Supporting Statement A for

Electronic Application for NIH Certificates of Confidentiality (CoC E-application System)

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LIST OF ATTACHMENTS:

Attachment 1 - NIH Certificate of Confidentiality (CoC) Application form ("Attach 1 CoC online application full form Aug 22 2013 version.pdf")

Attachment 2 - List of DHHS Agency CoC Coordinators informed about NIH's plan to create an on-line application system

A.1 Circumstances Making the Collection of Information Necessary

The 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 potential negative consequences of access to their research data by individuals outside the research team. This situation can make it difficult to recruit subjects 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 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. Currently, researchers who wish to obtain a CoC from NIH provide the appropriate NIH IC with a request containing the required information for review and approval. Less than half of the 24 NIH ICs that issue CoCs allow (but do not require) researchers to submit their request electronically while the other ICs rely on email and mailed requests. Because requests are initiated by researchers and there has been no standard application form to be filled out, OMB clearance was not considered necessary for CoC requests to DHHS prior to 1997 or for requests submitted to the DHHS agencies since that time.

Annually, NIH issues approximately 1000 CoCs. NIH is proposing to improve the efficiency of requesting a CoC through the use of an electronic application system that will be used by research organizations that wish to obtain a CoC from NIH. An electronic submission system that can be accessed through the internet will be of benefit both to requestors and NIH staff involved in the issuance of CoCs. Additionally, it will enable the production of basic program metrics on a routine basis to ensure efficient service to research organizations seeking this protection.

A.2 Purpose and Use of the Information Collection

The information to be collected via the electronic CoC application system will be 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 copy of the application form. Additionally, the system will assist 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 will use the data from the system for routine internal program monitoring for NIH.

A.3 Use of Information Technology and Burden Reduction

The CoC application will be electronic; researchers will access it from the CoC public internet site (http://grants.nih.gov/grants/policy/coc/). The application only requests required information as described in the regulations that is needed to determine eligibility for a CoC. The system will be used for all CoC requests to NIH. It will be more efficient for the requesting organizations and will improve NIH's efficiency in issuing this important research protection. The system will allow required documents (such as consent forms and the signed assurance) to be uploaded to the application. This capability will reduce the burden on the investigators from having to mail signed assurance forms as they currently do. 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 will

facilitate email communication with applicants by 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). Furthermore, the system will allow applicants to track the status of their applications through the planned login (see A-10).

The CoC application information submitted to NIH will be maintained on protected NIH servers and will be accessible only to NIH staff involved in CoC administration. The NIH CoC Coordinator in OER will administer the permissions to access the system.

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

The proposed electronic CoC application will be 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. Other DHHS agencies, including CDC, HIS, SAMHSA, and HRSA issue CoCs only for research they support. The FDA can issue CoCs for clinical research for which the FDA has oversight responsibility (for example, clinical trials being conducted under an IND). The 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 only about 5% 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 placed in the Federal Register, Vol. 78, No. 82, April 29, 2013 page 25090 for public comment on this data collection system, thereby providing the research community with the opportunity to provide input into the proposed electronic CoC application system. NIH also placed a link to the notice on our informational website for Certificates of Confidentiality (http://grants.nih.gov/grants/policy/coc/). No comments were received.

8B Efforts to Consult Outside the Agency:

The development of an NIH CoC electronic application system was discussed with the other DHHS agencies which issue CoCs at the regular bi-annual coordinators meeting held on November 7, 2012. See Attachment 2 for a listing of the CoC coordinators at other DHHS agencies who either attended this meeting or received minutes of this meeting.

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 will log into the on-line application system using NIH's single sign-on (SSO) which allows users to sign on either through an Open ID login that they create through a variety of options (such as, Google, Yahoo, VeriSign) or through the Federated Research Institution login if their institution is set up in this manner with NIH. The users are responsible for managing their login information and resolving any login issues (such as forgotten passwords) either through the Open ID login provider or their institution (if using a Federated Research Institution login). Having a secure login service will allow applicants to save their application in draft before submission if they desire and will also allow them to track the status of applications after submission. After logging in, applicants will be able to view a list of prior applications and their statuses (pending NIH

review, under review, CoC issued, or CoC request denied). They will also be able to start an application for a new CoC request.

The information collected in the NIH CoC electronic application will be maintained on a secure NIH sever and will require use of NIH login for access. The information will be only used internally and will be controlled via role based access controls (i.e., only IC and OER staff involved in CoC administration will have permission to access the application information). The NIH COC Coordinator will have responsibility for granting system access to IC staff upon request. The same NIH security standards will be applied to the CoC application information as to other grant information that NIH maintains. The OER Privacy Officer has reviewed the request and has determined that the Privacy Act does apply and is covered under SORN 09-25-0156 published in the Federal Register Vol. 67, No. 187, September 26, 2002, page 60765. . A formal Privacy Impact Assessment (PIA) was completed and is pending Departmental approval.

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

NIH receives approximately1000 new requests for CoCs each year. Based on past experience assisting researchers who request a CoC via the current paper-based application system, we estimate that each application will take 90 minutes to complete, including time needed to gather the necessary documents. We estimate that 40% of requests will be from private research institutions and organizations, 45% will be from state/local research institutions/organizations, 5% will be from small business research organizations, and 10% 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 average hourly rate used for all burden hours ($35) represents an average of combined clerical ($15), administrative ($25), and professional staff ($45) hourly rates.

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	400	1	90/60	600
CoC Applicants-State/local	450	1	90/60	675
CoC Applicants-Small business	50	1	90/60	75
CoC Applicants-Federal	100	1	90/60	150
Total	1,000	1	90/60	1,500

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	1000	1	90/60	$35	$52,500

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

The total costs to the Federal Government for the first three years of the CoC electronic application system is $156,185. This includes the cost of development in year one ($ 80,000), annual security assessment costs ($5,000 per year), annual maintenance costs ($10,000 per year), and 7% annually of a GS15-7 FTE for oversight ($10,395 per year). The average annual cost for the 3-year period is $52,062.

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

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
Make researchers aware of new on-line application system for all CoC requests to NIH	1-2 months after OMB approval
Enable system access for researchers who wish to request a CoC	2-3 months after OMB approval
Monitor system and correct any unrecognized system errors	On-going after system is available (2+ months after OMB approval)
Tabulate annual system administrative metrics for internal NIH use	14 - 18 months after OMB approval

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

Not Applicable.