Sister Study Proposal Application Form (PAF)

Please complete the on-line application available after logging onto Sister Study STaRS

A. ADMINISTRATIVE (For Sister Study Use) SISTER STUDY ID: |__|__|__|__|-|__|__|__|

A.1. DATE OF SUBMISSION:
|__|__| / |__|__| / |__|__|__|__|
Month Day Year

A.2.a. IS THIS A RE-SUBMISSION?
☐ YES: Provide Sister Study ID: _____
☐ NO

A.2.b. DID YOU PREVIOUSLY SUBMIT AN EARLY STUDY CONCEPT (ESC) FORM FOR THIS STUDY?
☐ YES: Provide Sister Study ID: _____
☐ NO

A.3. PROJECT TITLE:

_____

_____

A.4 CORRESPONDING INVESTIGATOR:

Name: _____ Phone: |__|__|__|-|__|__|__|-|__|__|__|__|

Affiliation ☐ NIEHS EB/BB ☐ NIEHS Other ☐ Other Fax: |__|__|__|-|__|__|__|-|__|__|__|__|

Institution: _____ E-mail: _____
Department: _____
Street: _____ Attached NIH Biosketch : ☐ Yes
City: _____ State: __ Zip: _____
Country: _____

A.5 EXPECTED TIME PERIOD FOR STUDY: From: |__|__| / |__|__|/|__|__|__|__| to |__|__| / |__|__|/|__|__|__|__|
Month Day Year Month Day Year

A.6 DO YOU HAVE HUMAN SUBJECTS APPROVAL OR WAIVER FROM YOUR INSTITUTION FOR THE PROPOSED STUDY?

☐ **Yes: Outside Institution**
Approving Institute:_____
Approval Number: _____
☐ Attached a copy of IRB approval letter

☐ **Covered under existing NIEHS IRB**

☐ **No**

☐ **Pending**: Expected date: |__|__| / |__|__| / |__|__|__|__|
Month Day Year

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A.7 DID YOU PREVIOUSLY SIGN AND SUBMIT THE SISTER STUDY DATA SHARING AGREEMENT (DSA) WITH YOUR EARLY STUDY CONCEPT APPLICATION? Before a Sister Study data set can be delivered to you, please note that there may be additional requirements (e.g., signing of data or material transfer agreements) depending on your institution. Sister Data Sharing Agreement (hyperlink on STaRS)

☐ **Yes**

Provide Sister Study ID : ___________________

☐ **No**

If No, have you printed and attached the signed DSA to your proposal?

☐ Yes ☐ No

A.8 INVESTIGATOR TEAM: Please select "Insert" to save information for each collaborator. When you are finished, please select "Save and Continue" to proceed to next section.

Name	Affiliation	Institute and Department	Role/ Contributions/ Qualifications for this Study	NIH Biosketch Attached:	Email
	☐ NIEHS EB/BB ☐ NIEHS Other ☐ Other			☐ Yes ☐ Submitted Previously ☐ Not needed (NIEHS Investigator)	
	☐ NIEHS EB/BB ☐ NIEHS Other ☐ Other			☐ Yes ☐ Submitted Previously ☐ Not needed (NIEHS Investigator)	
	☐ NIEHS EB/BB ☐ NIEHS Other ☐ Other			☐ Yes ☐ Submitted Previously ☐ Not needed (NIEHS Investigator)	
	☐ NIEHS EB/BB ☐ NIEHS Other ☐ Other			☐ Yes ☐ Submitted Previously ☐ Not needed (NIEHS Investigator)	

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B. FUNDING	
B.1 HAVE FUNDS BEEN RECEIVED FOR THIS PROJECT?	☐ Yes – Source: _____ ☐ No ☐ Not Needed
B.2 IF NOT YET FUNDED: WHAT IS THE EXPECTED SOURCE OF FUNDING FOR THIS PROJECT? (MARK ALL THAT APPLY)	☐ NIH- Institute ☐ Foundation ☐ Private corporation ☐ Existing funds ☐ Other: _____
B.3 IF NOT YET FUNDED:	Planned Submission Date to Funding Agency: |__|__| / |__|__|/|__|__|__|__| Month Day Year Project Approval Date: |__|__| / |__|__|/ |__|__|__|__| Month Day Year

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C. DETAILED RESEARCH PLAN:
Provide a detailed research plan. Address all items listed below.

C.1 ABSTRACT:
Provide a brief abstract of 300 words or less.

C.2 SPECIFIC AIMS OF THE PROPOSAL:
Provide 3-5 sentences describing each specific aim of the study including the hypotheses to be tested. Please describe each specific aim separately. In addition, please indicate the purpose of this data request (e.g. analysis for manuscript, pilot data for grant application, etc).

C.3 SIGNIFICANCE OF RESEARCH:
Provide a narrative describing the significance and the benefits this research will have to the scientific understanding of cancer/other disease processes, genetic contributors to disease, or general health.

C.4 AVAILABLE PRELIMINARY DATA REGARDING TESTING OF THE HYPOTHESIS:
Provide a brief synopsis of the current scientific understanding and data to support the study aims and hypotheses.

C.5 STUDY DESIGN, METHODOLOGY, SAMPLE SIZE AND POWER CALCULATION:
Provide a detailed description of the study design, methodology (including laboratory analyses if requesting specimens), study population, sample size, and effect size and power calculations to justify the number of participants. Each specific aim must be supported by the proposed methodology presented in this section. Include a paragraph detailing your study variables (i.e. outcome, exposure, and covariates) and statistical analysis plans.

C.6 JUSTIFICATION/SUITABILITY TO SISTER STUDY COHORT:
Given the unique design of the Sister Study, provide a specific and detailed justification on why it is an appropriate source of data or specimens to address the specific aims of this study.

C.7 REFERENCES:
Provide a list of publications supporting the scientific basis of this study.

C.8 IS THIS APPLICATION FOR AN INDIVIDUAL STUDY USING EXISTING DATA OR SPECIMENS OR A NEW STUDY REQUIRING DATA OR SPECIMEN COLLECTION AMONG PARTICIPANTS? [CHECK ONLY ONE]

- ☐ Individual study using existing data or specimens
- ☐ New study requiring data or specimen collection among participants

C.9 WHAT BEST DESCRIBES THE MAIN OUTCOME OF THE STUDY?
[MARK ONLY ONE]

- ☐ Breast Cancer
- ☐ Autoimmune Disease
- ☐ Body Size
- ☐ Cardiovascular
- ☐ Diabetes
- ☐ Gastrointestinal
- ☐ Neurodegenerative
- ☐ Psychosocial
- ☐ Reproductive
- ☐ Respiratory/Atopic
- ☐ Other Cancer (Specify) _____
- ☐ Other (Specify) _____

C.10 WHAT BEST DESCRIBES THE STUDY TYPE:
[MARK ONLY ONE]

- ☐ Descriptive
- ☐ Gene-Environment Relationship
- ☐ Biomarkers
- ☐ Analytic
- ☐ Methodology
- ☐ Other (Specify) _____

C.11 WHAT BEST DESCRIBES THE STUDY DESIGN:
[MARK ONLY ONE]

- ☐ Cohort
- ☐ Case-cohort
- ☐ Case-control
- ☐ Cross-sectional
- ☐ Other (Specify) _____

C.12 KEYWORDS:
Please select keywords to describe your proposed study (from drop-down menu). Other (Specify) options are also available.

_____
_____
_____

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D. DATA REQUEST

Create your list of **Requested Variables** in Excel using the variable checklists and documentation on the Sister Study Data Documentation website (hyperlink on STaRS). Please follow the detailed instructions on the Sister Study Data Documentation website (listed on the homepage under "Create a Data Request Variable Checklist"). Attach your list of **Requested Variables** to the Attachments tab at the end of your Proposal Application Form.

D.1 ADDITIONAL EXISTING DATA FROM LABORATORY OR OTHER SOURCE:

- ☐ Existing Laboratory Results (e.g., methylation data)
- ☐ Existing Environmental Exposure Measurements (e.g. air pollution data)
- ☐ CDC Special Survey (Sister Study participants without breast cancer)
- ☐ CDC Survivorship Survey (Sister Study and Two Sister Study participants with breast cancer)
- ☐ Other Existing Data

  Please explain: _____

D.2 HOW DO YOU WANT THE DATA SET TRANSFERRED TO YOU?

- ☐ Secure FTP
- ☐ Shared drive (NIEHS investigators only)
- ☐ CD

D.3 PLEASE SPECIFY THE FORMAT OF THE REQUESTED DATA FILE. Note: If you would like data files in multiple formats, please select "Other" and specify all requested formats.

- ☐ SAS dataset
- ☐ STATA dataset
- ☐ Other (Specify) _____

D.4 WHAT IS YOUR STUDY POPULATION?

Please provide the information below on the Sister Study participants you would like to study.

What is your sample size?	

All items must be filled. If not applicable for your study proposal, please indicate not applicable (N/A).

Age Restriction:	
Race/Ethnicity Restriction:	
Other Restriction(s):	
Please specify your Case Definition:	
Please specify your Definition of Noncases or Controls:	

Please fill in if you are planning a case-control or case-cohort analysis; otherwise indicate not applicable (N/A).

Ratio of Cases to Controls (or Subcohort):	
Please specify any matching criteria:	

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E. SPECIMENS:

E.1 DOES YOUR PROPOSAL INVOLVE THE REQUEST OF BIOLOGICAL OR ENVIRONMENTAL SPECIMENS?

☐ YES
☐ NO

Please answer the following questions in this section if you answered yes to E.1.

E.2 JUSTIFICATION/SUITABILITY TO SISTER STUDY COHORT:

Given that these specimens are a valuable and limited resource, their use requires additional justification. Include a brief 3-5 sentence description below explaining how you propose using the specimens. Include why the Sister Study is an appropriate source of specimens for your study. Attach documented proof of the laboratory assay or methodology being employed (add to your proposal using the Attachments tab).

_____

E.3 SPECIMEN REQUIREMENTS:

E.3a What biological and/or environmental specimens are required for your project? Complete the table below by checking all specimen types that apply and indicate the population size (number of subjects) and the volume needed per specimen type selected. Optimal and minimal volumes refer to assay of a single specimen. Number of duplicates desired is asked in E.6c.

Specimen Type	Population Size	Optimal Volume for a Single Specimen (in µl for blood/urine)	Minimal Volume for a Single Specimen (in µl for blood/urine)
☐ Serum			
☐ Plasma			
☐ Whole Blood (EDTA)			
☐ Whole Blood (DMSO)			
☐ Blood Clot			
☐ Lymphocytes			
☐ DNA			
☐ Blood Spot Punches			
☐ Urine			
☐ Toenails			
☐ Household Dust (alcohol wipes)			
☐ Tissue (Formalin fixed paraffin-embedded)			

E.3b Include additional comments regarding your study design (if applicable). Do selected specimen types or quantities vary according to participant characteristics? Examples of characteristics are case status, age, menopausal status, race/ethnicity, etc.

_____

E.4 SPECIMEN ANALYSIS LABORATORIES

Provide a list of all laboratories you intend to use and select the assays/tasks to be conducted at each laboratory (e.g., GWAS, methylation, etc.), from the dropdown menu. If the assay/task is not found in the dropdown menu, use the Other (Specify) option. Indicate the person responsible at the laboratory and their email address, if available. (This will assist coordination of specimen transfer, if approved.) After completing the information for a given lab, click **"Add Laboratory".** If you do not click **"Add Laboratory"**, the laboratory information will not be added to your application.

Laboratory	Assays/Tasks	Name of Person Responsible	Email of Person Responsible

E.5 SPECIMEN CONDITIONS

a. Can you accept specimens that have been previously thawed and re-frozen?

☐ YES ☐ NO ☐ DON'T KNOW

b. Can you accept specimens that had a delay between collection and processing/freezing of…

More than 30 hours? ☐ YES ☐ NO ☐ DON'T KNOW

More than 48 hours? ☐ YES ☐ NO ☐ DON'T KNOW

c. Can you accept specimens that were shipped from collection site to processing lab at a less than optimal temperature for that specimen type (e.g., serum that was not kept cold)?

☐ YES ☐ NO ☐ DON'T KNOW

E.6 SPECIMEN BATCHING AND CONTROL REQUIREMENTS

a. Do the specimens have special batching requirements before they are shipped to you?

☐ YES ☐ NO ☐ DON'T KNOW

b. Do the specimens need special labeling such as what might be needed for blinding purposes?

☐ YES ☐ NO ☐ DON'T KNOW

c. Do you require a proportion of the specimens to be duplicates for quality control purposes?

☐ YES ☐ NO ☐ DON'T KNOW

If yes, describe the number or proportion of duplicates that you need.

_____

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F. ATTACHMENTS:

Use this area to attach the following materials, as appropriate. Click **"Browse"** to select a file and then click **"Upload File"** to attach the file to your application.

All applications

- Requested Variable List (Excel file)

Other materials, as appropriate

- Signed Sister Study Data Sharing Agreement (if not previously submitted with your Early Study Concept)
- Any image or graphic that is part of the **Detailed Research Plan** (Section C). NOTE: If you attempt to enter an image/graphic into one of the **Detailed Research Plan** entry fields and it does not appear in the entry field, you must save it as a separate file (e.g. Word, PDF, Excel or PowerPoint) and upload it to the application as an attachment. Please make sure to reference the attachment in the **Detailed Research Plan** section and provide the complete file name as it appears on the Attachments page, so reviewers can identify it.
- Detailed documentation/references for all laboratory procedures that will be used on requested specimens.
- Any additional materials you think may assist reviewers to evaluate your application.