

US DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

NATIONAL INSTITUTES OF HEALTH (NIH)

OFFICE OF THE DIRECTOR (OD)

OFFICE OF EXTRAMURAL RESEARCH (OER)

NIH/OD/OER/OEP HUMAN SUBJECTS
COC APPLICATION SCREENS

November 2016



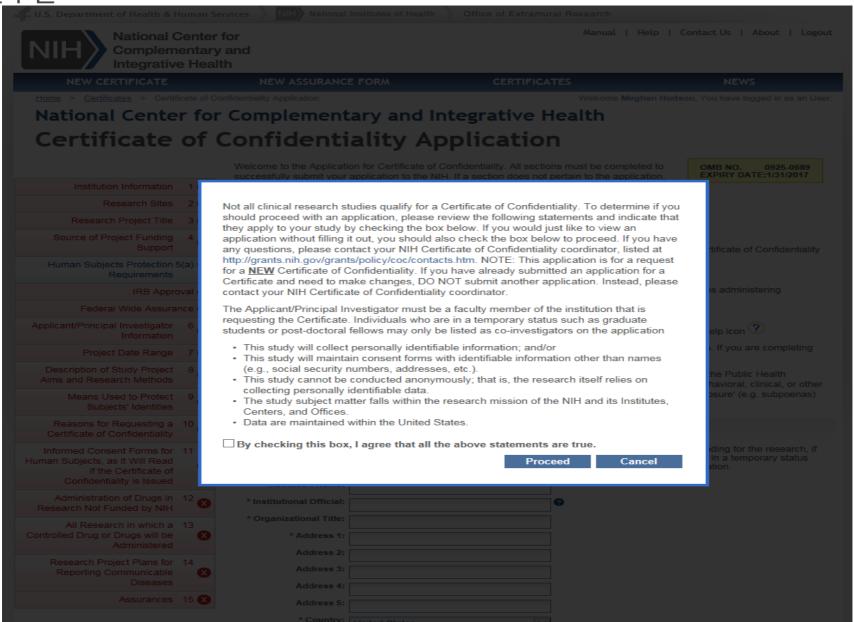
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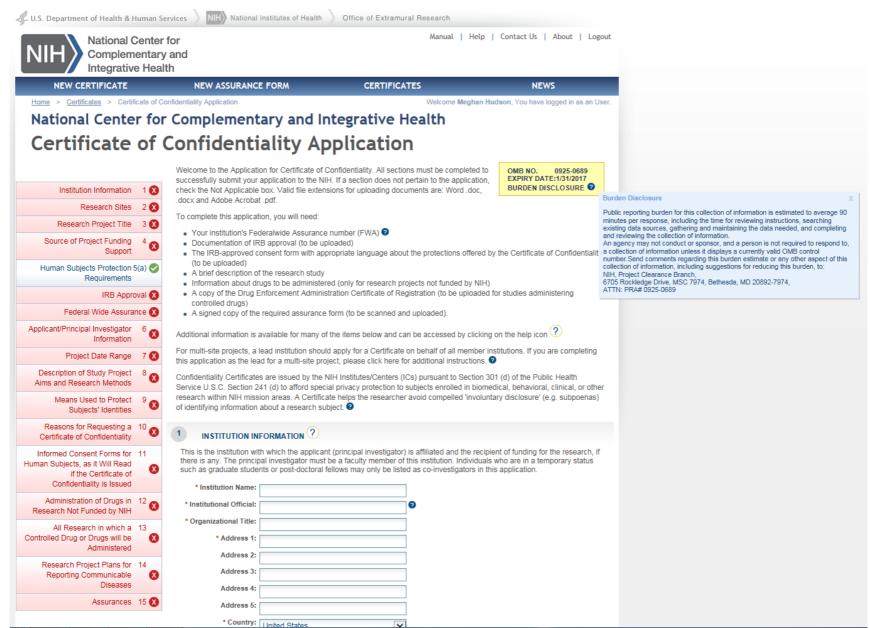


APPLICATION SECTION SCREENS CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION





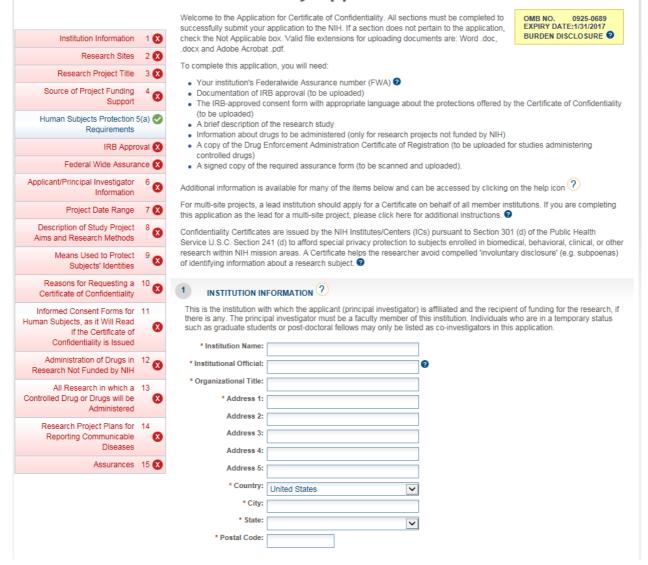






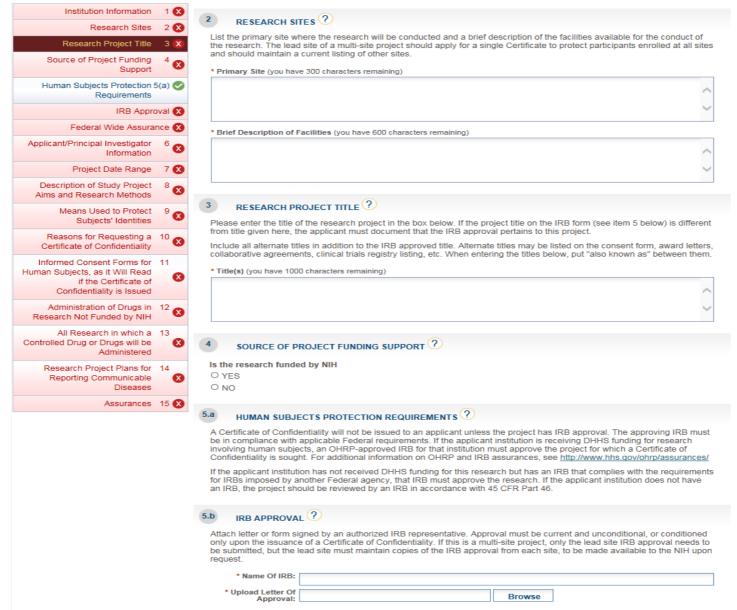
CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (1)

National Center for Complementary and Integrative Health Certificate of Confidentiality Application



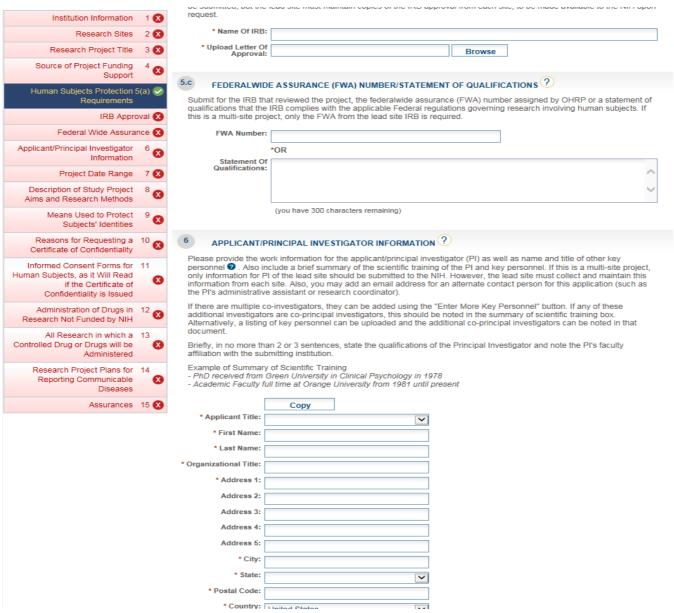


CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (2 TO 5b)





CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (5c TO 6)





CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (6 TO 7)

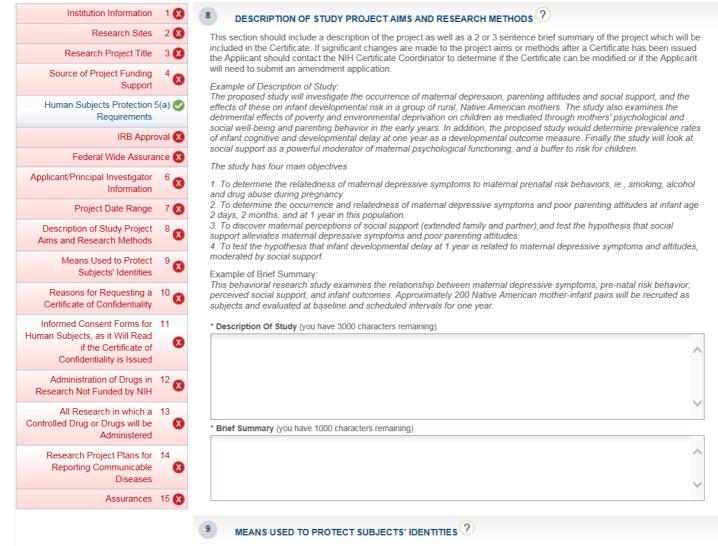
* End Date (mm/dd/yyyy):

Institution Information	1 🐼	* City:				
Research Sites	2 🛭	* State:		~		
Research Project Title	3 🛭	* Postal Code:				
Source of Project Funding	4 🗙	* Country:	United States	~		
Support	•	* Telephone:				
Human Subjects Protection ! Requirements	5(a) 🕢	Fax:				
IRB Appro	oval 🛭	* Email:				
Federal Wide Assura	nce 🛭	Alternate Email:				
Applicant/Principal Investigator Information	⁶ ⊗	* Summary Of Scient	tific Training (you have 300 charac	ters remaining)		
Project Date Range	7 🐼					
Description of Study Project Aims and Research Methods	8 🐼					~
Means Used to Protect Subjects' Identities	9 🐼		one key person to add, either add ti containing a list of the key personn			
Reasons for Requesting a Certificate of Confidentiality	10 ❷	personnel, you must up	pload a document.		, , , ,	
Informed Consent Forms for Human Subjects, as it Will Read if the Certificate of Confidentiality is Issued	11	орюва роситент	Containing All Key Personnel:	R	Browse	
Administration of Drugs in Research Not Funded by NIH	12 🐼			Key Person 1		
All Research in which a Controlled Drug or Drugs will be Administered	13		Name Title		ining	
Research Project Plans for Reporting Communicable Diseases	14		Summary of Scientific Training	: Total nave out what actions remain	0	
Assurances	15 🔉			Add More		
		7 PROJECT DA	TE RANGE			
		start and expiration of	e the project began or will begin dates on your Certificate. If the re I Certificate Coordinator about e	esearch will not be completed by	by the expected end date,	the Applicant

* Beginning Date (mm/dd/yyyy):



CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (8 TO 9)



Describe the procedures used for collection and storage of personally identifiable information.

For Example: Subjects are coded by numbers not names, linking information is kept in locked files, identifiers will be destroyed when the study is completed, etc.

* Means Used (you have 1000 characters remaining)



CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (9 TO 11)

Institution Information	1 🐼	* Means Used (you have 1000 characters remaining)		
Research Sites	2 🐼			^
Research Project Title	3 🐼			
Source of Project Funding Support	⁴ 🐼			
Human Subjects Protection Requirements	5(a) 🐼			
IRB Appro	oval 🐼	10 REASONS FOR REQUESTING A CERTIFICATE OF CONFIDENTIALITY ?		
Federal Wide Assura	ince 🛭	Include a brief description of sensitive and identifying information to be collected.		
Applicant/Principal Investigator	6 🐼	Examples for Reason for Requesting Certificate of Confidentiality:		
Information Project Date Range	7 (X)	 Sensitive information regarding drug and alcohol use, physical habits and dream content Genetic material is being collected in patients and their families who may be at risk of de 	developing sp	pecified diseases.
Description of Study Project	8 🐼	Genome analysis will be performed to search for familial, disease-influencing genes and		
Aims and Research Methods	× ×	This information, if disclosed, could expose subjects or their families to adverse economic, consequences	c, legal, psyc	hological or social
Means Used to Protect Subjects' Identities	9 🐼	* Reason for Request (you have 1000 characters remaining)		
Reasons for Requesting a	10 👧			^
Certificate of Confidentiality				
Informed Consent Forms for Human Subjects, as it Will Read				v
if the Certificate of Confidentiality is Issued	× ×	INFORMED CONSENT FORM(S) FOR HUMAN SUBJECTS, AS IT WILL READ IF	IE TUE CED	TIFICATE
The state of the s	42	of confidentiality is issued (attach copy)?	IF THE CER	IFICATE
Administration of Drugs in Research Not Funded by NIH	12 🐼	The informed consent form must include an accurate description of the protections and limit	mitations of th	he Certificate of
All Research in which a		Confidentiality, including the circumstances in which the investigators plan to voluntarily dis research participants (e.g., child abuse, harm to self or others, etc.).	disclose ident	ifying information about
Controlled Drug or Drugs will be Administered	8	Researchers may adapt the sample language below to the needs of their research participal	ipants and the	e subject matter of their
Research Project Plans for	14	study. However, the consent must cover the basic points about Certificates of Confidentiality (CoC) note should also review any institutional "boilerplate" language about confidentiality and data security often in forms to be certain that it is consistent with the protections of the CoC. Please contact the NIH IC CoC		oted below. Researchers
Reporting Communicable	8			
Diseases		have any questions about your consent language. Sample language can be viewed here		leaure to authorities
Assurances	15 🐼	The researchers must also include language regarding circumstances that could lead to vol and appropriate professionals, without consent of the participant, such as information about others, or other disclosures (including a description of the circumstances under which disclo	out child abus	se, intent to hurt self or
		If this is a multi-site project, only submit the consent form used by the lead site. The lead sit approved consent form(s) from each participating site and must ensure that informed conse appropriate language about the protections and limitations (voluntary disclosures) of the Ce	sent form for	each site contains
		If a study uses several consent forms (e.g. a consent form and an assent form), please mer prior to uploading.	nerge them in	to a single document
		If significant changes are made to the informed consent form after the Certificate has been contact the Certificate Coordinator to determine if a revised consent form should be submitted.		
		Information for research projects with children: A Certificate of Confidentiality cannot be identifiable research information about a minor if a parent or legal guardian requests it. The for a refusal to disclose information - after checking with their IRB about waivers of parental any case, researchers should discuss this possibility with their institution's officials.	he researche	rs may use other basis
		Researchers may contact the Certificate Coordinator at the NIH IC for which they are apply recommendations and suggestions on language to be included in consent and assent form: Confidentiality. (IC Contacts)		
		* Upload Informed Consent Form(s):	Browse	



CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (12 TO 13)

Institution Information	1 🐼				
Research Sites	2 🛭	12 ADMINISTRATION OF DRUGS IN RE	SEARCH NOT FUNDED BY NIH ?		
Research Project Title	3 🛭		will be administered to human subjects must provide	le the following add	ditional
Source of Project Funding Support	⁴ ⊗	information: Identification of drugs to be administered;	e.g. Phenobarbital		
Human Subjects Protection 5 Requirements	(a) 🕢	 Description of methods for administration of Evidence that individuals who will receive the 	of these drugs, including a statement of dosages; e the drugs are authorized to do so under applicable se anti-epileptic medications in the State of Rhode	Federal and State	
IRB Appro	val 🛚	If you have more than one drug to be adminis	stered, add each one individually by selecting the E	Enter More Drugs b	outton.
Federal Wide Assuran	ice 🗴	Select this checkbox if this section is not	applicable (n/a) to your application:		
Applicant/Principal Investigator Information	⁶ ⊗		DRUG 1		
Project Date Range	7 🐼	* Description Of Identification Of Drug (you ha	ave 300 characters remaining)		
Description of Study Project Aims and Research Methods	⁸ 🐼				^
Means Used to Protect Subjects' Identities	⁹ 🐼	* Description Of Administration Of Drug (you	have 300 characters remaining)		~
Reasons for Requesting a Certificate of Confidentiality	¹⁰ 🐼				^
Informed Consent Forms for	11				\sim
Human Subjects, as it Will Read if the Certificate of	×.	* Evidence Of Authorization (you have 300 cha	aracters remaining)		
Confidentiality is Issued					^
Administration of Drugs in Research Not Funded by NIH	¹² 🐼				~
All Research in which a					
Controlled Drug or Drugs will be Administered	Ø	Add More			
Research Project Plans for	_				
Reporting Communicable Diseases	Ø	13 ALL RESEARCH IN WHICH A CONT	ROLLED DRUG OR DRUGS WILL BE ADMINIST	TERED (ATTACH	COPY) ?
Assurances	15 🐼		gs will be administered must upload a copy of the A Form 223) under which the research project will		
		Select this checkbox if this section is not appl	licable (n/a) to your application:		
		* Upload Scanned Copy Of The DEA Form:		Browse	

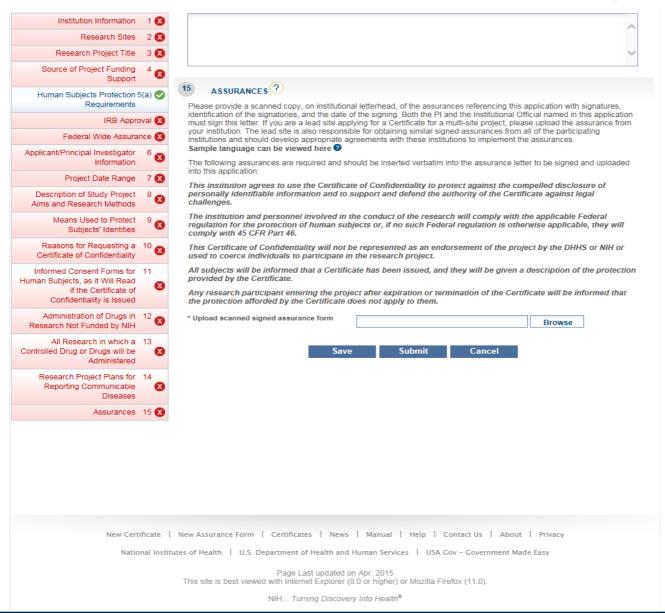


CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (14 TO 15)

Institution Information	1 🐼	14 RESEARCH PROJECT PLANS FOR REPORTING COMMUNICABLE DISEASES ?				
Research Sites	2 🗴	If the research project is testing for reportable communicable diseases, the applicant must submit information relating to its plans for working with State and local authorities as specified in the August 9, 1991 memorandum from the Assistant				
Research Project Title	3 🐼	Secretary for Health (http://grants.nih.gov/grants/policy/coc/cd_policy.htm).				
Source of Project Funding	4 🗙	Select this checkbox if this section is not applicable (n/a) to your application: \Box				
Support	•	* Plans for Reporting Communicable Diseases (you have 1000 characters remaining)				
Human Subjects Protection Requirements	5(a) 🕢	^				
IRB Appro	oval 🔇					
Federal Wide Assura	nce 🔇					
Applicant/Principal Investigator Information	⁶ ⊗	15 ASSURANCES ?				
Project Date Range	7 🐼	Please provide a scanned copy, on institutional letterhead, of the assurances referencing this application with signatures,				
Description of Study Project Aims and Research Methods	8 🐼	identification of the signatories, and the date of the signing. Both the PI and the Institutional Official named in this application must sign this letter. If you are a lead site applying for a Certificate for a multi-site project, please upload the assurance from your institution. The lead site is also responsible for obtaining similar signed assurances from all of the participating institutions and should develop appropriate agreements with these and should develop appropriate agreements with these institutions and should develop appropriate agreements with these institutions and should develop appropriate agreements.				
Means Used to Protect Subjects' Identities	9 🐼	institutions and should develop appropriate agreements with these institutions to implement the assurances. Sample language can be viewed here The following assurances are required and should be inserted verbatim into the assurance letter to be signed and uploaded				
Reasons for Requesting a Certificate of Confidentiality	10 🐼	into this application: This institution agrees to use the Certificate of Confidentiality to protect against the compelled disclosure of				
Informed Consent Forms for	11	personally identifiable information and to support and defend the authority of the Certificate against legal challenges.				
Human Subjects, as it Will Read if the Certificate of Confidentiality is Issued	&	The institution and personnel involved in the conduct of the research will comply with the applicable Federal regulation for the protection of human subjects or, if no such Federal regulation is otherwise applicable, they will comply with 45 CFR Part 46.				
Administration of Drugs in Research Not Funded by NIH	12 🐼	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.				
All Research in which a Controlled Drug or Drugs will be Administered	13	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. Any research participant entering the project after expiration or termination of the Certificate will be informed that				
Research Project Plans for Reporting Communicable Diseases	14	* Upload scanned signed assurance form Browse				
Assurances	15 🔀					
		Save Submit Cancel				



CERTIFICATE OF CONFIDENTIALITY ONLINE APPLICATION FORM – DETAILED VIEW (15 WITH FOOTER)





THANK YOU

NET ESOLUTIONS CORPORATION (NETE)

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