Supporting Statement A for

Specimen Resource Locator (SRL) (NCI)

OMB# 0925-0703 Expiration Date 11/30/2023

This is an extension to the original submission; all changes are highlighted in yellow.

June 8, 2023

Check off which applies:

* New
* Revision
* Reinstatement with Change
* Reinstatement without Change

X Extension

* Emergency
* Existing Collection in Use Without an OMB Number

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**Table of Contents**

A. JUSTIFICATION 1

A.1 Circumstance 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 3

A.4 Efforts to Identify Duplication and Use of Similar Information 3

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 the Federal Register Notice and Efforts to Consult Outside the Agency 4

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 5

A.12 Estimates of Hour Burden Including Annualized Hourly Costs 5

A.13 Estimates of Other Total Annual Cost Burden to Respondents or

Record Keepers 6

A.14 Annualized Cost to the Federal Government 7

A.15 Explanation for Program Changes or Adjustments 7

A.16 Plans for Tabulation and Publication and Project Time Schedule 7

A.17 Reason(s) Display of OMB Expiration Date as Inappropriate 8

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions 8

**List of Attachments**

Attachment 1 – Invitation Letter

Attachment 2 – Initial Request -Website screenshots- Resource Requirement

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

Attachment 4 – NIH Privacy Act Memo

1. **Justification**

Department of Health and Human Services (DHHS), National Institutes of Health (NIH), and National Cancer Institute (NCI) seek to obtain OMB approval to extend the Specimen Resource Locator (SRL) collection for an additional three (3) years. The availability of specimens and associated data is critical to increase our knowledge of cancer biology and to translate important research discoveries into clinical applications. 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 scientists in the research community and the NCI to locate specimens needed for their research. The SRL list non-commercial, either NCI or non-NCI-supported human biorepositories and their links. This administrative submission is an online 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 into clinical applications. The development of molecular technologies in cancer patients with defined molecular abnormalities advances the 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 developed, and is expanding, a searchable database: Specimen Resource Locator (SRL) <https://specimens.cancer.gov/tissue/default.htm>. The SRL allows scientists 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. Instead, the collections are descriptions of the available data that can act as a resource and be shared with interested researchers and scientists.

**A2. Purpose and Use of the Information Collection**

The SRL was created in 2002 and populated with information from approximately 40 different biorepositories. There was no additional information collected through 2010. In 2010, data from nine biorepositories was collected. Individuals who managed the project until then did not realize that PRA/OMB clearance was needed. In late 2013, when the program was getting ready to request information from grantees, 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 respondents[[1]](#footnote-2). The data collected allows scientists to search the database and retrieve the biospecimens and annotations needed for their research. Currently, there are 44 participating resources that include cooperative groups, networks, consortiums, universities, and projects ([https://specimens.cancer.gov/resources/#participating\_resources](https://specimens.cancer.gov/resources/%23participating_resources)) that have contributed information about their biospecimens inventories.

The respondents are sent an initial letter requesting that 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

The Cancer Diagnosis Branch Chief, the SRL Program Director, and the website administrator review the information collected. 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.

The respondents will request an annual update of the information by email to ensure that the biospecimens inventory remains current, accurate, and available (**Attachment 3**). Since the last approval, two new resources have been accrued. And no resources dropped out of the SRL—a total of 44 human biospecimen resources accrued with hundreds of collections. NCI’s Specimen Resource Locator (SRL) mission is to make human biospecimens available to the research community. The SRL is a searchable database of NCI, non-NCI resources, and non-commercial human resources that may have specimens needed for scientific research.

The NCI contractor serves as the tissue expediter, assisting researchers in locating resources if their initial search fails. Also, he/she can help researchers to identify potential collaborators when needed.

**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 their convenience. Information Management Services Inc. (IMS), an 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 intramural[[2]](#footnote-3) and non-NCI funded, non-commercial biospecimen resources.

**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 asked to complete the questionnaire and then update the information annually afterward. The annual updates will keep the SRL accurate and current on the inventory. The consequences of not updating the inventory may result in inaccurate inventory numbers, available specimens, and an accurate depiction of human biospecimen resources available for the distribution of specimens.

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

This project will be implemented in a manner that fully complies with the 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 12, 2023, Vol. 88, No. 70, P. 22049, allowing 60 days for public comment. No comments were received.

**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; instead, meta-data is collected to describe the specimen collections. Though name and contact information is collected, the biospecimen resource institutions respond on their company’s behalf, not themselves. Thus, no personally identifiable information (PII) will be collected, so it was determined that the Privacy Act would not apply to this information collection. (**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**

The annualized hour burden will be estimated to be 105 hours to conduct 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 the Private Sector ( business or other for-profits and not-for-profits institutions), State and Federal Governments.

**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 $2,535.04, about $7,605.12, over the three-year information collection phase (Table A.12-2).

**Table A12-2. Annualized Cost to Respondents**

|  |  |  |  |
| --- | --- | --- | --- |
| Type of Respondents | Total Annual Burden Hours | Hourly Respondent Wage Rate\* | Respondent Cost |
| Private Sector, State and Federal Governments | 68 | $40.21 | $2,734.28 |
| **Total** |  |  | **$2,737.28** |

\*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 Occupations.

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

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

**A14. Annualized Cost to the Federal Government**

The annualized cost to the Federal Government is $39,712.50, amounting to $119,137.50 over the three-year information collection (Table A.14-1).

**Table A14-1 Annualized Cost to the Federal Government**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Staff** | **Grade/Step** | **Salary** | **% of Effort** | **Fringe (if applicable)** | **Total Cost to Gov’t** |
| **Federal Oversight** |  |  |  |  |  |
| Program Director | 14/10 | 172,075 | 10% |  | $17,207.50 |
| Branch Chief | 15/10 | 183,500 | 3% |  | $5,505.00 |
| **Contractor Cost** |  |  |  |  | $17,000.00 |
| Travel |  |  |  |  | $0 |
| Other Cost |  |  |  |  | $0 |
| **Total** |  |  |  |  | **39,712.50** |

\*\*The salary in the table above is cited from <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/23Tables/html/DCB.aspx>

**A15. The explanation for Program Changes or Adjustments**

This is an Extension of a currently approved submission. There are no substantive changes to this submission other than the cost of living and pay increase.

**A16. Plans for Tabulation and Publication and Project Time Schedule**

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

1. Respondents and biospecimens resource institutions are used interchangeably in this request. The institutions are responding on behalf of their company not themselves. [↑](#footnote-ref-2)
2. 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. [↑](#footnote-ref-3)