

Supporting Statement A For:

Specimen Resource Location (SRL) (NCI)

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Joanne Demchok

Program Director

Cancer Diagnosis Program

Division of Cancer Treatment and Diagnosis (DCTD)

National Cancer Institute

Cancer Diagnosis Program

9609 Medical Center Drive Suite 4W-444

Rockville, MD 20892-7420

Phone: 240-276-5959

Fax: 240-276-7889

peterjo@mail.nih.gov

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List of Attachments

Attachment 1 - Letters to NCI Resource Directors

Attachment 2 - Website screen shots- Resource Requirement

Attachment 3 - Annual Email Update Letter to Confirm Availability/Type of Biospecimens

Attachment 4 – NIH Privacy Act Officer Memo

A. Justification

This is a request for approval of an “Existing Collection in use without OMB Control Number.” The availability of specimens and associated data is critical to increase our knowledge of cancer biology, and to translate important research discoveries to clinical application. The discovery and validation of cancer prevention markers require access, by researchers, to quality clinical biospecimens. In response, to this need, the National Cancer Institute’s (NCI) Cancer Diagnosis Program has developed, and is expanding, a searchable database: Specimen Resource Locator (SRL). The SRL allows scientist in the research community and the NCI to locate specimens needed for their research. The SRL lists all NCI supported repositories and their links. This administrative submission is an on-line form that collects information to manage and improve a program and its resources for the use of all scientists. This submission does not involve any analysis.

A1. Circumstances Making the Collection of Information Necessary

Section 410 of the Public Health Service Act (42 USC § 285) authorizes the collection of the information. The availability of specimens and associated data is critical to increase our knowledge of cancer biology, and to translate important research discoveries to clinical application. The development of molecular technologies in cancer patients, with defined molecular abnormalities, advances identification and development of clinically useful biomarkers and diagnostic assays that guide treatment.

The discovery and validation of cancer prevention markers require access, by researchers, to quality clinical biospecimens. In response, to this need, NCI’s Cancer Diagnosis Program has developed¹, and is expanding, a searchable database: Specimen Resource Locator (SRL) <https://specimens.cancer.gov/tissue/default.htm>. The SRL allows scientist in the research community and the NCI to locate specimens needed for their research. The SRL lists all NCI supported and non-NCI supported biospecimens repositories and their links. It is not NCI’s intent to collect the biospecimens; rather the collections are descriptions of the available data that can act as a resource and be shared with researchers and scientists who are interested.

¹ The SRL was originally created in 2002 and populated with information from approximately 40 different biorepositories. In 2013, it was recognized that this is an Existing Collection in Use and thus PRA/OMB Clearance is being requested. For additional historical information regarding SRL, refer to Section A.2.

A2. Purpose and Use of the Information Collection

The SRL was originally created in 2002 and populated with information from approximately 40 different biorepositories. There was no additional information collected through 2010. In 2010, information from nine biorepositories was collected. Individuals who managed the project up until that time did not realize that PRA/OMB clearance was needed. It was in late 2013, when the program was getting ready to request information from grantees, that the Office of Communications and Education (OCE) became aware of this project and forwarded them to the NCI PRA Liaison to make a determination as to whether PRA/OMB Clearance was needed.

The information collected is used to characterize the biospecimen inventory of the respondents². The information collected allows scientist to search the database and retrieve the biopsecimens and annotation needed for their research. Currently, there are 22 participating resources that include cooperative groups, networks, consortiums, universities, and projects (https://specimens.cancer.gov/resources/#participating_resources) who have contributed information about their biospecimens inventories.

The respondents are sent an initial letter requesting they complete the information about the biospecimens in their inventory (**Attachment 1**). The letter includes a link to complete the requested information (**Attachment 2**) :

- Specimen Type: tissue, blood, DNA, RNA and more
- Preservation Method: Formalin-fixed Paraffin-embedded
- Tumor Type: carcinoma, malignant tumor, sarcoma
- Types of Annotation: demography, risk factors, treatment, family history
- Organization: academia, commercial, non-profit
- Number of specimens
- Type of collection: Cancer clinical trials, collaboration, NIH/NCI

² Respondents and biospecimens resource institutions are used interchangeably in this request. The institutions are responding on behalf of their company not themselves.

The information collected is reviewed by the Cancer Diagnosis Branch Chief, the SRL Program Director, and the administrator of the web site. The collected information is used for the management of the website to benefit the research community. Additionally, the information is available to investigators, via queries to the SRL database, seeking to locate available biospecimens by the above listed categories.

An annual update of the information will be requested by email of the respondents to ensure that the biospecimens inventory remains up to date, accurate and available (**Attachment 3**).

A3. Use of Information Technology and Burden Reduction

The use of an electronic form to gather information on the resources allows the respondent to complete the questionnaire at his/her convenience. Information Management Services Inc. (IMS), a NCI contractor, serves as the website administrator. They are contracted to provide expertise in web management, software development, and as the tissue expediter.

The NCI Privacy Act Coordinator has been consulted and determined on March 20, 2014 that no Privacy Impact Assessment (PIA) is needed.

A4. Efforts to Identify Duplication and Use of Similar Information

The SRL is a unique website that collects a list of a variety of biospecimen resources and makes them available to the scientific community. Although biospecimen resources provide a website to retrieve specimens, the SRL has a broader scope in that it is a one stop search engine that contains both NCI intramural³ and non-NCI funded biospecimen resources.

³ Intramural refers to NCI internal research staff, program and resources. This is differentiated by NCI's extramural program which funds grantees and programs outside of NCI.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved.

A6. Consequences of Collecting the Information Less Frequently

The respondent is initially be asked to complete the questionnaire and then to update the information annually thereafter. The annual updates will keep the SRL accurate and up to date on the inventory. The consequences of not updating the inventory may result in inaccurate inventory numbers, available specimens, and resources eligibility to participate in the SRL.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This project will be implemented in a manner that fully complies with Guidelines of 5 CFR 1320.5

A8. Comments in Response to Federal Register Notice and Efforts to Consult Outside Agency

The 60-day Federal Register Notice was published on April 8, 2014 (Vol. 79, P. 19345) and allowed 60 days for public comment. No comments were received.

The NCI contractor serves as the tissue expediter; an individual who assists researchers in locating resources in the event their initial search failed. Also he/she can assist researchers to identify potential collaborators when needed.

A9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be given to the respondents.

A10. Assurance of Confidentiality Provided to Respondents

No individual level data are collected but rather meta-data is collected to describe the specimen collections. Though name and contact information are collected, the biospecimen resource institutions are responding on behalf of their company not themselves and thus no personally identifiable information (PII) will be collected (**Attachment 4**).

Since this is not considered research nor will there be publications, thus Federal regulations for the protection of human subjects do not apply to this activity.

A11. Justification for Sensitive Questions

No sensitive questions or PII are being asked.

A12. Estimates of Hour Burden Including Annualized Hourly Costs

It is estimated that the annualized hour burden will be 105 hours to conduct both the initial request and an annual update (Table A.12-1). This amounts to approximately 315 hours over the three-year information collection phase. The respondents would include private sector (business or other for-profits and not-for profits institutions), State and Federal Governments. A majority of the respondents are NCI funded grantees.

Table A12-1. Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses Per Respondent	Average Burden Per Response (in hours)	Total Burden Hour
Private Sector	Initial Request	70	1	30/60	35
State Government		70	1	30/60	35

Federal Government		60	1	30/60	30
Private Sector	Annual Update	20	1	5/60	2
State Government		20	1	5/60	2
Federal Government		10	1	5/60	1
Total		250			105

The annualized estimated cost to respondents is \$2,310; which is about \$6,930 over the three-year information collection phase (Table A.12-2).

Table A12-2. Annualized Cost to Respondents

Type of Respondent	Number of Respondents	Total Annual Burden Hours	Wage Rate	Respondent Cost
Private Sector, State and Federal Governments	200	100	\$22.00	\$2,200.00
	50	5	\$22.00	\$110.00
Totals	250	105		\$2,310.00

Refer to http://www.bls.gov/oes/current/oes_nat.htm#19-0000 , for the mean hourly wage rate for Life, Physical and Social Science Technicians May, 2013.

A13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital costs, operating costs, or maintenance costs to report.

A14. Annualized Cost to the Federal Government

The annualized cost to the Federal employees is \$10,980 and for the contractors \$27,000. It is estimated that the annualized cost to the Federal Government is \$42,605; which amounts to \$127,816 over the three-year information collection (Table A.14-1).

Table A14-1 Annualized Cost to the Federal Government

Staffing	Task	Annualized Cost
NCI	Program Director, Grade 14, Step 2 (10% time for 12 months at \$109,804)	\$10,980.40
	Branch Chief, Grade 15, Step 8 (3% time for 12 months at \$154,160)	\$4,624.80
Contractor	Project Management Support, Web Management support, collecting data, sending emails, and managing data	\$27,000
Total		\$42,605.20

A15. Explanation for Program Changes or Adjustments

This is an existing collection in use without OMB Control Number, which is considered a “Change Due to Violation.” The Specimen Resource Location (SRL) was originally created in 2002 and populated with information from approximately 40 different biorepositories. In 2013, it was recognized that this database existed and thus PRA/OMB Clearance is being requested.

A16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for detailed statistical analysis of the information collected. However, descriptive analyses are used to monitor the metrics such as queries by number, tissue type, successful queries, and more.

The project time schedule can be seen in Table A16-1.

Table A16-1 Project Time Schedule

Task	Months After OMB Approval
Web start up, design, content, URL	ongoing
Presentations to Program Directors	4-6 months
Review incoming electronic applications	ongoing
Annual updates 2 times per year	ongoing

A17. Reason(s) Display of OMB Expiration Date Is Inappropriate

There is no request for exemption from displaying expiration date for OMB approval.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

These data are collected in a manner consistent with the certification statement. No exceptions are requested.