



## **EPR Specimen Sharing Agreement**

It is required that collaborators review and sign the following pledge of confidentiality prior to receiving EPR specimens. If approved, other documents may also be required such as a Memorandum for the Transfer of Human Research Materials to an NIH Intramural Laboratory, or a Human Material Transfer Agreement (MTA).

I hereby certify that I will keep completely confidential all information arising from EPR specimen data concerning individual participants to which I gain access. I also certify that I will abide by all requirements of the NIEHS Institutional Review Board (IRB) and other applicable IRBs. Beyond the research team, I will not discuss, disclose, disseminate, or provide access to specimens, data, and identifiers except as authorized in writing by the EPR Investigators. I shall use the EPR specimens only for approved purposes. I am also aware that I am responsible for the compliance of all other personnel under my supervision who have access to the specimens provided to me by the EPR. I agree to report any breaches in confidentiality to the EPR Investigators within 24 hours of their being discovered. I give my personal pledge that I shall abide by this assurance of confidentiality.

If participant contact is planned, I agree to provide quarterly reports to the EPR contractor detailing results of contact outcomes and enrollment status. If genotyping of samples is planned, I agree to submit genotype data to the EPR coordinating center within six months of completion. I will submit written progress report summarizing on-going work on data analyses, analytes measured, and/or data collected annually to the Principal Investigator.

Principal Investigator's Signature: \_\_\_\_\_

Principal Investigator's Name (Print): \_\_\_\_\_

Date: \_\_\_\_\_

**EPR CONCEPT PROPOSAL & SPECIMEN REQUEST FORM**

**1. Proposal Title:**

**2. Point(s) of contact:**

Requestor's Name:

Title:

E-Mail:

Organization:

**3. Investigators/personnel involved in the processing of specimens and analysis of the data.**

*Include names, titles, and degrees of the person(s) performing the processing of specimens and analysis of the data, the interpretation of results, and/or the writing of the resulting scientific manuscript(s) or grant(s).*

Lead investigator:

Other investigators:

Other personnel:

**4. Proposal abstract/ Request description:**

**5. Background (scientific justification for the proposed analysis):**

**6. Hypothesis(es) to be tested:**

**7. Plan for funding (include grant number and project period if appropriate):**

**8. Date specimen(s) needs to be received by requesting investigator:**

Requested Receipt Date: \_\_\_\_\_

Are you requesting specimens for an IRB approved protocol?

Yes                       No

If yes, specify protocol #: \_\_\_\_\_

A Human Material Transfer Agreement (MTA) is required for the transfers of specimens outside of NIH. Will you need a MTA?

Yes                       No

Transfers within NIH require a Memorandum for the Transfer of Human Research Materials to an NIH Intramural Laboratory. Will you need a Memorandum?

Yes                       No

**9. Specimens requested (check all that apply):**

Existing samples or new collection?  Existing     New collection (Also complete page 7)

Blood

Total Volume (Adults: up to 200mL; Minors: up to 60mL): \_\_\_\_\_ mL

DNA (1000 ng limit) requested per sample: \_\_\_\_\_ ng    Number of samples: \_\_\_\_\_

Provide rationale for request for over 50 ng/ SNP:

- Clinical labs:
  - CBC with differential
  - CBC without differential
  - Lipid Panel
  - Reticulocyte Count
  - Cortisol
  - Other: (*Specify*) \_\_\_\_\_

Skin cells 1<sup>st</sup> Location of biopsy: \_\_\_\_\_, 2<sup>nd</sup> Location of biopsy: \_\_\_\_\_  
 Total number of biopsies (up to 4 in one visit): \_\_\_\_\_ per visit  
 Total number of Visits: \_\_\_\_\_

- Hair
  - Saliva
  - Baby Teeth
  - Urine
  - Plasma
  - Serum
  - Stool
  - Induced Sputum
  - Dust
  - Sputum
  - Cheek Cells
  - Exhaled breath condensate
  - Sperm
  - Nail Clippings
  - Nasal cells
- Total number: \_\_\_\_\_

One Nare  Both Nares

Other environmental or occupational samples (ex. Receipt tape)

**10. Number and type of participants involved :**

1. **Subject Population:** Select the desired demographics of subjects.

Gender:  Female Only  Male Only  Both

Age: Specify the age range to include (must be at least 8 years old): \_\_\_\_\_

Ethnicity:  Hispanic Only  Non-Hispanic Only  Both

Race: Select all that apply.

- |   |  |
|---|--|
| <input type="checkbox"/> White  | <input type="checkbox"/> Black or African American         |
| <input type="checkbox"/> Asian  | <input type="checkbox"/> American Indian or Alaskan Native |
| <input type="checkbox"/> Native Hawaiian or<br>Other Pacific Islander |  |

**Specify the number of subjects needed in each cohort:**

*(e.g. 20 Non-Hispanic White Males and 20 Non-Hispanic Black or African American Males between 25-45 years old.)*

Cohort 1: \_\_\_\_\_ Cohort 2: \_\_\_\_\_

Total: \_\_\_\_\_ Total: \_\_\_\_\_

Cohort 3: \_\_\_\_\_ Cohort 4: \_\_\_\_\_

Total: \_\_\_\_\_ Total: \_\_\_\_\_

**2. Subject Matching:** Will subjects need to be matched based on any criteria?

Yes  No

If yes, describe the criteria on which participants need to be matched: {ex. Age (+/- 5ys), race, gender, etc.):

**11. Analytic/statistical plan (if applicable):**

Will you require data?

Yes (Please complete the EPR Data Request Form)  No

**12. Genotyping Project Overview (if applicable):**  Not Applicable

Name of gene(s) to be genotyped:

Approximate number of SNPs: \_\_\_\_\_

For each gene listed, provide a list of specific SNPs (with dbSNP rs# if available) to be genotyped and relevance to function, clinical trait or disease (if known):

Genotype prevalence (estimation) in populations, if known:

Primary and secondary outcomes:

Any other relevant supporting data:

**EPR Principal Investigator Comments:**

\_\_\_\_\_  
Signature of EPR Principal Investigator

\_\_\_\_\_  
Date

## EPR Specimen Request Form: New Collections Only

### Sample Collection, Storage and/or Transfer:

Complete the chart below for each type of specimen requested. For any column, if unknown or not applicable, enter 'UNK' or 'n/a'. If you are providing the container or processing in your lab, please also enter '(INV)'.

Sample Type	Quantity	Collection Container (include size & media, if applicable)	Special Collection Instructions	Processing Instructions	Storage Instructions
<i>Ex. Blood</i>	<i>50mL</i>	<i>Falcon tube (INV)</i>	<i>Process immediately</i>	<i>CD14 Cell Isolation</i>	<i>Freeze( -80C )</i>
<i>Ex. Blood</i>	<i>UNK</i>	<i>UNK</i>	<i>n/a</i>	<i>Ship for Clinical Labs</i>	<i>UNK</i>
<i>Ex. Skin</i>	<i>2 bx</i>	<i>Screwtop Vial containing 1 mL of Hank's buffered salt solution</i>	<i>on ice for pickup</i>	<i>(INV)</i>	<i>On Ice until pickup</i>