

SUPPORTING STATEMENT A:

**National Cancer Institute Cancer Genetics Services Directory
Web-based Application and Update Mailer (NCI)**

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Submitted by:

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TABLE OF CONTENTS

| | | |
|-----------|---|----------|
| A. | JUSTIFICATION..... | 1 |
| A.1 | Circumstances Making the Collection of Information Necessary..... | 1 |
| A.2 | Purpose and Use of the Information Collection..... | 2 |
| A.3 | Use of Improved Information Technology and Burden Reduction..... | 4 |
| A.4 | Efforts to Identify Duplication and Use Similar Information..... | 4 |
| A.5 | Impact on Small Businesses or Other Small Entities..... | 4 |
| A.6 | Consequences of Collecting the Information Less Frequently | 4 |
| A.7 | Special Circumstances Relating to the Guidelines of 5 CFR 1320.5..... | 4 |
| A.8 | Comments in Response to Federal Register Notice and Efforts To Consult Outside the Agency..... | 5 |
| A.9 | Explanation of Any Payment or Gift to Respondents..... | 5 |
| A.10 | Assurance of Confidentiality Provided to Respondents..... | 5 |
| A.11 | Justification for Sensitive Questions..... | 6 |
| A.12 | Estimates of Annualized Burden Hours and Costs | 6 |
| A.13 | Estimate of Other Total Annual Cost Burden to Respondents and Record keepers..... | 7 |
| A.14 | Annualized Cost to the Federal Government..... | 7 |
| A.15 | Explanation for Program Changes or Adjustments..... | 8 |
| A.16 | Plans for Tabulation and Publication and Project Time Schedule..... | 8 |
| A.17 | Reason(s) Display of OMB Expiration Date in Inappropriate..... | 9 |
| A.18 | Exceptions to Certification for Paperwork Reduction Act Submission..... | 9 |

Attachments

1. NCI Cancer Genetics Services Directory Web-based Application Form
2. Inclusion Criteria for Genetics Professionals
3. NCI Cancer Genetics Services Directory Web-based Update Mailer
4. Privacy Act Memo

A. Justification

A.1 Circumstances Making the Collection of Information Necessary

Legislative Authority. NCI, established under the National Cancer Act of 1937, is the Federal Government's principal agency for cancer research and training and has a direct congressional mandate to disseminate information related to cancer to the public. The National Cancer Act of 1971 broadened the scope and responsibilities of the NCI and created the National Cancer Program. Over the years, legislative amendments have maintained the NCI authorities and responsibilities and added new information dissemination mandates as well as a requirement to assess the incorporation of state-of-the-art cancer treatments into clinical practice.

The Health Omnibus Programs Extension of 1988 (Public Law 100-607, Nov. 4, 1988, 102 Stat. 3048) and its amendments require the NCI to “establish an information and education program to collect, identify, analyze, and disseminate on a timely basis, through publications and other appropriate means, to cancer patients, their families, physicians and other health professionals, and the general public, information on cancer research, diagnosis, prevention, and treatment” (Section 413 of the Public Health Service Act (42 USC § 285a-2)). Additionally, the Public Health Service Act, under the Special Authorities of the Director, also requires the NCI to “maintain and operate the International Cancer Research Data Bank, which shall collect, catalog, store, and disseminate insofar as feasible the results of cancer research and treatment undertaken in any country for the use of any person involved in cancer research and treatment in any country; and to the extent practicable, in disseminating the results of such cancer research and treatment, utilize information systems available to the public” (Section 413 (42 USC § 285a-2d

and 2e).

International Cancer Research Data Bank Branch (ICRDB). ICRDB was established in response to the Public Law 100-607_000 (see above) and has the responsibility for creating, maintaining and disseminating cancer information for the public. The Physicians Data Query (PDQ) database, which is maintained within ICRDB, contains evidence-based summaries about the treatment of adult and pediatric cancer, screening and prevention of cancer, genetics of cancer, topics related to supportive and palliative care of cancer patients, and cancer complementary and alternative medicine. Other information maintained by ICRDB and disseminated on the NCI Cancer.gov Web site includes the NCI Dictionary of Cancer Terms, the NCI Drug Dictionary, summaries about individual and combination drugs used in cancer, a list of cancer clinical trials, and the NCI Cancer Genetics Services Directory.

The ICRDB is a branch located within the Office of Communications and Education (OCE). OCE serves as the NCI's primary voice for communicating information about cancer to the Nation and OCE's mission is to effectively communicate the most up-to-date, evidence-based information related to cancer prevention, detection, diagnosis, treatment and survivorship.

A.2 Purpose and Use of the Information Collection

The [NCI Cancer Genetics Services Directory](http://www.cancer.gov/cancertopics/genetics/directory) (<http://www.cancer.gov/cancertopics/genetics/directory>) is a unique resource for cancer patients and their families who are looking for information about their family risk of cancer and genetic counseling. The Directory on NCI's Web site Cancer.gov is a searchable collection of

information about professionals who provide services related to cancer genetics. These services include cancer risk assessment, genetic counseling, and genetic susceptibility testing.

The professionals have applied to be in the directory using an online application form (**Attachment 1**) and have met basic inclusion [criteria](#) (<http://www.cancer.gov/cancertopics/genetics/directory/applicationform>) (**Attachment 2**). The NCI does not solicit applications for the Directory. The respondents find information on their own about the Directory, and voluntarily fill out the form online in order to apply.

There are currently 567 genetics professionals listed in the directory. Approximately 30 to 60 new professionals are added to the directory each year. The applicants are nurses, physicians, genetic counselors, and other professionals who provide services related to cancer genetics. The information collected on the application form includes name, contact information including email, professional qualifications, practice locations, and the area of specialization. The information is updated annually using a Web-based update mailer (**Attachment 3**) that mirrors the application form and is sent to the email address collected on the application form. There is no confirmation completed in regards to the information the respondents provide about their memberships and certifications. Collecting applicant information and verifying it annually by using the NCI Cancer Genetics Services Directory Web-based Application Form and Update Mailer is important for providing this information to the public and for keeping it current and partially fulfills a Federal mandate of the ICRDB.

A.3 Use of Improved Information Technology and Burden Reduction

The respondent's burden from this survey will result from the time spent reading the online questions and responding to them. There are no pencil and paper forms, nor do any forms need to be returned by fax or mail.

A Privacy Impact Assessment (PIA) has been completed, entered into SPORT, and is currently under review by the NCI Privacy Act Coordinator. The IT system title is, "NIH NCI Cancer Genetics Services Directory (CGSD)."

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

The data collection is designed to obtain information about individuals who offer services related to cancer genetics. The information provided in the NCI Cancer Genetics Services Directory is unique, and is not available as an online, searchable directory from any other source.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses or other small entities will be involved in this study.

A.6 Consequences of Collecting the Information Less Frequently

Collection of information on the application form is completed once by the respondent. The updates to the directory are made annually using the Web-based update mailer. Annual updates of the respondent's information allow the directory provided to the public to be current.

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

The data collection will be implemented in a manner consistent with 5 CFR 1320.5.

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

Federal Register Notice

The 60-Day Federal Register notice was published on March 15, 2011 (76 FR 14034). No comments were received.

Consultations

In 1996, when ICRDB initially developed this directory, consultations with practicing genetics professionals determined what information would be valuable to a user searching for someone with expertise in a cancer genetics related field. There have been no enhancements to the Directory since that time, so there has been no need for further consultation.

A.9 Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift for completing the application or update mailer.

A.10 Assurance of Confidentiality Provided to Respondents

Respondents fill out an application form in order to be listed in the Genetics Directory. All information collected is publicly accessible on the Cancer.gov Web site, so there is no need for confidentiality. The NIH Privacy Act office has reviewed this collection of information and it was determined that we are not collecting any personally identifiable information (PII) (**Attachment 4**).

Since this is an application form only and there is no analysis or publications, there is no need for the Office of Human Subjects Protection (OHSR) or Internal Review Board determinations. There

is no consent form used since the respondent’s contribution to the directory is voluntary and implied. Should the respondent not want their information in the directory then they are under no obligation to submit information.

A.11 Justification for Sensitive Questions

The application form and update mailer do not include any sensitive questions. Personally identifiable information (PII) is not collected as part of the application or the annual update mailer.

A.12 Estimates of Annualized Burden Hours and Costs

It is estimated that there will be approximately 30-60 applicants, as well as approximately 600 respondents to the update mailer, per year. Annualized estimates for numbers of respondents and respondent burden are presented in Table A.12-1. The total annual number of respondents is estimated at 660, with a burden of 180 hours. This amounts to an estimate of 1,980 respondents and 540 hours over the course of three years.

| Table A.12-1. Estimates of Annual Burden Hours | | | | | |
|---|---|------------------------------|------------------------------|--|----------------------------|
| Type of Respondents | Tool | Number of Respondents | Frequency of Response | Average Time per Response Minutes/Hours (Hours) | Annual Burden Hours |
| Genetics Professionals | Web-based Application Form (Attachment 1) | 60 | 1 | 30 (0.50) | 30 |
| | Web-based Update Mailer (Attachment 3) | 600 | 1 | 15 (0.25) | 150 |
| Totals | | 660 | | | 180 |

An estimate of annualized cost to respondents for the hour burden for this information collection is presented in Table A.12-2. There are no direct costs to the respondents themselves. The cost to

respondents may, however, be calculated in terms of the costs of their time spent in responding to the questions. Assuming an hourly wage of \$50.11 per hour and the annualized estimated total burden of 180 hours, the annualized cost to respondents is estimated to be \$9,020. The hourly wage rate was calculated using an average salary for health diagnosing and treating practitioners, therapists, registered nurses, physician assistants, physicians including surgeons and family and general practitioners (based on the mean U.S. hourly wage, May 2009, Bureau of Labor Statistics).

| Table A.12-2. Estimates of Annual Cost to Respondents | | | | |
|--|----------------------------|----------------------------|-------------------------|------------------------|
| Type of Respondents | Tool | Annual Burden Hours | Hourly Wage Rate | Respondent Cost |
| Genetics Professionals | Web-based Application Form | 30 | \$50.11 | \$1,503.30 |
| | Web-based Update Mailer | 150 | \$50.11 | \$7,516.50 |
| Totals | | 180 | | \$9,019.80 |

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

There are no Capitol Costs, Operating Costs, and or Maintenance Costs to respondents to report.

A.14 Annualized Cost to the Federal Government

The estimated average annual cost to the Federal government for collection of data per year is \$66,652, which amounts to a total of \$199,960 over the course of three years. Labor costs for Year 1 are computed as follows: \$65.58/hour for data entry contractors for 940 hours/year; \$35.91/hour for technical maintenance for 40 hours/year; \$28.88/hour for NCI quality assurance for 12 hours/year. Estimates for all years are escalated at 5 percent per year. Labor covers the time to prepare the database files from the submitted application and mailers and quality assurance of

records, maintain the application form and update mailer, and do quality assurance on published records.

| Table A.14-1 Annual Cost to the Federal Government | | | | | |
|---|---------------|---------------|---------------|-------------------------------------|----------------------------|
| | Year 1 | Year 2 | Year 3 | Total Costs Over Three Years | Annual Average Cost |
| Contractor for data entry | \$61,645.20 | \$64,727.46 | \$67,963.83 | \$194,336.49 | \$64,778.83 |
| Contractor for technical development and maintenance | \$1,436.40 | \$1,508.22 | \$1,583.63 | \$4,528.25 | \$1,509.42 |
| NCI Personnel | \$346.56 | \$363.89 | \$382.08 | \$1,092.53 | \$364.18 |
| Total | \$63,428.16 | \$66,599.57 | \$69,929.54 | \$199,957.27 | \$66,652.42 |

A.15 Explanation for Program Changes or Adjustments

This is an Existing Collection in Use without an OMB Number. This information collection has been ongoing since 1996 and was discontinued in February, 2011. As a result of a change in branch chiefs, the submitter was not aware that this application form and annual mailer needed OMB clearance until recently. The submitter took immediate steps to discontinue the collection of information until OMB clearance is approved.

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

There are no plans for tabulation since this is a form that does not require statistical calculations. This is an ongoing collection of information based on when applicants fill out the online application form and submit it. Once the record has been created in the database, it is published to the Directory on the Web. Publishing is done on a daily basis. Update mailers are sent to each respondent annually to keep their information current.

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

The OMB expiration date will be displayed.

A.18 Exceptions to Certification for Paperwork Reduction Act Submission

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