

## Mini Supporting Statement A

National Children's Study (NCS) Vanguard Data and Sample Archive and  
Access System (NICHD)

OMB clearance #0925-0730, expiration date 2/28/2019

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**NIH/Program Official**

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## **Mini Supporting Statement A**

### **A.1 Circumstances Making the Collection of Information Necessary**

NICHD requires institutional and investigator contact information from users of the NCS Data and Sample Archive and Access System (NCS Archive). This information collected from potential data users is necessary to fulfill the requirements of their proposed research projects, ensure compliance with Department of Health and Human Services regulations for the protection of human subjects in research (45 CFR 46) and the Common Rule (45 CFR 46 Subpart A), and to document, track, and monitor the use of the NCS Archive, which provides opportunities for qualified researchers to use data and samples collected by the NCS Vanguard phase, for approved research projects. There is no plan to publish the data collected under this request other than to post on the NCS Archive website the titles of approved research projects together with project investigators' institutional affiliations.

Authority for the collection of the information requested from the submitting investigators comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289I-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the [Privacy Act System of Record Notice 09-25-0200](#) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD."

### **A.2 Purpose and Use of the Information Collection**

This is a request for substudy of a generic OMB approval for three years to allow for the collection of information from potential archive users. The primary use of this information collected from potential data users is to fulfill requirements necessary to conduct their proposed research projects, ensure regulatory compliance, and to document, track, and monitor the use of the NCS Archive.

This information is required fulfill the requirements of the proposed research projects, ensure compliance with Department of Health and Human Services regulations for the protection of human subjects in research (45 CFR 46) and the Common Rule (45 CFR 46 Subpart A), and to document, track, and monitor the use of the NCS Archive. In addition, the information will help NIH better understand the use of archived data and samples by the research community.

### **A.3 Use of Information Technology to Reduce Burden**

The NCS Archive relies on a web-based portal that enables investigators to request data access and obtain data electronically. The NCS Archive will allow for access to electronic data files and biological and environmental samples.

Data users provide basic contact information and agree to terms and conditions of data and archive use prior to accessing any data.

The NCS Data Archive has three components: a public website, an NCS Registered Website and a secure Researcher Portal.

Access to the Public Website does not require any information from the user. To access the downloadable files a user must create a user account and complete Data User Training. To access microdata the user must complete the same user account creation and Data User Training (if not already completed), then complete a Data Request form followed by a Research Materials Distribution Agreement. Specimen requests are similar, starting with a user account, Data User Training then a Sample and Data Request form followed by the Research Materials Distribution Agreement.

The NICHD Chief Information Officer issued information system security accreditation and full Authority to Operate on January 12, 2016 for the NCS Archive, the security assessment for which included a Privacy Impact Assessment.

#### **A.4 Efforts to Identify Duplication**

No similar data are gathered or maintained by the agency or are available from other sources known to the agency.

#### **A.5 Impact on Small Businesses or Other Small Entities**

N/A

#### **A.6 Consequences of Collecting the Information Less Frequently**

The information requested in the NCS Archive forms does not ask investigators to generate any new information, because the type of information being requested is fundamental to conducting any research study. The data are collected on an as needed basis. Data will be collected only once for each investigator request.

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

No special circumstances relating to the guidelines of 5 CFR 1320.5 are applicable to this request.

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

N/A

## **A.9 Explanation of Any Payment of Gift to Respondents**

No incentives have been nor will be provided to respondents.

## **A.10 Assurance of Confidentiality Provided to Respondents**

The Privacy Act of 1974 ensures that no sensitive or personally identifiable information, located in federal systems of records (e.g., Recipient NIH records), is shared. A system of records is any group of records under the control of a federal agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. The NIH and any sites that are provided access to the datasets will have access to the data collected from the Recipient (which includes personally identifiable information) for the purposes described above. In addition, the Act allows, in accordance with the routine uses made of the information stored in the system, the release of some information in the Recipient's records without his/her permission; for example, for research purposes and if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for obtaining access to data.

The information requested from the investigator seeking access to the NCS Archive, as part of the NCS Data Use Agreement, Data Request, and RMDA forms, may be made public in part or in whole for tracking and reporting purposes.

A Privacy Act Notification is displayed on the face page of the Data User Agreement, Data Request, and RMDA forms pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the [Privacy Act System of Record Notice 09-25-0200](#) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." The NIH System of Record Notice was previously published in the Federal register on September 26, 2002, Volume 67, No 187, page 60742. Although the NCS Vanguard Study data will be coded (de-identified) and the NIH will not hold direct identifiers to individuals within the NCS Archive, the agency recognizes the personal and potentially sensitive nature of NCS Vanguard Study data. All investigators who request access to NCS Vanguard Study data must be authorized by the NCS and the Federal government to receive and store study information and agree to protect participant privacy by reporting aggregate results only. Investigators and their institutions must complete an RMDA and abide by the RMDA terms.

## **A.11 Justification for Sensitive Questions**

The NCS Archive asks no sensitive questions of any prospective data users.

**A.12.1 Estimated Annualized Burden Hours**

Table 12-1 Estimated Annualized Burden Hours

Type of Respondent	Form	Number of Respondents	Frequency of Response	Average Time Per Response (hours)	Total Annual Burden Hours
Research scientists	NCS Vanguard Downloadable Data Access Form (Attachment A.1)	150	1	10/60	25
Research scientists	NCS Vanguard Data Request Form (Attachment A.2)	20	1	20/60	7
Research scientists	NCS Vanguard Specimen and Data Request Form (Attachment A.3)	10	1	30/60	5
Research scientists	Research Materials Distribution Agreement (Attachment A.4)	25	1	10/60	4
	Total	200	200		41

**A.12-2 ANNUALIZED COST TO RESPONDENTS**

Table 12-2 Annualized Cost to Respondents

Type of Respondent	Form	Estimate Total Annual Burden Hours	Wage Rate	Total Costs
Research scientists	NCS Vanguard Downloadable Data Access Form (Attachment A.1)	25	\$ 35.76	\$ 894
Research scientists	NCS Vanguard Data Request Form	7	\$ 35.76	\$ 250

	(Attachment A.2)			
Research scientists	NCS Vanguard Specimen and Data Request Form (Attachment A.3)	5	\$ 35.76	\$ 179
Research scientists	Research Materials Distribution Agreement (Attachment A.4)	4	\$ 35.76	\$ 143
	Total	41		\$ 1466

Salary/Wage Source: Bureau of Labor Statistics/Occupational Employment Statistics [May 2017 "Life, Physical, and Social Scientist"](#), occupational code 19-0000.

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

There are no additional costs other than the respondents' cost burden given in Table 12-2.

#### A.14 Annualized Cost to the Federal Government

Staff	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
<b>Federal Oversight</b>					
Program Officer	GS-14 Step 4	\$126,049	10		\$12,065
Branch Chief	GS-15 Step 4	\$148,267	5		\$7,413
<b>Contractor Cost</b>					
Technical Support		\$130,970	50	\$39,291	\$85,131
Total Annualized Cost					\$104,609

Salary/Wage Source: Office of Personnel Management [2018 General Schedule Locality Salary Table](#) for various GS-levels; Bureau of Labor Statistics/Occupational Employment Statistics [May 2017 "Computer and Information Research Scientists"](#), occupational code 15-1111, Washington-Arlington-Alexandria, DC-VA-MD-WV Metropolitan Division.

#### A.15 Explanation for Program Changes or Adjustments

N/A

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

A.16 - 1 Project Time Schedule	
Activity	Time Schedule
Data archive open to public	On OMB approval
Information collection from data users	Ongoing after data archive opens to public

There are currently no plans to publish the data collected through requests for data access other than to post on the NCS Archive website the titles of approved research projects together with project investigators' institutional affiliations. The data otherwise are for internal monitoring purposes only, to assess the archive resource requirements and for quality improvement.

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

We are not requesting an exemption to the display of the OMB Expiration date.

#### **A.18 Exceptions to Certification for Paperwork Reduction Act Submissions**

This survey will comply with the requirements in 5 CFR 1320.9.

### **Mini Supporting Statement B**

This information does not involve statistical methods.