Supporting Statement A for

Electronic Application for NIH Certificates of
Confidentiality (CoC E-application System)
OMB#: 0925-0689
Expiration Date: 1/31/2017

Request for OMB Extension
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Certificates of Confidentiality provided research participants with an additional layer of protection by allowing researchers with a CoC to refuse compelled disclosure of identifying information about participants. NIH, through its 24 funding Institutes and Centers (ICs), has issued Certificates of Confidentiality since 1997 to researchers who request this protection. In 2015, to imporve the efficency of the CoC process, NIH launched an on-line application system for researchers to request a CoC from all the NIH ICs. The system allows researchers to submit an application with all required documentation, track its status and receive automatic email alerts when the status changes. It also allows NIH staff to move the application through each IC's review and approval process, to generate the Certificate for IC signature, to maintain a record of all CoC requests and to generate basic system metrics.

LIST OF ATTACHMENTS:

Attachment 1 - NIH Certificate of Confidentiality (CoC) Application form ("Attach 1 CoC online application form (pdf version)

Attachment 2 – List of HHS CoC Coordinators who have been kept informed about the NIH CoC Application System

A.1   Circumstances Making the Collection of Information Necessary

The successful recruitment of human research subjects into NIH funded studies is critical to the success of the agency's mission to enhance health, lengthen life, and reduce the burdens of illness and disability. However, human research subjects are often concerned about the confidentiality of the information, including biosamples that they provide to researchers. This situation can make it difficult to recruit subjects, particularly for research projects on sensitive topics. Recognizing this problem, in 1970, Congress enacted legislation to permit the Department of Health and Human Services (DHHS) to issue Certificates of Confidentiality (CoCs) to authorize covered researchers to protect the privacy of research subjects by withholding their names and other identifying characteristics from those not connected with the research. The legislation was initially limited to research on the use and effect of drugs. Since then, the scope of the CoC legislation has been expanded several times, most recently in 1988 when it was expanded to include "biomedical, behavioral, clinical, and other research" (see Section 301(d) of the Public Health Service Act, 42 U.S.C. §241(d)). The regulations that describe DHHS implementation of this authority are codified at 42 CFR Part 2a. In 1997, DHHS delegated the authority to issue CoCs to NIH and the other DHHS agencies that fund research. The Director of NIH further delegated this authority within NIH to the individual NIH Institutes and Centers (ICs). NIH's Office of Extramural Research (OER) is responsible for coordinating this activity across NIH.

The CoC regulations at 42 CFR Part 2a describe the required content of applications to DHHS for CoC protection. In addition, the regulations make clear that DHHS funding is

not required to apply for a CoC. Within DHHS, NIH is the main agency that issues CoCs

for research projects that are not federally funded; other agencies either only issue CoCs

for research they fund or for research that clearly falls within their legislated jurisdiction

(FDA). Within NIH, CoC's are issued by the individual NIH ICs, either for research they

fund or for research that is similar to the research an IC supports. With the goal of having

a consistent application process across NIH, the Office of Extramural Research at NIH

developed an online application system. OMB approval was obtained for this application

system in 2014 (OMB No. 0925-0689, expiration 01/31/2017) and the system was

launched in early 2015.

In the past, NIH has issued approximately 800-1000 CoCs each year. The new online

system launched in 2015 has improved the efficiency of requesting a CoC through the use

of a standard, electronic application system that is used by all researchers who wish to

obtain a CoC from NIH. This electronic submission system can be accessed through the

internet and has benefits for both requestors and NIH staff involved in the issuance of

CoCs. Additionally, it has enabled the production of basic program metrics on a routine

basis to help ensure efficient service to research organizations seeking this protection. In

the FY2016 omnibus bill that funded NIH, Congress included language to require that all

new and competing research projects funded by NIH that are designed to "generate and

analyze large volumes of data derived from human research participants" obtain a CoC.

NIH is discussing options for implementing this language with HHS officials. For the

purposes of this OMB clearance request, NIH estimates this new requirement will

increase CoC applications by about 30%.

A.2   Purpose and Use of the Information Collection

The information collected via the electronic CoC application system is used by the NIH IC's to determine eligibility for a CoC and to help create the actual Certificate that will be issued to the requesting organization; see Attachment 1 for a PDF version of current application form. Additionally, the system assists NIH staff with the administrative management of requests, for example, by tracking progress of requests and key dates (receipt of request, issuance of CoC, expiration dates). Additionally, OER uses the data from the system for routine internal program monitoring for NIH. Between the time that OER obtained OMB approval for this application system in January 2014 and its launch in April 2015, OER continued system development, testing, and refinement, developed manuals for users, trained NIH staff in its use, and completely revised our public CoC internet site to guide users in the use of this new system. Between system launch in 2015 and June, 2016, NIH has received 944 applications and issued 872 CoCs in response, figures which are comparable to other years.

A.3   Use of Information Technology and Burden Reduction

The CoC application is electronic; researchers access it from the CoC public internet site (http://grants.nih.gov/grants/policy/coc/). The application only requests information that is required by the CoC regulations to determine eligibility for a CoC and enables required documents (such as the signed assurance form) to be uploaded to the application. This system reduces the burden on the investigators by enabling the entire request to be done electronically. Since most NIH research grant applications are submitted electronically

and communication between NIH and researchers is done through the NIH electronic research administration (eRA) system, researchers are quite able to use electronic research application and information systems.   The system also keeps applicants informed about the status of their request through automatic notifications when applications are received and when NIH has made a determination regarding an application (CoC issued or request denied with explanation for denial); the system also provides a summary listing of all the requestor's CoC applications at login.

The CoC application information submitted to NIH is maintained on protected NIH servers and will be accessible only to NIH staff involved in CoC administration. Each IC is able to administer permissions to access the system within the IC. Within OER, only the NIH CoC Coordinators have access to the system.

The required Privacy Impact Assessment (PIA) is pending and will be submitted prior to the final OMB approval request.

A.4   Efforts to Identify Duplication and Use of Similar Information

The proposed electronic CoC application is the only CoC application system for researchers applying for a CoC to NIH.   NIH issues CoCs for research that is NIH-funded and also for non-federally funded research that is relevant to the mission of DHHS.   The CoC-issuing DHHS agencies other than NIH each have their own CoC application processes.

A.5   Impact on Small Businesses or Other Small Entities

Only small businesses that are conducting research would potentially apply for a CoC.

We estimate that 10% of requests to NIH for a CoC will be from small business entities.

We only require the minimum amount of information necessary in all CoC applications

to make a determination about eligibility. The procedure for and the burden associated

with a CoC application for small businesses that are conducting research would be the

same as for other research organization that wants to request a CoC from NIH. The

impact on small business or other small entities is anticipated to be negligible.

A.6   Consequences of Collecting the Information Less Frequently

The information collected with the on-line application is a onetime collection to request a

CoC for a specific research project. Applications to NIH for a CoC are submitted as

necessary to obtain a CoC. There are no application deadlines.

A.7   Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances related to the electronic CoC application.

**A.8   Comments in Response to the Federal Register Notice and Efforts to Consult
        Outside Agency**

8A Federal Register Notice:

An announcement was published in the Federal Register on August 18, 2016 (Document number:

2016-19523, pages 81 FRN 55207-55208) for public comment on the intent to extend this data

collection system, thereby providing the research community with the opportunity to provide input into it. No comments were received.

8B Efforts to Consult Outside the Agency:

The status and continued development of the NIH CoC electronic application system has been discussed with the other DHHS agencies which issue CoCs at the regular bi-annual coordinators meeting held since late 2012 (see Attachment 2 for a list of these agency CoC Coordinators with contact information)

A.9   Explanation of Any Payment of Gift to Respondents

Not applicable; we do not pay applicants to apply for a CoC.

A.10   Assurance of Confidentiality Provided to Respondents

No assurance of confidentiality is provided to respondents.

Applicants log into the on-line application system using NIH's single sign-on (SSO) which allows users to sign on using an Open ID login that they create through either Google or Pay Pal. The users are responsible for managing their login information and resolving any login issues (such as forgotten passwords) either through the Open ID login. Having a secure login service allows applicants to save their application in draft before submission if they desire and also allows them to track the status of applications after submission. After logging in, applicants are able to view a list of prior applications and their statuses (pending NIH review, under review, CoC issued, or CoC request denied). They are also able to start an application for a new CoC request.

The information collected in the NIH CoC electronic application is maintained on a secure NIH sever and requires the use of NIH login for access. The information is only used internally and is controlled via role based access controls (i.e., only IC and OER staff involved in CoC administration have permission to access the application information). Both the NIH COC Coordinator and the IC Coordinator are able to grant access to other IC staff involved in CoC administration system. The same NIH security standards are applied to the CoC application information as to other grant information that NIH maintains.

A.11   Justification for Sensitive Questions

The application collects only information as required by the authorizing legislation to help NIH determine whether the applicant is eligible for a CoC and for administrative purposes. The information collected related to the PI and requesting institution is information that would be available publicly; there is no sensitive information collected.

A.12   Estimates of Hour Burden Including Annualized Hourly Costs

We estimate that starting in 2017, NIH will receive approximately1300 new requests for CoCs each year. Based on our experience testing the online system and comments from system users, we estimate that each application takes 90 minutes to complete, including time needed to gather the necessary documents. Based on application submitted between January 1 and March 31, 2016, we estimate that 35% of requests will be from private research institutions and organizations, 5% will be from state/local research

institutions/organizations, 10% will be from small business research organizations, and 5% will be from federal research organizations such as the VA.

Regardless of the type of research organization, applications are generally completed by researchers or research staff. The hourly wage rate used for all burden hours ($36) was estimated as an average of the mean hourly wage figures published in May 2015 by the Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm#19-0000) for the following occupational categories: life/physical/and social science technicians and research assistants ($23), life scientists ($39), social scientists ($38) and medical scientists ($45)

A.12 - 1 ESTIMATES OF HOUR BURDEN				
Type of Respondents	**Number of Respondents**	**Frequency of Response**	**Average Time per Response**	**Annual Hour Burden**
CoC Applicants-Private	455	1	90/60	683
CoC Applicants-State/local	650	1	90/60	975
CoC Applicants-Small business	130	1	90/60	195
CoC Applicants-Federal	65	1	90/60	98
Total	1,300	1300		1951

A.12 - 2 ANNUALIZED COST TO RESPONDENTS*

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Respondents	Hourly Wage Rate*	Respondent Cost
Researcher	1300	1	90/60	$36	$70,200

*source: May 2015 Bureau of Labor Statistics (http://www.bls.gov/oes/current/oes_nat.htm#19-0000)

A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no special requirements for using the online CoC application system beyond internet access. Thus, there are no other costs to users.

A.14. Annualized Cost to the Federal Government

Cost Descriptions	Grade/Step	Annual Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
NIH Extramural CoC Coordinator	GS 15-9	$158,700	10		$15,870
Contractor Cost					$22,000
Travel					
Other Cost (NIH IT security scan)					$5000
TOTAL					$42,870

A.14   Annualized Cost to the Federal Government

The total costs to the Federal Government for the next three years of the CoC electronic application system is $128,620. This includes the costs of correction of minor system problems ($10,000 per year) and annual maintenance costs ($12,000 per year), annual NIH IT security assessment costs ($5,000 per year), and 10% annually of a GS15-9 FTE for oversight ($15,870 per year). The average annual cost for the 3-year period is $42,870.

A.15   Explanation for Program Changes or Adjustments

There are no changes planned to the system for the next 3 years. This extension clearance is being submitted as an adjustment. Total burden hours have increased from the last submission due to the overall increase in the number of applications anticipated.

A.16   Plans for Tabulation and Publication and Project Time Schedule

NIH will only use the application information to tabulate internal statistics for administrative purposes only. No publications of this information are planned.

A.16 - 1 Project Time Schedule	
Activity	**Time Schedule**
Continue to make researchers aware of on-line application system for all CoC requests to NIH	ongoing
Continue to enable system access for researchers who wish to request a CoC	ongoing
Monitor system and correct any unrecognized system errors	ongoing
Tabulate annual system administrative metrics for internal NIH use	annually

A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

Not Applicable; we are not seeking a waiver of this requirement.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

This is not applicable to our request.