa58676e7c82aed9f3adb5bb52e7ca&mc=true&node=pt45.1.46&rgn=div5

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 you are using the informed consent as described in Title 45 (Public Welfare) Part 46 (Protection of Human Subjects) of the Code of Federal Regulations. If you are **not** using a waiver or alteration to the informed consent described, answer **No** to this question.

See section §46.116 at the following link for a description of informed consent:

https://www.ecfr.gov/cgi-bin/text-idx?SID=57fa58676e7c82aed9f3adb5bb52e7ca&mc=true&node=pt45.1.46&rgn=div5#se45.1.46_1116

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 at the following link and scroll to section (e) and (f):

https://www.ecfr.gov/cgi-bin/text-idx?SID=57fa58676e7c82aed9f3adb5bb52e7ca&mc=true&node=pt45.1.46&rgn=div5#se45.1.46_1116

After answering all questions, click the 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.

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:

Top section titled Project Details

You must enter the project details before completing other sections of this form; otherwise you won't be able to save performance sites, key personnel, or drugs later in the form.

In the top section titled Project Details, enter the following:

- **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 its future start date.
- **9. Project End Date.**

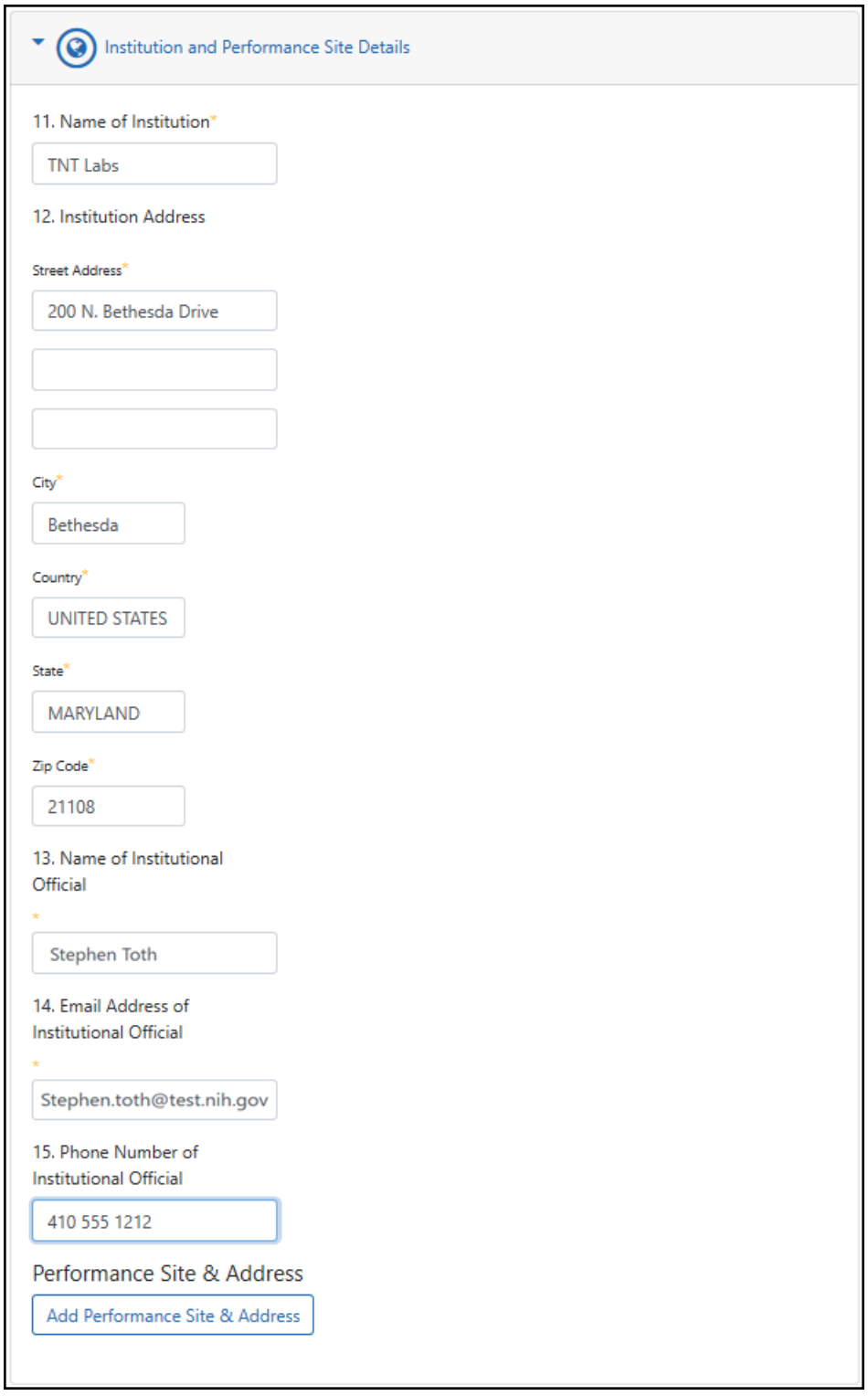
- **10. Project Description.** Include enough detail to show that the research project falls within the health-related missions of NIH or HHS. This field is limited to 1000 characters.

Institution and Performance Site Details section

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.

Also, you will receive a warning if the institutional official (IO) and the principal investigator (PI) are the same person or share the same email address. Go here to view the FAQ about institutional officials. If this information is accurate, you may proceed through this warning.

In the Institution and Performance Site Details section, enter the following:



11. Name of Institution. The institution that will be conducting the research project. 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

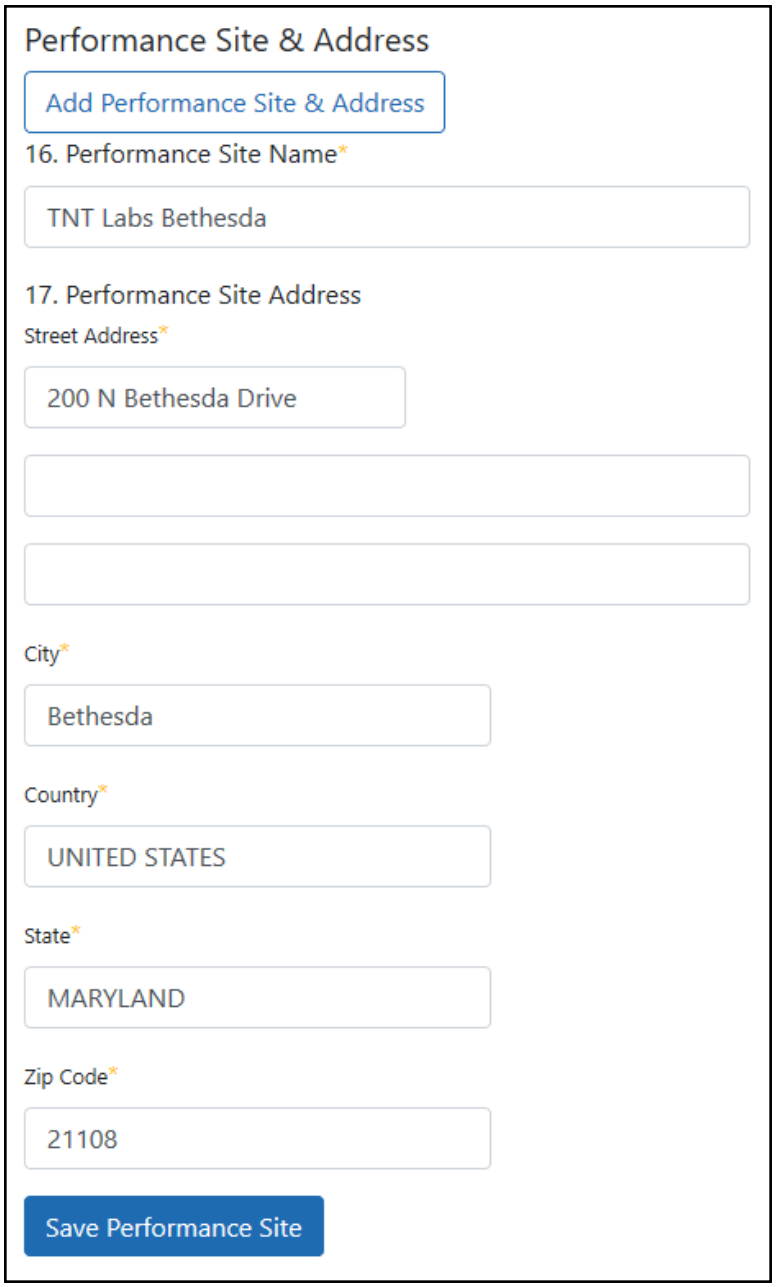
institution name.

- **12. Institution Address.**

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.

- **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.
- **14. Email Address of Institutional Official.** After you submit the CoC request, the email address you enter for the IO will receive an 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.**

Next you add one or more performance sites. 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:

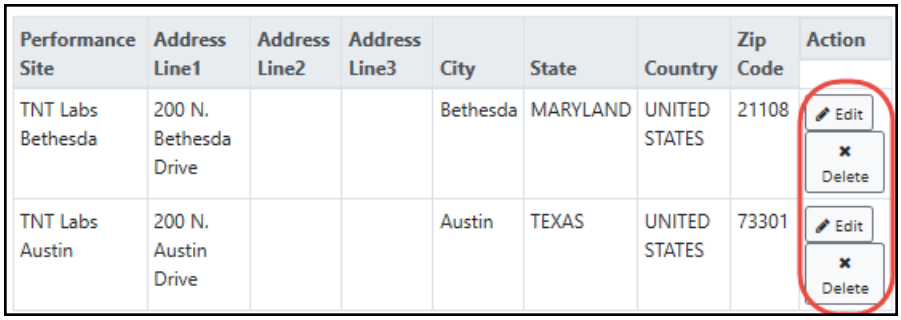


Performance Site & Address section

- **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.

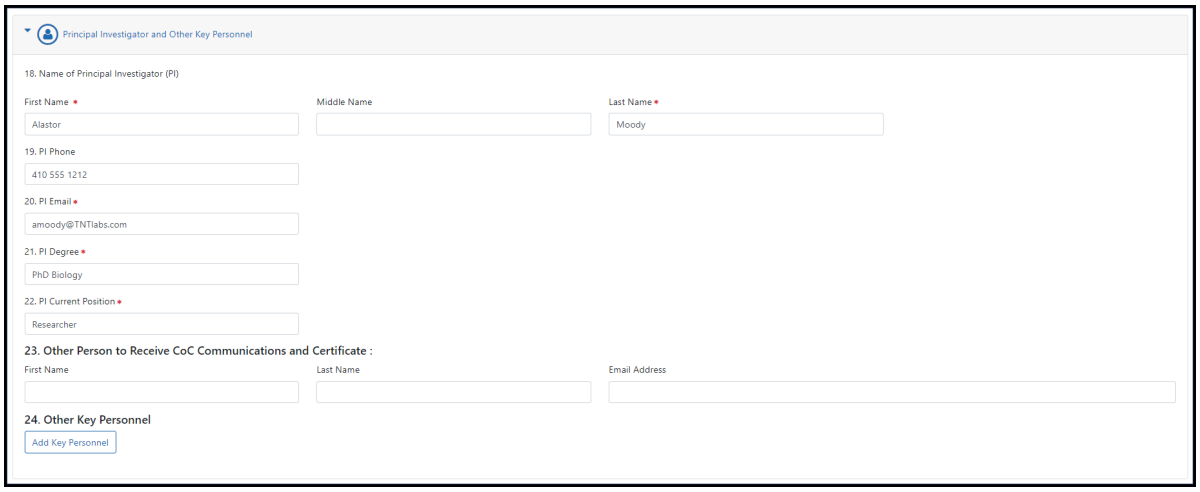
Click the **Save Performance Site** button when finished. For multisite projects, click the **Add Performance Site & Address** repeatedly to enter the name(s) of all member institution(s) (e.g., participating sites). A table displays, listing the performance sites that you have added. You can edit or 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
TNT Labs Bethesda	200 N. Bethesda Drive			Bethesda	MARYLAND	UNITED STATES	21108	Edit Delete
TNT Labs Austin	200 N. Austin Drive			Austin	TEXAS	UNITED STATES	73301	Edit Delete

Principal Investigator and Other Key Personnel section

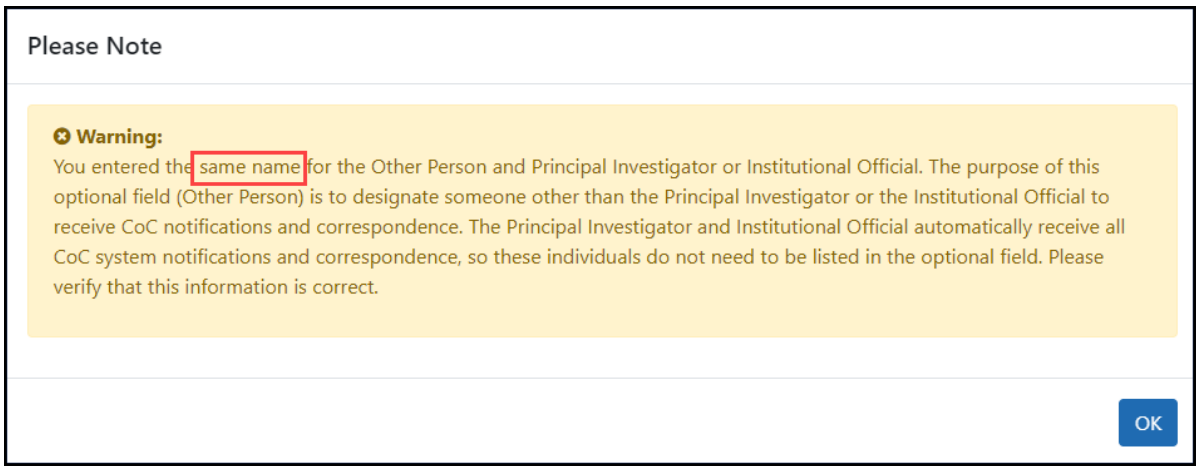
In the Principal Investigator and Other Key Personnel section, enter the following:



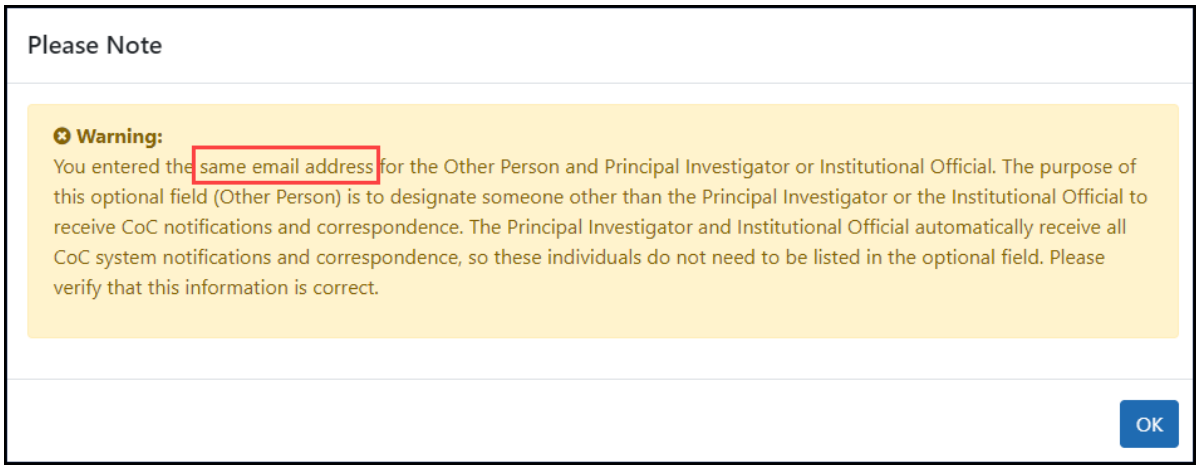
- **18. Name of Principal Investigator (PI).** The person leading the research team.
- **19. PI Phone.**
- **20. PI Email.** The PI will receive a notification when the IO submits the CoC request to NIH. See *Confirmation Email*.

- **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 you list the **same name** for this section as either the IO or the PI, a same-name warning appears.



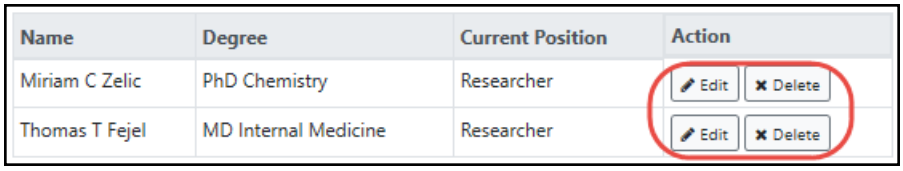
  If you list the **same email address** for this section as either the IO or the PI, a same-email warning appears.



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**).

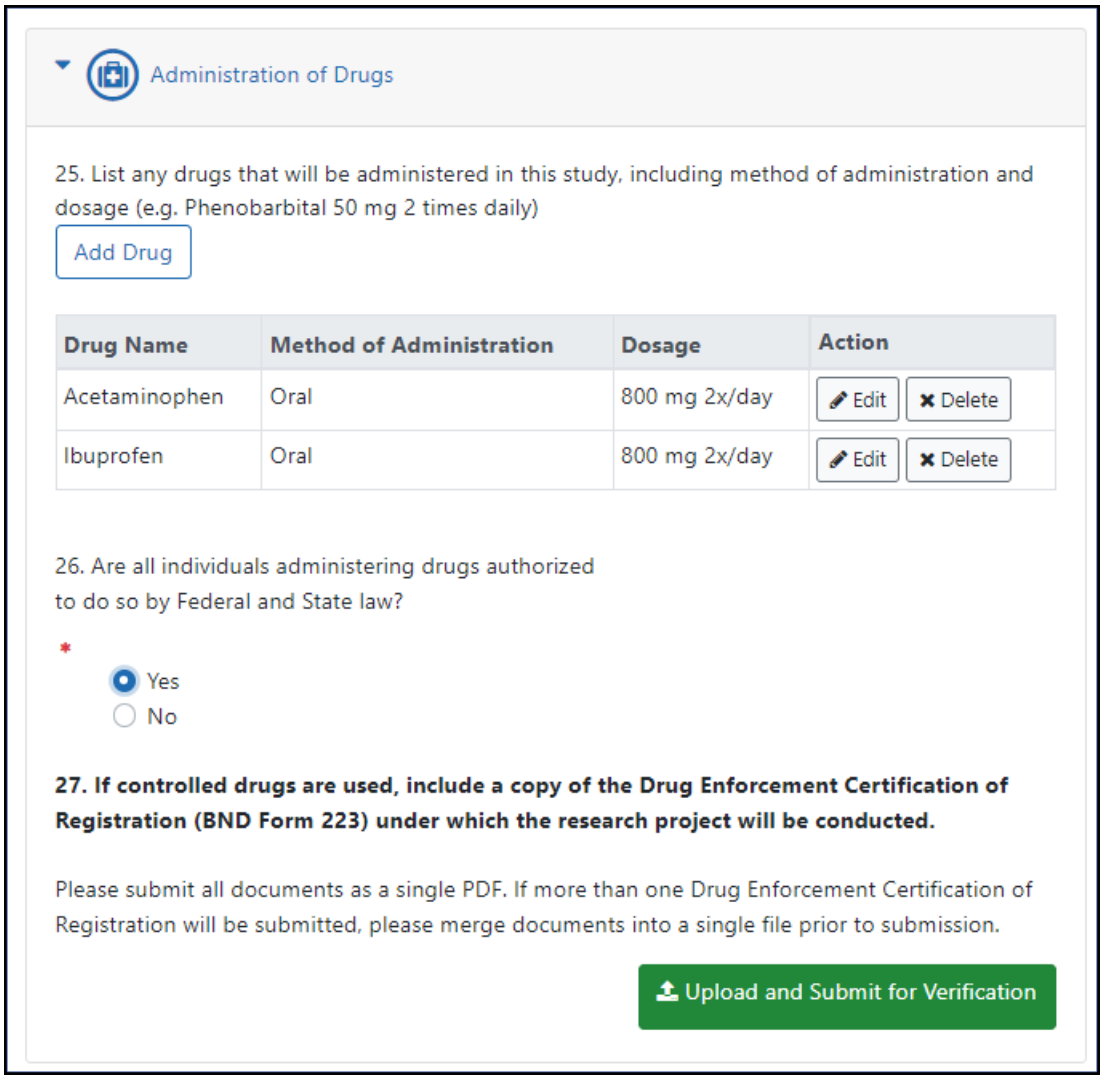
- **24. Other Key Personnel.** Click the **Add Key Personnel** button to display fields where you can record key personnel name, degree, and position. ***Key personnel*** are *individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether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

  Click the **Save Key Personnel** button when finished. Click **Add Key Personnel** again to add additional individuals if necessary. 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:



Administration of Drugs section

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



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 drugs that you have added. You can edit or delete individual drug information by clicking the **Edit** or **Delete** buttons in the Action column of the table.
3. After you are done adding drug(s), answer **Yes** or **No** to *"Are all individuals administering drugs authorized to do so by Federal and State law?"* Answering **No** will result in a message indicating ineligibility for a CoC.

4. For item 27, if one or more drugs being administered in your study are a controlled drug, you must include a PDF copy of the Drug Enforcement Certification of Registration (BND Form 223) under which the research project will be conducted. If you need to upload multiple certification forms, merge them into one PDF file. This file must be under 6 MB in size. Merging and compression can be done with Adobe Acrobat. Do not upload until you are ready to submit the request; see *Methods to Submit the CoC Request*.

Methods to Submit the CoC Request

There are two ways to submit the CoC request: The **Upload and Submit Verification** button or **Submit for Verification** button:

- Use the **Upload and Submit for Verification** button if there are one or more controlled drugs that will be administered in your research project, which lets you upload your drug enforcement certification of registration form(s).
- Use the **Submit for Verification** button if there are no controlled drugs that will be administered in your research project.

To Submit the CoC Request for Verification:

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

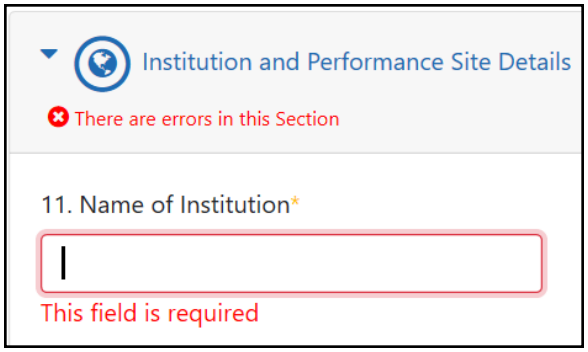
3. Click a **Submit** button:
   - If you don't need to upload a Certification, click the **Submit for Verification** button at the bottom of the page:

     In the *Confirmation Needed* dialog, click the **Yes** button.
   - If you need to upload a Certification, click the **Upload and Submit for Verification** button (found under the *Administration of Drugs* section):

In the *Confirmation Needed* dialog, click the **Yes Proceed with Upload** button, then browse to select the Certification PDF.

4. In the browser, you will see a success message:

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



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* for details on the institutional official verification process.

Verifying a Certificate of Confidentiality

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

Verification Email

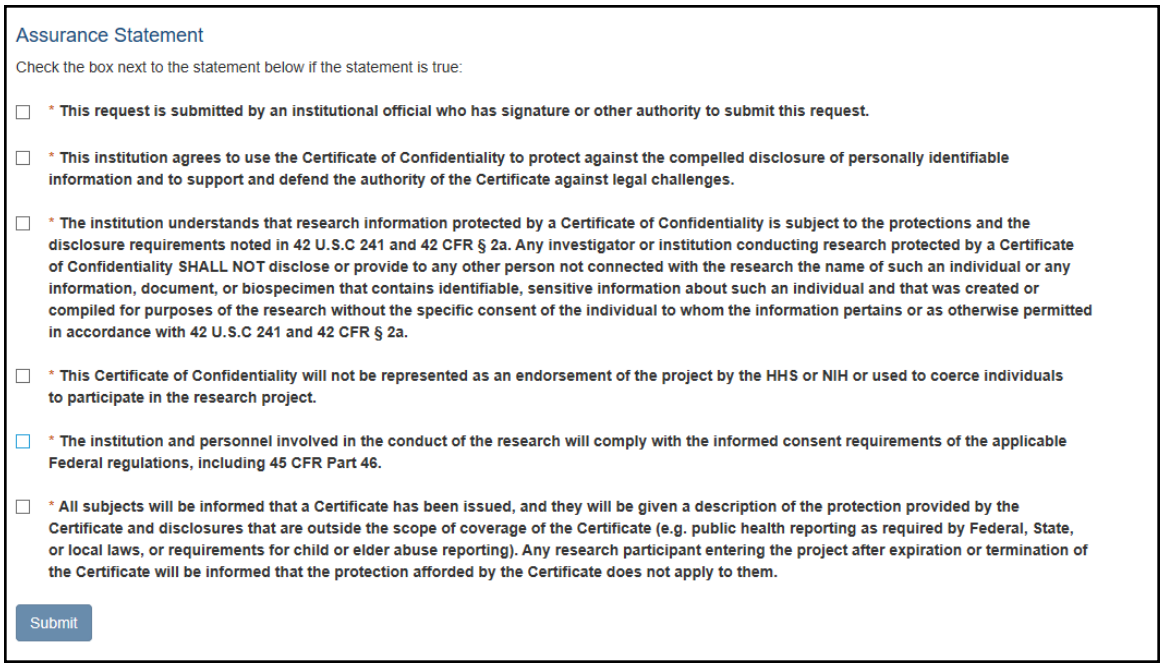
Once the request to apply for a Certificate of Confidentiality (CoC) has been completed by clicking a **Submit for Verification** button, the CoC system sends an automated message to the email address entered for the institutional official. (see sample email below) The email is from NIH-CoC-Coordinator@mail.nih.gov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

IMPORTANT: The NIH CoC Coordinator is not able to access or view your request until after the institutional official verifies and submits the request. If you have questions about your CoC request before the institutional official has taken action, contact the eRA Service Desk.

At this point, the institutional official (IO) must take the following steps to verify and submit the CoC request to NIH:

1. Click the link in the *Verification and submission* email.
   The browser opens to a page that contains the original CoC request.
2. Review the information in the request and verify it is correct. Edit and make corrections if necessary.
   See *Requesting a Certificate of Confidentiality* for details on fields.

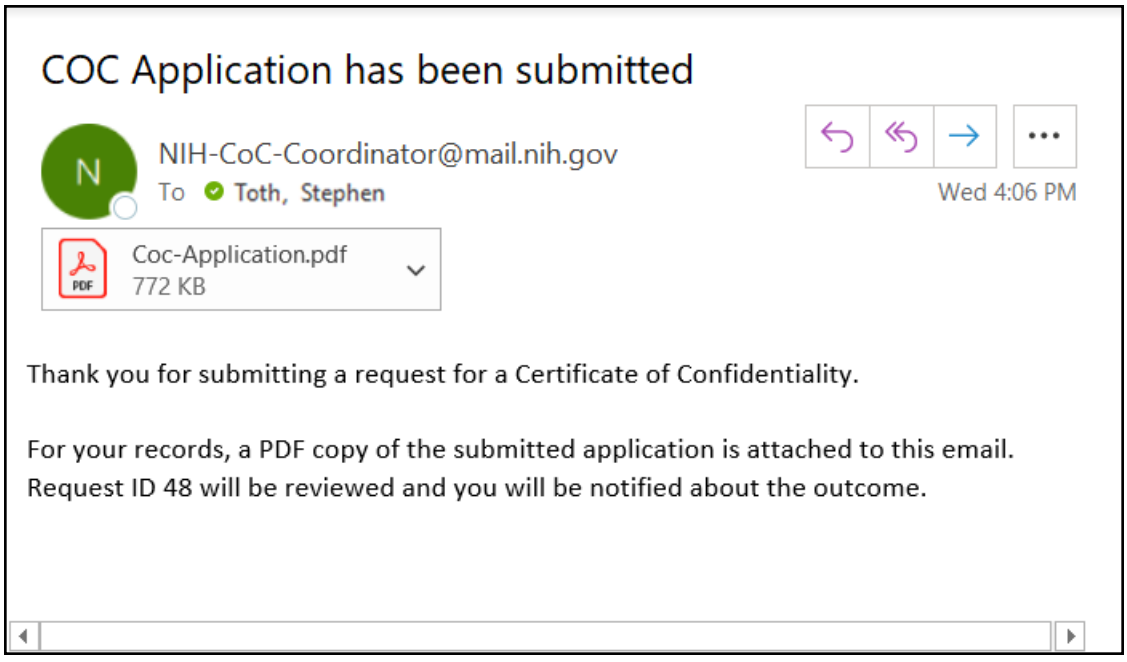
   At the bottom of the request, a section titled **Assurance Statement** appears.



3. Carefully read each institutional assurance statement and mark each checkbox if you agree that the statement is true.
4. When all checkboxes are marked, click the **Submit** button.

Confirmation Email

Both the IO and the PI will receive a confirmation email such as this, which includes a PDF of all submitted information:



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 one week 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 and PI will receive an email from the NIH CoC Coordinator with a PDF copy of the Certificate.