Supporting Statement A for

NCI Genomic Data Commons (GDC) Data Submission Request Form – Center for Cancer Genomics (CCG)

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Check off which applies:

- X New
- Revision
- Reinstatement with Change
- Reinstatement without Change
- Extension
- Emergency
- Existing

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List of Attachments

Attachment 1 – GDC Data Submission Request Form

Attachment 2 – PIA

Attachment 3 – Privacy Act Memo

Attachment 4 – Automated E-mail Response

A. Justification

This is a New Information Collection Request seeking approval for 3 years. The purpose of the NCI Genomic Data Commons (GDC) Data Submission Request Form is to provide a vehicle for investigators to request submission of their cancer genomic data into the GDC in support of data sharing. The purpose is to also provide a mechanism for the GDC Data Submission Review Committee to review and assess the data submission request for applicability to the GDC mission. The scope of the form involves obtaining information from investigators that: 1) would like to submit data about their study into the GDC, 2) are affiliated with studies that adhere to GDC data submission conditions. The benefits of the collection are that it provides the needed information for investigators to understand the types of studies and data that the GDC supports, and that it provides a standard mechanism for the GDC to assess incoming data submission requests.

A.1 Circumstances Making the Collection of Information Necessary

The GDC allows investigators to request data submission into the GDC in support of data sharing. The GDC follows the NIH Genomic Data Sharing policy (GDS) (https://gds.nih.gov/03policy2.html) which provides the administrative requirement for data sharing for all NIH-funded research (grants, contracts, intramural research). In order for the GDC to support the NIH GDS, The GDC must collect information from potential data submitters to understand their genomic data management needs so that the GDC can review their needs and decide on whether their needs can be supported.

The Public Health Law Title 42 of the United States Code provides the legal authority that allows the GDC to collection this information. 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 (Sections 410 and 412 of the Public Health Service Act (42 USC § 285 and 285a-1)).

A.2 Purpose and Use of the Information Collection

The purpose of the GDC Data Submission Request Form (Attachment 1) is to provide a mechanism in which investigators can request data submission for a study into the NCI GDC. Respondents of the form are Investigators interested in submitting data from their cancer genomic studies into the GDC. Investigators will navigate to the GDC Web Site, select a link to complete the GDC Data Submission Request Form, and submit the completed form. Information in the completed form will be routed to the GDC Support System and maintained in the Kayako Help Desk Software. The principal investigator will receive an automated e-mail message (Attachment 4) providing confirmation that the data submission request was received.

Once GDC Support receives the completed form, the information will be sent to the GDC Data Submission Review Committee composed of members of the NCI and GDC subcontractor team leads. The GDC Data Submission Review Committee reviews the information on the form and makes a decision as to whether: 1) The request should be approved, 2) The request should not be approved, 3) Additional information is required. GDC Support informs the investigator of the outcome of the review. For investigators whose studies are approved for GDC Data Submission, GDC Support works with the investigators to assist them with GDC data submission. Requests that are not approved may results in recommendations to support the study data in alternative repositories.

Without this form, the GDC will have difficulties in determining in a structured fashion whether the study is applicable to cancer genomics research and whether the GDC has the available resources to support the management of study data. The GDC is currently funded through May 19, 2018 and this form is needed throughout the course of the effort.

A.3 Use of Information Technology and Burden Reduction

The GDC Data Submission Request Form (Attachment 1) will be implemented as a Web-based form and made available on the existing GDC Web Site (https://gdc.cancer.gov) which uses the Drupal Content Management System (CMS). Use of existing GDC technologies will facilitate re-use and allow investigators to review information on the GDC, supported data types, and data submission policies prior to submitting a GDC Data Submission Request Form. A PIA (Attachment 2) is attached to this application.

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

The information that is being collected is unique to the GDC as it is structured around GDC data submission processes and is not found elsewhere in the government.

A.5 Impact on Small Businesses or Other Small Entities

Small businesses or other small entities will not be impacted.

A.6 Consequences of Collecting the Information Less Frequently

This is a one-time information collection.

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

There are no special circumstances related to the guidelines of 5 CFR 1320.5 in regards to the collection of information in the GDC Data Submission Request Form.

A.8.1 Comments in Response to the Federal Register Notice

The 60-Day Federal Register notice soliciting comments was published on Monday, November 8, 2016 p. 78609 (81 FR 78609). No comments were received.

A.8.2 Efforts to Consult Outside Agency

No outside agency has been consulted

A.9 Explanation of Any Payment of Gift to Respondents

No incentives (neither payments nor gifts) will be distributed to individuals.

A.10 Assurance of Confidentiality Provided to Respondents

All information will be kept secure to the extent allowable by law. Information is collected in the Kayako Help Desk system located within the University of Chicago Data Center. The University of Chicago Data Center is FISMA Moderate compliant and operates as a Trusted Partner to the NCI. The Kayako Help Desk system is scanned on a regular basis to identify security vulnerabilities. Only designated GDC Support personnel and management have access to the Kayako Help Desk system. Information collected from the form will be reviewed by the GDC Data Submission Review Committee composed of NCI Senior Management and key members of the subcontracting team. Both GDC Support and members of the GDC Data Submission Review Committee will ensure that care is taken regarding the confidentiality of the respondents.

PII will be collected in the form of name and e-mail address of the principal investigator as well as any bioinformatician who will be assisting with data submission (Attachment 1). Once the principal investigator submits the form, an automated e-mail message will be sent to the e-mail that they providing confirming that the data submission request was received. (Attachment 4) The name and e-mail addresses will be used by the GDC Support Team in order to correspond with the principal investigator and bioinformatician regarding the outcome of the GDC's decision on whether to approve or not approve the GDC Data Submission Request. The Privacy Act is applicable as determined in the Privacy Act Memo (Attachment 3).

A.11 Justification for Sensitive Questions

The GDC Data Submission Request Form contains no sensitive questions.

A.12.1 Estimated Annualized Burden Hours

The estimated annualized burden hours is 50. There are 200 investigators that will complete the form and it will take approximately 15 minutes for the respondent to complete the form. Additional information about the annual burden is provided in the table below.

Table A.12-1 Estimated Annualized Burden Hours

Form Name	Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden Hour
GDC Data Submission Request Form (Attachment 1)	Principal Investigator	200	1	15/60	50
Total		**200**	**200**		**50**

A.12-2 ANNUALIZED COST TO RESPONDENTS

The estimated annualized costs to the respondents for completing the GDC Data Submission Request Form is $3,298 as described in the table below. The wage rate, $65.96, was calculated using the most recent data from Bureau of Labor Statistics for occupation code "19-1040" and occupation title "Medical Scientists", http://www.bls.gov/soc/2010/soc191042.htm.

Table A.12-1 Annualized Cost to the Respondents

Form Name	Type of Respondent	Total Annual Burden Hour	Hourly Wage Rate	Respondent Cost
GDC Data Submission Request Form	Principal Investigator	50	$65.96	$3,298
Total		**50**		**$3,298**

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

There are no other costs to respondents other than their time.

A.14 Annualized Cost to the Federal Government

The annualized cost to the Federal Government for the collection of data is $43,359.70. The tasks performed by Federal Personnel include reviewing GDC Data Submission Request Forms, evaluating data submission requests against the requirements and resources available in the GDC, determining whether the Data Submission Request should be accepted or not accepted, and overseeing the contractors. Contractor costs include start-up time required to develop the web-based GDC Data Submission Form and time required to perform operations and maintenance activities such as time required to review and summarize data submission requests and time required to correspond with the investigators requesting data submission into the GDC.

Table 14.1 Annualized Cost to the Federal Government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
GDC Project Officer	Grade 14/Step 9	$ 137,926	2%		$6,714.80
CCG Director	SES	$267,806.00	2%		$13,390.30
TCGA Director	Grade 15/Step 5	$145,162.00	2%		$7,258.10
OCG Director	Grade 15/Step 10	$160,300	2%		$8,015.00
Contractor Costs					
Total Capital and Start-up Cost (1st year only)					$3,400.00
Total Operations and Maintenance					$4,400.00
Total					**$43,359.70**

A.15 Explanation for Program Changes or Adjustments

This is a new information collection.

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

Results collected from the GDC Data Submission Request Form will not be published. Below is the list of activities and a timeline for making the GDC Data Submission Request Form available on the GDC Web Site.

A.16 - 1 Project Time Schedule

Activity	Time Schedule
Data Submission Request Form available on the GDC Web Site	1 week after OMB approval
Completion of review of GDC data submission requests received from investigators	2 weeks after investigator submits request

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

The GDC Data Submission Request Form will display the OMB Expiration Date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions for the GDC Data Submission Request Form.