For Internal Use Only	
Study #:	_____
Study Type:	☐ Ancillary ☐ Collaborative ☐ Core (funded by WHI Contract) ☐ Core (externally funded)

WHI STUDY INTAKE FORM FOR CLINICAL COORDINATING CENTER PARTICIPATION AND BUDGET PREPARATION

Please provide the following information to assist the CCC in developing a scope of work and budget.

A. General

Today's Date:

1. Title of Proposal (as it will be listed on grant submission):
2. Principal Investigator:

   Institution:

   Address:

   Email:

   Phone:
3. Grants Administrator (or administrative contact):

   Email:

   Phone:
4. Sponsoring WHI PI:
5. Proposed project period (mm/dd/yy): to

B. Funding Information

1. Is this project funded (Government Agency Commitment, Core WHI funds, etc)?

   Yes ☐ Please describe: (skip to Recruitment Requirements)

   No ☐
2. Expected funding agency:

   NIH Institute (if applicable): Funding submission date:
3. Date final institutionally signed budget documents requested by
4. Program/Funding announcement number for Grants.gov:
5. Will this budget submission be:

   ☐ Modular ☐ Non-Modular ☐ Unsure

C. Recruitment Requirements

1. Is there recruitment for this study? Yes ☐ (go to 1a.) No ☐ (skip to Study Operations/Logistics)
   (*As part of basic support, WHI Regional Centers involved in recruitment for a study will have access to recruitment lists, recruitment mailing labels, and an accrual report.)*

   1a. Is CCC support needed for participant recruitment?
   Yes ☐ No ☐

   1b. Will the CCC be consenting?
   Yes ☐ No ☐

D. Study Operations/Logistics

1. Please indicate which of the following cohorts will be included and the corresponding sample sizes (mark all that apply).

Cohort	Total Number of Participants / Specimens	Number of Cases	Number of Controls
OS			
CT			
HT*			
DM*			
CaD*			
SHARe			
BMD			
MRC			
Other			

*If it does not matter which CT, there is no need to provide details for HT, DM, CaD.

2. Primary study design:

   a. Cross sectional or cohort study: Please describe eligibility criteria and sampling scheme, as appropriate:

   b. Case-Control: Please provide your definition and describe how controls will be selected:

   Case:

   Exclusion Criteria:

   How will controls be matched? ☐ Clinical center ☐ age ☐ race/ethnicity

   ☐ Other, please list:

   Number of matched controls per case:

3. Will CCC investigators or staff be involved in designing study procedures or materials?

   ☐ Yes Please describe:

   ☐ No

E. Blood Product and Urine Specimen Requirements

1. Please indicate your projected specimen requirements:

   Please note:

   - ***10% of the blood and urine sample size, and 5% of the DNA sample size will be added for QC. Please budget accordingly for assay costs.***
   - ***The CCC no longer adds padding ("dead volume") to the volume amount you are approved for. All sample volume approvals must include necessary padding.***

Type of Specimen	**N of samples**	**Volume Required**	**Time Collected (e.g.,baseline, AV3)**	**Analytes to be measured.** **Be specific, e.g., list each polymorphism separately, and list both full analyte name and abbreviation.**	**Unit of measure per analyte**	**Method of analysis per analyte***
Plasma citrate		µl				
Plasma EDTA		µl				
Serum		µl				
DNA		µg				
Urine		µl				
RBC		µl				
RNA		µg				

*Please provide copy of laboratory procedures.

2. Describe how frequently and in what budget year(s) you would like the samples provided:

   ☐ Once, please specify budget year:

   ☐ Other, please specify:

3. Please identify each lab that will be used and indicate exactly what quantities of each specimens will be sent to each lab (needed to calculate aliquoting and shipping costs)

Laboratory name, city	**Contact person, phone number, or email address**	**Amount and type of specimen**

4. Please indicate which if any of the laboratory analyses that are sensitive to freeze/thaw cycles:

5. Do you require any of the following? PLEASE CHECK THESE DETAILS WITH YOUR LAB

DNA plating	☐Yes ☐No
Multiple aliquots	☐Yes ☐No
Pooling of samples	☐Yes ☐No
Specialized sort orders or batching	☐Yes ☐No
Replacements for QNS, etc. (fallout averages 3-5%)	☐Yes ☐No

F. Data Analysis requirements

1. Will you administer any additional Food Frequency Questionnaires?

   Yes No

   (If yes, please note that additional study FFQs MAY NOT be scanned into WHIX. Please contact the Nutrition Assessment Shared Resource (NASR) 1-800-460-7270 at Fred Hutch to discuss analyzing additional study FFQs.).

2. Who will conduct data analyses for this ancillary study?

   CCC

   Other, please specify:

3. Will the study require data files from the WHI database for analysis or other purposes that are not on the WHI investigator's website?

Please note:
For studies using biologic specimens, the samples will be sent to the lab with a Draw ID. After all assays are complete and results returned to the CCC, a paper proposal has been submitted to and approved by the P&P, and a signed DDA is on file, the PI will be provided a link between lab data and Common ID.

The PI will then be required to download all data items needed for preliminary analyses, presentations and manuscripts from the WHI investigator's website (using Common ID). Data needed for P&P approved manuscripts that are not available from the website will be provided by the CCC.

☐ Yes, require data that are not available on the WHI investigator's website

a) Please be as detailed as possible, with form numbers and specific variables:

b) How often will data extracts be needed? ☐ Once ☐ Annually ☐ Other: _____

☐ No

Are there any other data requirements for this ancillary study that are not listed above?

Please describe:

G. Additional questions or comments?