Supporting Statement A For:

cancer Biomedical Informatics Grid® (caBIG®) Support Service Provider Program **(NCI)**

Submitted by:
Center for Biomedical Informatics and Information Technology, OD
National Cancer Institute

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Table of Contents

LIST OF ATTACHMENTS

A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The National Cancer Institute (NCI), through its cancer Biomedical Informatics Grid®, or caBIG®, initiative has developed an open source, open access information network that connects the cancer research community and enables the sharing of tools and data through a common, standards-based electronic infrastructure. The caBIG® network allows investigators to answer research questions more rapidly and efficiently, thereby promising to accelerate progress in all aspects of cancer research– from etiologic research to prevention, early detection and treatment. Because the caBIG® network will provide a common unifying force that facilitates progress in cancer research, the most important beneficiaries will be cancer patients and the public at large.

The NCI Center for Biomedical Informatics and Information Technology (NCI CBIIT) conducted the caBIG® initiative first as a pilot during 2004-2006 and then launched the enterprise phase of caBIG® in early 2007 with an emphasis on widespread institutional adoption of the program and tools. This emphasis on widespread adoption has generated an expanding community with diverse needs for support, which are met largely through the resources available through the caBIG® Enterprise Support Network (ESN), including the caBIG® Support Service Provider (SSP) Program. The caBIG® SSPs provide caBIG® end-users with the freedom to match what caBIG® has to offer to their organizational needs. Each organization connecting via the caBIG® network has unique goals and a different mix of in-house resources to consider, so having this customized support option available to the community is critically important to advancing the goals of the caBIG® program.

The caBIG® SSP program was initiated in 2008 as a way to scale support services to serve the growing caBIG® community after the close of the pilot phase of the caBIG® initiative. The first request for applications was issued in April 2008, with additional application rounds following. caBIG® SSP applicants are evaluated against well-defined and published criteria and must successfully demonstrate that they have the technical capabilities, staffing and scalability, geographic coverage (when applicable), and the domain expertise in biomedicine to effectively serve caBIG® users.

The caBIG® SSP Announcement is not a procurement, and no funds are awarded to successful applicants. caBIG® SSPs are independent entities (from commercial, academic or non-profit organizations) that are approved by NCI as having met specific criteria for performance. Actual services are rendered by caBIG® SSPs to their clients under separate business arrangements organized by and between those parties only. Such contractual arrangements are independent of the NCI and the caBIG® program. Designation of the applicant as a caBIG® SSP does not constitute an endorsement of the SSPs business by NCI. Rather, the designation serves merely as an indication that the SSP has successfully complied with the evaluation criteria described in the Announcement.

Successful applicants are invited to enter into negotiations to be granted a limited license to use NCI's caBIG® program trademarks adequate to identify the applicant as a caBIG® SSP and market the caBIG® SSPs support services. Specifically, once licensed, they will be granted the right to label themselves as "Licensed caBIG® Support Service Providers" and may use that label in marketing and other communications in connection with the caBIG® program. NCI CBIIT collects information based on eligibility criteria described below in Section A.2 from SSP applicants that enables NCI to determine whether such applicants are qualified to enter into

trademark license negotiations with NCI to use the caBIG® trademarks in connection with their services and become designated as caBIG® SSPs. Thus, the collection of information from SSP applicants, is critical to both ensuring that the goals and objectives of the caBIG® program will be maintained and furthered by the organizations designated as SSPs and facilitating NCI's ability to exercise appropriate stewardship of the caBIG trademarks.

The caBIG® website lists currently licensed SSPs and the services they provide and includes links to each organization's individual caBIG® SSP webpage a public electronic message board (forum) specifically designed for caBIG® SSPs and people with a need or possible interest in caBIG® SSP services (https://cabig.nci.nih.gov/esn/service_providers). caBIG® SSP customers have the ability to leave feedback regarding their experiences with the SSPs via an email address posted on the SSP website (https://cabig.nci.nih.gov/esn/service_providers?pid=primary.2006-07-07.4911641845&sid=SSP&status=True). The caBIG® ESN program management staff conducts teleconferences with caBIG® SSPs every few months to share information regarding critical caBIG® program activities and events, such as the caBIG® Annual Meeting at which caBIG® SSPs have been exhibitors and tool presenters.

In addition, licensed caBIG SSPs will provide a report annually to NCI CBIIT concerning customer satisfaction. However, NCI does not prescribe the manner in which its licensees should collect such information and NCI has no legal relationship with its licensees' customers. NCI licensees collect such information in order to demonstrate to NCI that they are complying with their quality control obligations under their existing licenses with NCI. NCI, an agency of the U.S. Department of Health and Human Services (DHHS), has worked with the DHHS Office of General Counsel (OGC) to discuss the proposed use and register the trademarks in connection

with the caBIG Support Service Provider Program. OGC reviewed the initial announcement before it was issued and thereafter the model trademark license to be used in connection with the program. As questions arise during negotiation of specific trademark licenses, NCI consults with OGC prior to agreeing to any deviations from the template license that raise legal issues. In addition, NCI works with OGC when the caBIG trademark license template needs to be updated or legal questions arise with respect to trademark management practices.

This is a request for OMB to approve this information collection as an "Existing Collection in Use without an OMB Number submission." The Public Health Service Act authorizes this information collection under the Sections 410 and 411 (42 USC *§§* 285 and 285a).

A.2 Purpose and Use of the Information

NCI CBIIT considers applications for the caBIG® SSP program in five service categories:

- Help Desk Support
- Adaptation and Enhancement of caBIG® -Compatible Applications
- Deployment Support for caBIG® Software Applications
- Documentation and Training Materials and Services
- Data Sharing and Security Framework Implementation Support Services

Applications for each service category are evaluated against the following criteria (described in more detail in ***Attachment 1****: caBIG® Support Service Provider Program Call for Applications*):

- **Technical capabilities**. The applicant must be able to demonstrate organizational expertise and the ability to comply with the technical capabilities relevant to each category in which SSP designation is sought.

- **Staffing and scalability**. Depending on the support service category in which the applicant is applying, the applicant may be asked to: document that it has sufficient

personnel currently on staff with the ability to spot issues across the domains covered by the caBIG® bundles or provide a detailed staffing and training plan; provide a staffing plan that will scale as the caBIG® program grows while maintaining service for its existing caBIG® clients

- **Geographic coverage (when applicable)**. Depending on the support service category in which the applicant is applying, the applicant must demonstrate the ability to provide: Complete US coverage across time zones within the U.S.; complete US coverage for potential deployment of on-site personnel at a client's location in at least two tiers of time- and urgency-related responsiveness

- **Domain expertise in biomedicine.** Depending on the support service category in which the applicant is applying, the applicant must demonstrate organizational expertise relevant to the service category in which SSP designation is sought.

Applicants are also asked to include proposals for assessing customer satisfaction, *i.e.*, receiving feedback from the clients they serve.

Application review teams established by NCI CBIIT determine the field of initially qualified applicants who are then notified that they may seek to enter into negotiations with NCI to become licensed to use the caBIG® trademarks. The initial determination of qualification does not guarantee that an applicant will be designated a Licensed caBIG® SSP since, as a prerequisite for the designation, a trademark license acceptable to NCI at its discretion must first be negotiated with the qualified applicant. NCI CBIIT reserves the right to limit the number of caBIG SSPs to ensure it can provide effective stewardship over the caBIG® trademarks within the available resources of the caBIG® program. Renewal of caBIG® SSP will be based on demonstrated adherence to the terms and conditions of the license and continued maintenance of high quality services, assessed in part through feedback from customers of caBIG® SSPs.

A.3 Use of Improved Information Technology and Burden Reduction

Inquiries concerning the application process and responses to the call for applications are submitted electronically in order to save time and reduce burden.

On April 27, 2011, The NCI Privacy Act Coordinator determined that a Privacy Impact Assessment (PIA) is not needed for the caBIG Support Service Program because there is no IT System associated with this information collection.

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

NCI is unable to identify similar information collected through other means.

A.5 Impact on Small Businesses or Other Small Entities

The information being requested has been held to the minimum required for the intended use.

A.6 Consequences of Collecting the Information Less Frequently

Information will be collected once upon application for review or renewal of application. Failure to collect the information will interfere with the NCI's ability to screen applicants to determine eligibility to negotiate a license with NCI to for DHHS trademarks used in connection with the caBIG program.

The announcements, or call for applications, have occurred two to three times a year, since 2008, with an open period in between to submit an application. Reviews of the applications occur at the close of the announcement.

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

No special circumstances inconsistent with the guidelines in 5 CFR 1320.5 are known.

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

The 60-Day Federal Register notice soliciting comments on this information collection prior to initial submission to OMB was published on February 11, 2011 (76 FR 7867). No public comments were received.

In addition, NCI solicited and received public input from entities interested in participating in the caBIG Support Service Providers program regarding the proposed structure of the program and evaluation criteria for prospective applicants. A Request for Information (RFI) using web-based caBIG® communication channels that was issued in September 2006 by the NCI caBIG® Program Management Contractor, Booz-Allen-Hamilton, and an informational meeting in August 2007 of invitees drawn from all respondents to the RFI and additional respondents who responded to a public posting of the meeting on the caBIG® announce list.

A.9 Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift for responding to the call for applications.

A.10 Assurance of Confidentiality Provided to Respondents

No personally identifiable will be collected from respondents but some of the information provided by applicants is considered commercial confidential information. All applications are submitted by email and stored on the secure NCI Confluence wiki. The NIH Privacy Act Officer has stated that the Privacy Act does not apply to this collection of information **(Attachment 2)**.

The Office of Human Subjects Projection (OHSR) exemption or Internal Review Board approval is not needed for this information collection since there will be no analysis or publication of the information and the collection of information is not a research activity.

A.11 Justification for Sensitive Questions

No sensitive questions are involved.

A.12 Estimates of Annualized Burden Hours and Costs

The annualized respondent's burden for record-keeping is estimated to require 24 hours for completion of a responsive application (see Table A.12-1). On average, 15 organizations are anticipated to complete the application annually.

A.12 - 1 Estimates of Annual Burden Hours

Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (MinutesHour)	Annual Burden Hours
Commercial Organizations	14	1	1440/60 (24 hours)	336
Nonprofit Organizations	1	1	1440/60 (24 hours)	24
Totals	15			360

The annualized cost burden to the respondents is estimated at $15,606.00 (see Table A.12-2). Cost estimates are based upon burden hours at an average hourly wage rate for a Computer Software Engineer of $43.35 per hour (http://www.bls.gov/oes/current/oes151031.htm).

A.12 - 2 ANNUALIZED COST TO RESPONDENTS

Type of Respondents	Form: SSP Application	Total Hour Burden	Hourly Wage Rate	Respondent Cost
Commercial Organizations	14	24	$43.35	$14,565.60
Nonprofit Organizations	1	24	$43.35	$1,040.40
			Total	**$15,606.00**

A.13 Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There is no additional cost burden to the respondents or the record-keepers.

A.14 Annualized Cost to the Federal Government

Since the applications are read and submitted electronically there are no costs to the Federal government associated with printing or distribution. The annualized cost to the Federal government for collecting, evaluating, and coordinating renewals requires 1/3 FTEs at an estimated $29,002.

A.15 Explanation for Program Changes or Adjustments

This information collection is an “Existing Collection in Use without an OMB Number." There have been seven previous announcements, request for applications, since April, 2008. NCI’s Center for Biomedical Informatics and Information Technology (CBIIT) was under the impression that since the DHHS Office of General Counsel has been involved from the

beginning, and did not mention the need for OMB clearance, that OMB clearance was not needed. It was not until April, 2010 that the NCI PRA Liaison became aware of this information collection as a result of meeting with the submitter. The submitters were told on May 25, 2010 to discontinue the request for new applications, after it was determined by NIH OPERA, that OMB clearance is needed and corrective action needed to occur. The last round of request for applications occurred with a deadline of December 2010.

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

There are no plans to publish this data for statistical use. There is an average of 2 to 3 calls for applications per year. This will resume once OMB clearance is approved.

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

The date will appear on all forms and information.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the certification statement are required by this information collection.