OMB# 0925-0730

2/28/2019

The National Children's Study Vanguard Data & Sample Request Form

Request Identifier

Request Name (required)

Create a brief title for your research plan:

Privacy Act Notification: Information collected as part of the data use agreement, data request forms, and distribution agreement may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided 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 09-25-0156 09-25-0200 (https://oma.od.nih.gov/forms/Privacy%20Documents/PAfiles/0200.htm) covering "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD." The primary uses of this information are to document, track, and monitor and evaluate the submission of data from clinical, basic, and
population-based research activities and to notify Submitters in the event a potential error in the dataset is identified or in the event of updates or other changes to the database. The Federal Privacy Act protects the confidentiality of the Submitter's NIH records. The NIH will use the information collected for the purposes described above. In addition, the Act allows the release of some information in the Submitter's records without the Submitter's permission; for example, if it is requested by members of Congress or other authorized individuals. The information requested is voluntary, but necessary

Requesting Investigator Information

Name:

Title:

Institution:

Email:

Department:

Website:

Address:

Phone (Required):

Fax:

Recipient Information

Institution type (required)

- o Non-Profit Organization
- o Commercial Organization
- o Academic
- o Government

Number of years in scientific research
Approximately how many years has the lead investigator been involved in scientific research?

- o 0-5
- o 5-10
- o 10+

Is funding currently available for this research? (required)
If yes, please upload documentation of primary funding

- o Yes
- o No

If no and funding is not yet available, please indicate anticipated primary funding source:

Specimen Shipping Information

Will the results be used for a commercial purpose? (required)

- o Yes
- o No

Shipping Address

Note: All specimens will be shipped to the account holder's address unless specified below.

FedEx Acct. #

Shipping PO #

Lab Contact Name:

Lab Contact Email:

Lab Contact Phone Number:

Request Details

Number of Specimens (required)

Approximate count of specimens required for your study.

Material Type (required)

Minimum volume (or mass if requesting DNA) (required)

Please include units

Optimum volume (or mass if requesting DNA) (required)

Please include units.

Specimen requirements

Describe any additional requirements pertaining to the biospecimens themselves, such as anticoagulant used, additives, preservatives, etc.

Subject characteristics

Describe the characteristics of the subjects to be searched for available specimens. Criteria might include gender, age, disease status, genotype, etc. Be as specific as possible.

Research Plan: Describe this request, including a summary of the rationale, main hypothesis and proposed research aims (required)

A brief overview of your research needs

Scientific background and rationale

Provide the research protocol background, objectives and hypothesis.

Analyte(s) or parameter(s) to be tested (required)

Describe the assay(s) to be performed and include any test volume requirements.

Type of assay(s)/ platform(s) to be used (required)

Describe the assay kit(s)/platform(s) to be used, if applicable

Rationale for number of biospecimens requested, including power calculations, and describe the use of covariates, if applicable (required)

Also describe your intended use of covariates from study datasets, if applicable.

Approved Users

Approved User #1

Name

Email

Approved User #2

Name

Email

Approved User #3

Name

Email

Approved User #4

Name

Email

Information Security: Please check the information security practices to be used (required)
Study data must be maintained in a secure and controlled environment

- o Institute supported, controlled access server
- o Institute supported, password protected desktop computer
- o Encrypted, password protected laptop computer
- o Encrypted portable media (encrypted external hard drive, encrypted thumb drive)
- o Encrypted portable media (encrypted external hard drive, encrypted thumb drive)

Comments

Upload checklist

- o I have uploaded Institutional sign off or a cover letter approving research
- o I have uploaded documentation of primary funding