



DATE: August 10, 2015

TO: Jack Moye, Jr., M.D.
Medical Officer, National Children's Study,
Eunice Kennedy Shriver National Institute of Child Health and Human
Development

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: National Children's Study (NCS) Vanguard Data
and Sample Archive and Access System

I have reviewed the NICHD submission to OMB referenced above which proposes to obtain approval to collect information from researchers who seek access to the NCS Vanguard study data that is securely housed in the NCS Vanguard Data and Sample Archive and Access System, or NCS Data Archive.

The NCS Data Archive will have three components: 1) a public website that will provide access to study description and documents and will require no information from the user; 2) a registered website that will provide access to downloadable datasets; and 3) a web-based researcher portal that will provide access to micro data. Both the registered website and the researcher portal will require the creation of a user account, data user training, a Data Access Request Form and a Research Materials Distribution Agreement.

Prior to accessing and receiving electronic data files, the requestor will download a Data Access Request Form and provide business contact information in order to register at the researcher portal and agree to the terms and conditions of data and archive use. The researcher can register to access additional study information, access the downloadable metadata files, and submit a proposal and request for additional study data/elements.

The researcher will then complete a Sample and Data Request Form to provide information about the proposed project, requestor, recipient and institution, as well as other details about the type of information or number and type of biological and environmental samples requested. This information is necessary to fulfill the requirements of the proposed research projects and in addition, will help NIH better understand the use of archived data and samples by the research community. If the request is approved by the NICHD Review Committee, the researcher will be given access to a secure virtual workstation in the researcher portal and a statistical and data support team member will work with the researcher to make the data available.

I have determined that the Privacy Act will not apply to this information collection because the NCS Data Archive was principally designed to allow researchers to perform a broad analysis of study data, not to retrieve information about the study participant.

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Although the NCS Vanguard study data is personal and potentially sensitive information, it will be coded (de-identified). NIH will not hold direct identifiers to individuals within the NCS Data Archive. 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, as well as agree to protect participant privacy by reporting aggregate results only. Additionally, there are currently no plans to publish the data collected through requests for data access. The data are for internal monitoring purposes only, to assess the enclave resource requirements.

If you have questions, please contact me at (301) 402-6201.



Karen M. Plá
NIH Privacy Act Officer

cc: Sarah Glavin, NICHD PRA Liaison