Supporting Statement A for

Specimen Resource Locator (SRL) (NCI)

OMB# 0925-0703 Expiration Date 11/30/2020

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

August 18, 2020

Check off which applies:

- New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- X Extension
- Emergency
- Existing Collection in Use Without an OMB Number

Federal Government Employee Information:

Name: Joanne Demchok, Program Director

Address: 9609 Medical Center Drive Suite 4W-444 Rockville, MD 20892-7420

Telephone: 240-276-5959

Fax: 240-276-7889

Email: peterjo@mail.nih.gov

Table of Contents

List of Attachments

A. Justification

Department of Health and Human Services (DHHS), National Institutes of Health (NIH), National Cancer Institute (NCI), seeks 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 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 list non-commercial either NCI or non-NCI supported human biorepositories 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 developed, 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.

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 respondents[1]. The information collected allows scientist to search the database and retrieve the biospecimens and annotation needed for their research. Currently, there are 42 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

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**). Since the last approval, no new resources have been accrued and 3 have dropped out of the SRL for a total of 42 human biospecimen resources accrued with hundreds of collections. The mission of NCI's Specimen Resource Locator (SRL) 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; 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.

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.

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

(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 intramural[2] 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 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 an accurate depiction of human biospecimen resources available for 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 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 June 18, 2010, Vol. 85, P. 36871 and allowed 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

[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.

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 so it was determined the Privacy Act will 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

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.

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; which is 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
State and Federal Governments	68	$37.28	$2,535.04
Total			**$2,535.04**

*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 costs, operating costs, or maintenance costs to report.

A14. Annualized Cost to the Federal Government

The annualized cost to the Federal Government is $31,681.80 which amounts to $95,045.40 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	14/7	145,578	10%		$14,557.80
Branch Chief	15/8	170,800	3%		$5,124.00
Contractor Cost					$12,000.00
Travel					$0
Other Cost					$0
Total					**$31,681.80**

**The salary in the table above is cited from https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/20Tables/html/DCB.aspx

A15. Explanation for Program Changes or Adjustments

This is an Extension of a currently approved submission. There are no substantive changes to this submission.

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.