|  |
| --- |
| **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):

Does this title differ from your Ancillary Study Committee approved study title? Yes  No

If ‘Yes’ does your study have any changes in specific aims? Yes  No

1. Principal Investigator:

Institution:

Address:

Email:

Phone:

1. Grants Administrator (or administrative contact):

Email:

Phone:

1. Sponsoring WHI PI:
2. 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

1. Expected funding agency:

NIH Institute (if applicable): Funding submission date:

1. Date final institutionally signed budget documents requested by
2. Program/Funding announcement number for Grants.gov:
3. 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.

1. 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?

Number of matched controls per case:

1. 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% QC will be added to the sample size for serum/plasma studies with <1,000 participantsamples and all Urine/RBC studies. 5% QC will be added to the sample size for serum/plasmastudies with ≥ 1000 participant samples and all DNA studies. 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.

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

Once, please specify budget year:

Other, please specify:

1. Please identify each lab that will be used, indicate exactly what quantities of each specimens will be sent to each lab, and indicate which lab(s) CCC will ship samples to (needed to calculate aliquoting and shipping costs).

|  |  |  |  |
| --- | --- | --- | --- |
| **Laboratory name, city** | **Contact person, phone number, or email address** | **Amount and type of specimen** | **Check box if CCC will ship samples to this lab** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

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

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

|  |  |  |
| --- | --- | --- |
| **Aliquot DNA samples for plating** | Yes  No | We aliquot DNA into tubes that are barcode-labeled with our de-identified sample IDs. Check “Yes” if your lab would instead like us to aliquot DNA samples into 96-well plates or pre racked tubes. |
| **DNA plates** | Yes  No | If plating, please check “Yes” if your lab will provide the DNA plates. |
| **Multiple aliquots** | Yes  No | Please check “Yes” if you will require multiple aliquots of the same sample (either to ship to separate labs or the same lab). For example, you are approved for a total of 200 ul and would like us to provide two aliquots of 100 ul each. |
| **Pooling of samples** | Yes  No | Please check “Yes” if you are performing pooled assays and would like us to combine samples from multiple individuals into a single vial prior to shipping to your lab. |
| **Specialized sort orders or batching** | Yes  No | We typically place the samples for cases and their matched controls next to each other (in random order), but otherwise samples are randomly distributed. If you require specialized ordering (e.g., cases before a certain year need to be in earlier runs) or batching (e.g., a set of case/control pairs must be in the same plate or run), please check “Yes”. |
| **Replacements for QNS etc. (fallout averages 3-5%)** | Yes  No | We select cases and controls based on information we have in the database. Sometimes, a case or control arrives at our processing lab with insufficient volume (quantity not sufficient - QNS). Some studies have the option of selecting back-up sets of participants that can be used to replace QNS samples. These cases and controls are selected ahead of time and the samples are sent to our processing lab to be used only in the event they are needed. Unused QNS replacements are sent back to our biorepository. If you would like this option to be available to you, please check “yes”. |

***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.).***

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

CCC

Other, please specify:

1. 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

1. Please be as detailed as possible, with form numbers and specific variables:

1. 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. IRB Considerations***

WHI-CCC requires proof of IRB from your site before releasing data/specimens. Fred Hutch IRB asks that you provide **non-exempt human subjects** IRB due to your collaboration with the CCC based on Office for Human Research Protections (OHRP) guidance. Note that federally supported **non-exempt human subjects research** must comply with the requirement for a single IRB (sIRB). Please confirm with your IRB their determination of human subjects. WHI IRB contact Jenny Schoenberg will contact you to answer any questions and provide more information: **jschoenb@whi.org**.

I will contact my IRB to confirm human subjects.

My IRB has already confirmed human subjects:

***H. Additional questions or comments?***