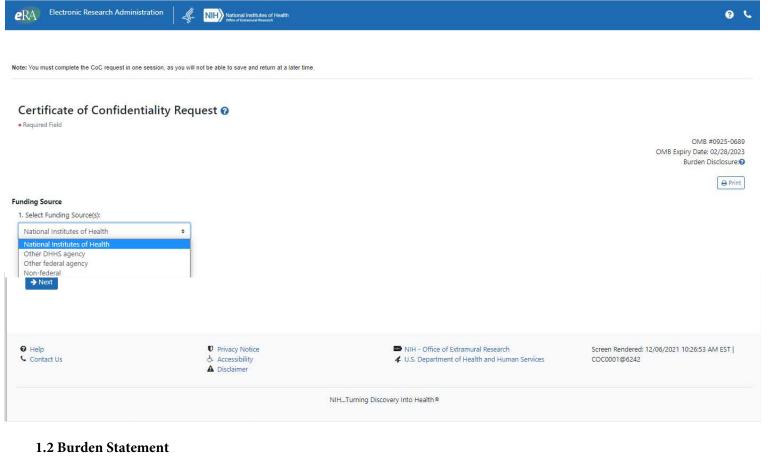
### 1.0 CoC Screens

#### 1.1 CoC User Interface, Question 1



Burden Disclosure Statement

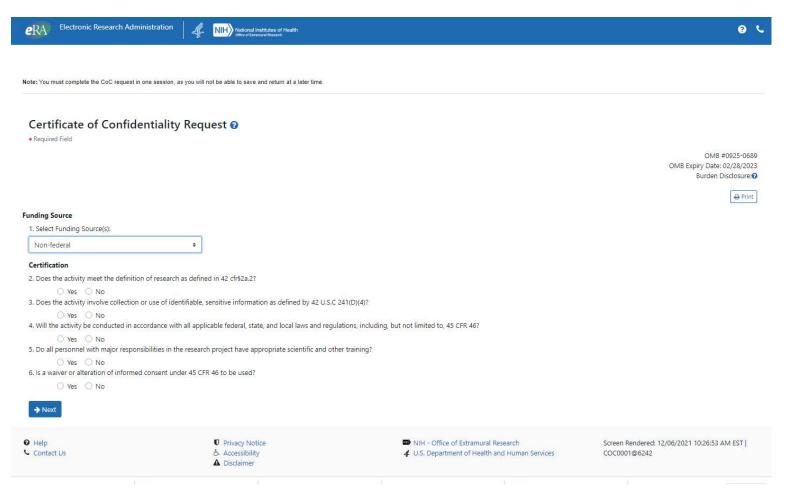
Public reporting burden for this collection of information is estimated to average 90 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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.

×

## 1.3 User Interface: Certification, Questions 2-6



1.3 User Interface, Certification	n Questions 7-16, Re	esearch, Institut	ion, and Performar	nce Sites	
Project Details					
7. Research Project Title*					
8. Project Start Date*					
9. Project End Date*					
10. Project Description*					
Institution and Performance Site Deta	ils				
11. Name of Institution*					
12. Institution Address: Street Address*					
City*					
State*					
Country*					
Zip Code					
13. Name of Institutional Of	ficial*				
14. Email Address of Institut	hianal Official*				
14. Email Address of Institut	lonai Officiai* —				
15. Phone Number of Institu	tional Official				
Peformance Site and Addresses					
16. Performance Site Name	*				

L7.	Performance	Site Address*	
	Street Addres		
	Street addres	ss line 3	
	City*		
	Country*		
	State*		
	Zip Code		
ipal In	vestigator and Oth	ner Key Personnel	
-	_	ipal Investigator (PI):	
	irst Name*	Middle Name	Last Name*
19. F	PI Phone		
20. F	PI Email*		
21. F	PI Degree*		
22. F	PI Current Pos	sition*	
23. 0	ther Person t	o Receive CoC Commun	ications and Certificate: (New)
First	t Name	Last Name	Email Address of Other Person
24.	Other Key Pers	sonnel	
Firs	t Name	Middle Name	Last Name
	er Key Personn	el Degree	
Othe			

Administration of Drugs				
25. List any drugs that wind Phenobarbital 50 mg 2 times		this study, including m	ethod of administration a	nd dosage (e.g.
Name of Drug	Method of A	Administration	Dosage	
26. Are all individuals adr	ministering drugs auth	orized to do so by Fed	leral and State Law?	
	○ Yes	O No		

1.3 User Interface: Certification, Questions 25-26, Administration of Drugs

### 1.4 For Instructional Purposes Only

#### 1.41 User Interface

# **Instructions Only**

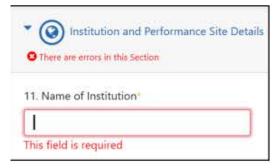
After the user completes questions 1-26, she/he will submit the CoC request.

- 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:



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:



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.
ic	*This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of personally dentifiable information and to support and defend the authority of the Certificate against legal challenges.
p c id v	*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 dentifiable, 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 2 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 o coerce individuals to participate in the research project.
	$\square$ *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.
p re p	*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 eporting 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.
$\cap$	will read each institutional assurance statement and mark each shockbox if she/he agrees that the statement is true. When a

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 Disclosure 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