



4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-day Comment Request; National Children's Study (NCS) Vanguard Data and Sample Archive and Access System (Eunice Kennedy Shriver National Institute of Child Health and Human Development)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Jack Moye, Jr., MD, Bldg. 6710B Rm. 2130 MSC 7002, 9000 Rockville Pike, Bethesda,

MD, 20892-7002, or call non-toll-free number (301) 594-8624 or E-mail your request, including your address to: NCSArchive@s-3.net.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the *Federal Register* on November 8, 2018, page 55905 (83 FR 55905) and allowed 60 days for public comment. No public comments were received.

The purpose of this notice is to allow an additional 30 days for public comment.

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection: National Children's Study (NCS) Vanguard Data and Sample Archive and Access System, 0925 – NEW exp. date xx/xx/xxxx, Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH).

Need and Use of Information Collection: This submission is being changed from a generic information collection request (0925-0730 exp. date 2/28/2019) to a NEW information collection request. 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. The information in addition will help NIH better understand the use of archived data and samples by the research community. 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. The data otherwise are for internal monitoring purposes only, to assess the archive resource requirements and for quality improvement.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 68.

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 Data User Agreement | 150 | 1 | 10/60 | 25 |
| Research scientists | NCS Vanguard Data Request Form | 50 | 1 | 20/60 | 17 |
| Research scientists | NCS Vanguard Data and Sample Request Form | 25 | 1 | 30/60 | 13 |
| Research scientists | Research Materials Distribution Agreement | 75 | 1 | 10/60 | 13 |

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|--|-------|-----|-----|--|----|
| | Total | 300 | 300 | | 68 |
|--|-------|-----|-----|--|----|

Dated: March 11, 2019.

Jennifer M. Guimond,

Project Clearance Liaison,

Eunice Kennedy Shriver National Institute of Child Health and Human Development,

National Institutes of Health.

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