## WHI ANCILLARY STUDY MODIFICATION FORM



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| **SUBMIT TO:** ASC@whi.org **REFER TO**: [Application Procedures Guide](https://www-whi-org.s3.us-west-2.amazonaws.com/wp-content/uploads/AS-Application-Procedures-Guide.pdf) in [whi.org](https://www.whi.org/) |

**Today’s** **current** **date:** **Click or tap to enter a date.** (Month/Day/Year)

Study #:       Study title:

Funding agency:        Funding submission date: **Click or tap to enter a date.** (Month/Day/Year)

Project period: From **Click or tap to enter a date.** to **Click or tap to enter a date.** (Month/Day/Year)

Principal Investigator:

Is this study already funded and underway?

[ ]  No

[ ]  Yes **🡪** Please describe the stage this study is in (participant selection, lab assays in progress, statistical analysis, etc.)

**REASON FOR MODIFICATION:** *(1) Check* ***all*** *changes that apply, and (2) provide rationale at the bottom of this form.*

**GENERAL CHANGES**

1. [ ]  Study aims (Paste below from proposal.)
2. [ ]  Funding (Describe):
3. [ ]  Other (e.g., Principal Investigator, title) (Describe):
4. [ ]  Adding data and/or specimens from another cohort.
5. If this is not an existing WHI Consortium, visit the [consortium/pooling study webpage](https://sp.whi.org/researchers/SitePages/Consortia.aspx) to determine if you need to fill out the WHI Consortium Project Application Form.
6. If you are making changes to an existing WHI Ancillary Study consortium project (e.g., changes to participating cohorts), a new WHI Consortium Project Application form is not required.

**CHANGES TO BIOSPECIMENS**

1. [ ]  Sample size: [ ]  Increase [ ]  Decrease

**Please enter your new sample size below:** (Participants and participant specimens you are requesting. If applicable, please specify the number requested **for each WHI cohort.**)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Total Number of:** | **Number/****Type of Cases** | **Number of Controls/****Cohort** | **Specific cohort(s) if applicable (e.g., OS, CT\*, BMD, MRC/SRC, LILAC, NPAAS, LLS, WHISPER, WHISH, COSMOS, etc.)** | **Notes** |
| **Participants** | **Biospecimens** |  |  |  |  |
|       |       |       |       |       |       |
|       |       |       |       |       |       |
|       |       |       |       |       |       |

\* If it matters which Clinical Trial (CT) arm (HRT, DM, CaD), specify.

1. [ ]  Biospecimen usage:

[ ]  Sample amount [ ]  Sample type [ ]  Testing lab [ ]  Time point [ ]  Analyte and/or method

 ***Please enter your new sample amount, sample type, testing lab, time point, analyte(s) and/or method below:***

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Biospecimen** | **N of samples** | **Amount Required(including padding)** | **Time Collected (e.g., baseline, AV3)** | **Proposed lab and analytes (including test method) to be measured at each lab. Be specific (e.g., list both full analyte name and abbreviation)** |
| Plasma citrate |       |       µl |       |       |
| Plasma EDTA |       |       µl |       |       |
| Serum |       |       µl |       |       |
| DNA |       |       µg at       ng/µl |       |       |
| Urine |       |       µl |       |       |
| RBC |       |       µl |       |       |
| RNA |       |       µg at       ng/µl |       |       |
| Tumor tissue |       |       µl |       |       |

***NOTE****: The WHI CCC will add blind duplicate QC samples IN ADDITION TO your participant samples as follows:*

10% QC added to the sample size for serum/plasma studies with <1,000 participant samples and all Urine/RBC studies.

5% QC added to the sample size for serum/plasma studies with ≥ 1000 participant samples and all DNA studies.

*Requests for modification of blind duplicate numbers will be considered based on QC data from the testing lab for assays being performed (data from vendors will not be considered). Investigators will not be un-blinded to the identity of WHI blind duplicate QC samples until results are received at the CCC. It is expected that the laboratory include its own QC samples in addition to the WHI blind duplicates.* ***Design the study accordingly for funding and/or supplies****.*

**CHANGES TO PARTICIPANT RECRUITMENT/BURDEN**

1. [ ]  Sample size:

Indicate the new number of participants you will need. If applicable, specify the number requested **for each WHI cohort**.

|  |  |  |  |
| --- | --- | --- | --- |
| **Target enrollment** | **Estimated number needed to contact** | **Specific cohort(s) if applicable (e.g., OS, CT\*, BMD, MRC/SRC, LILAC, NPAAS, LLS, WHISPER, WHISH, COSMOS, etc.)** | **Notes** |
|       |       |       |       |
|       |       |       |       |

\* If it matters which Clinical Trial (CT) arm (HRT, DM, CaD) specify.

**8.** [ ]  New participant data or biospecimens being collected:

Describe changes to the type ofnew participant data or biospecimen to be collected for the study. If questionnaire data are to be collected from the participants, **attach a draft of the questionnaire(s).**

|  |  |  |  |
| --- | --- | --- | --- |
| **Description of type of data, questionnaire, procedure, device, and/or biospecimen to be collected** | **Estimated time in minutes to administer** | **Interviewer (I) or Self-administered (S)** | **Estimated device wear time** |
| a.       |       |       |       |
| b.       |       |       |       |
| c.       |       |       |       |

1. **Required:** Describe rationale and specifics below or on a separate page. If there are any other changes not captured above, describe.

**APPLICATION CHECKLIST (REQUIRED)**

[ ]  Completed Modification Request form (new with current date)

[ ]  Revised AS proposal (submit both below):

[ ]  With tracked changes

[ ]  Clean proposal

**IF** there will be changes to participant recruitment/burden:

[ ]  Updated draft consent form

[ ]  Updated draft study questionnaire(s)

[ ]  New/Updated DSMB [Participant Burden Summary form](https://www-whi-org.s3.us-west-2.amazonaws.com/wp-content/uploads/DSMB-ppt-burden-summary.doc)