## WHI ANCILLARY STUDY APPLICATION FORM



|  |
| --- |
| **DUE DATE:** - **1st business day of the month**. * **Minimum of 2 months before** **funding agency deadline**. Additional time will be required if there are multiple rounds of committee review.

**SUBMIT TO:** asc@whi.org **REFER TO**: [Application Procedures Guide](https://www.whi.org/doc/AS-Application-Procedures-Guide.pdf) in [whi.org](https://www.whi.org/) |

Is this a re-submission to the ASC?

[ ]  No

[ ]  Yes **🡪** Submit **BOTH**:

1. **NEW** AS Application Form, **AND**
2. Revised proposal (**both** clean and with tracked changes)

**Section 1: GENERAL QUESTIONS (Required):**

**TODAY’S** Date: Click or tap to enter a date.

**1.** Study Principal Investigator(s)\*

Name:

Phone:        Email:

Institution:

**\*IF** this is a multiple PI study, list contact MPI above and paste additional MPIs’ information below. Co-Investigators do not need to be listed.

**2.** As study Principal Investigator, what is your affiliation to WHI? **(Mark all that apply.)** For WHI Investigator or Associate Investigator definitions, see the respective hyperlinks below.

Role: [WHI Sponsoring Investigator](https://www.whi.org/sponsors) not required: [WHI Sponsoring Investigator](https://www.whi.org/sponsors) required: (Signature required on form)

[ ]  [WHI Investigator](https://www.whi.org/doc/WHI%2BInvestigator%2BCategories%2Brevised%2BMarch.2022.pdf)

[ ]  [WHI Associate Investigator](https://www.whi.org/doc/WHI%2BInvestigator%2BCategories%2Brevised%2BMarch.2022.pdf) (Qualified to
 sponsor manuscripts and ancillary studies)

[ ]  [WHI Associate Investigator](https://www.whi.org/doc/WHI%2BInvestigator%2BCategories%2Brevised%2BMarch.2022.pdf) (Qualified to sponsor manuscripts only)

[ ]  WHI staff

[ ]  No official affiliation to WHI

**3.** [WHI Sponsoring Investigator](https://www.whi.org/sponsors) (if required): [WHI Sponsoring Investigator](https://www.whi.org/sponsors) Institution:

 **4**. Are you an Early Stage Investigator [as defined by NIH](https://grants.nih.gov/policy/early-investigators/index.htm)? [ ]  No [ ]  Yes

**5.** Is this your first WHI ancillary study? [ ]  No [ ]  Yes

**6.** Study title:

**7.** Is this a pilot study? [ ]  No [ ]  Yes (Plan to submit a grant proposal using the preliminary data.)

**8.** Will you be including cohorts in addition to WHI?

[ ]  No [ ]  Yes **🡪** List all cohorts

 A [consortium/pooling project](https://sp.whi.org/researchers/SitePages/Consortia.aspx) is a research project that is developed by an organized group of scientific investigators representing various study cohorts and usually with an independent governance structure.

Answer the 3 questions below. If you answer yes to any of these questions, complete the [WHI Consortium/Pooling Project Application Form](https://www.whi.org/doc/WHI-Consortium-Pooling-Project-Application-Form.docx).

Will the consortium have an independent governance structure? [ ]  No [ ]  Yes

Will the consortium have a Publications and Presentation Committee? [ ]  No [ ]  Yes

Will the consortium have an External Advisory Board? [ ]  No [ ]  Yes

**9.** Will you be requesting any existing WHI data that is not included in the WHI investigator dataset (see [WHI Ancillary Studies Application Procedures Guide](https://s3-us-west-2.amazonaws.com/www-whi-org/wp-content/uploads/AS-Application-Procedures-Guide.pdf), Section WHI Data Available for Ancillary Studies), such as ECG, CT or MRI scans, raw nutrient data, etc.?

[ ]  No

[ ]  Yes **🡪** Describe the data you need and what you will be doing with it:

**10.** Do you plan to submit genetic data into any genetic repository database (dbGaP, etc.)? [ ]  No [ ]  Yes

(Oftentimes, this is a requirement for the funding agency. This does not affect AS approval, but allows us to determine the sample size available for your study.)

**11.** Specific aims: (Paste below from proposal.)

**12.** Does this study build upon or use data from another WHI ancillary study?

[ ]  No

[ ]  Yes **🡪** List AS #s and describe how the studies are related:

**Section 2: FUNDING QUESTIONS (Required)**

**13.** Anticipated study dates: From **Click or tap to enter a date.** to **Click or tap to enter a date.** (Month/Day/Year)

**14.** Does this study require biospecimens, specialized datasets, recruitment of participants or investigating outcomes not already in the WHI dataset?

[ ]  No [ ]  Yes **🡪** After the ASC recommends approval, you will be instructed in the ASC memo how to contact the CCC to determine if a CCC subcontract is needed. PLEASE ALLOW A **MINIMUM OF
4 WEEKS** AFTER YOU HAVE RECEIVED A MEMO FROM THE ASC INDICATING APPROVAL for the subcontract preparation process.

**15.** Will any part of this study be funded by industry or a commercial entity?

[ ]  No

[ ]  Yes **🡪** Refer to the [Ancillary Studies Policy](https://www-whi-org.s3.us-west-2.amazonaws.com/wp-content/uploads/AS-Policy.pdf) to review requirements specific to industry or commercial entities.

**16.** Do you already have funds for this project?

[ ]  No **🡪** Planned submission date to the funding agency: **Click or tap to enter a date.** (Month/Day/Year)

[ ]  Yes

**17.** What is the expected/existing source(s) of funding for this project? **(Check as many as apply and specify.)**

Funding sources must cover all costs of the study, including WHI staff time, CCC costs and full indirect rate (also known as Facilities and Administration rate)

[ ]  NIH - Institute:

[ ]  Foundation:\*

[ ]  Commercial/Industry Partner:\*

[ ]  Existing funds:

[ ]  Other:

***\*NOTE:*** *If funding source is a foundation or commercial/industry partner, you may move forward with a funding* *application only if your own institution agrees in advance to cover the difference between the capped* rat*e (often 10-20%) and the* *FHCC indirect rate of 76% for the subcontract budget.*

**Section 3: WHI BIOSPECIMEN QUESTIONS (Skip this section if you are not requesting biospecimens.)**

**18.** Indicate which study design you will use. **(Check all that apply.)**

[ ]  Cross-sectional

[ ]  Case/control

[ ]  Cohort

[ ]  Other (Describe):

**19.** Indicate the number of participants and participant biospecimens you are requesting. If applicable, 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.

**20.** Enter your biospecimen details in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Type of Biospecimen** | **N of Samples** | **Amount Required****(including padding)** | **Time Collected (e.g., baseline, AV3, LLS, any)** | **Proposed lab and analytes 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\*\* |       |       micron |       |       |

*\*Please review the* [*WHI AS Policy*](https://www.whi.org/doc/AS-Policy.pdf) *for the max volume that can be requested, and justify if request is above this value.*

*Also, for analytes that are not standard, please add the assay method, CV and information on validation.*

\*\* *If you are requesting tissue slides, indicate the thickness of slide you will need in microns.*

*NOTE:* *Per LILAC policy, tissue blocks are not released outside of the Fred Hutch Cancer Center. Block sections can be released to your lab for approved studies.*  *LILAC Executive Committee approval is required prior to WHI ASC review. Please consult with LILAC investigators.*

***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****.*

**Section 4: PARTICIPANT RECRUITMENT QUESTIONS (Skip this section if you are not recruiting participants.)**

***NOTE:*** *AS studies that involve participant burden require review by the Data and Safety Monitoring Board (DSMB). This review takes additional time (~2 weeks) after the study has received SC approval. Consider this when planning for ASC review and funding submission.*

**21.** Will you be obtaining informed consent from participants for new data collection or procedures?

[ ]  No

[ ]  Yes 🡪 Submit a draft informed consent form with your proposal.

**22.** Indicate the 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.

**23.** Describe 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).**
* **IF** devices are to be used, **provide device data security information in addition to your research plan.**

|  |  |  |  |
| --- | --- | --- | --- |
| **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.       |       |       |       |

**24.** If you will be collecting new biospecimens, fill in the details below.

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of biospecimen to be collected** | **N of participants** | **Amount collected** | **Proposed lab and analytes to be measured at each lab.Be specific (e.g., list both full analyte name and abbreviation).** |
|       |       |       |       |
|       |       |       |       |
|       |       |       |       |

**25.** Will recruitment related to this study occur at WHI Regional Center Sites other than the sponsoring PI’s Center?

[ ]  No

[ ]  Yes 🡪 How many centers are needed?       **(Attach letters or emails of support.)**

**Section 5: FINAL ITEMS (Required)**

**26.** Additional comments or information you would like the ASC to consider with your application:

**27. Application Checklist**

[ ]  Completed and signed application form with current date.

[ ]  Proposal:

- Not to exceed 12 pages, including specific aims, research plan, and tables/figures (if this is a resubmission, submit
 both a proposal with tracked changes and a clean version)

- If requesting WHI biospecimens, include details about the reliability of the lab assay(s), the selected lab’s
 proficiency with each assay, and justification for the volume requested.

**IF** this is a consortium/pooling study:

[ ]  [Consortium study application form](https://www.whi.org/doc/WHI-Consortium-Pooling-Project-Application-Form.docx)

**IF** you will be recruiting participants:

[ ]  Draft consent form

[ ]  Draft study questionnaire(s)

[ ]  DSMB [Participant Summary Burden form](https://www-whi-org.s3.us-west-2.amazonaws.com/wp-content/uploads/DSMB-ppt-burden-summary.doc) (See ***Note*** in **Section 4**.)

**IF** devices are to be used:

[ ]  Device data security information

**IF** there will be Regional Center involvement:

[ ]  Letters or emails of support

**Section 6: SIGNATURES (Required)**

**Please sign the application (required) and email to** **ASC@whi.org** **at the WHI Clinical Coordinating Center (CCC).**

**Ancillary Study Principal Investigator Signature:**

By signing this document, you confirm that you have read and agree to abide by all [WHI Ancillary Studies policies](https://www.whi.org/doc/AS-Policy.pdf) and [WHI Publications and Presentations policies](https://www.whi.org/doc/PP-policy.pdf).

Ancillary Study Principal Investigator (PI):

 Signature Date

**WHI Sponsoring Investigator Signature:**

By signing below, you confirm that:

[ ]  I have read and reviewed this Ancillary Study Application, proposal, and attachments

[ ]  I have, and will advise the study PI on [WHI AS policies](https://www.whi.org/doc/AS-Policy.pdf) and [procedures](https://www.whi.org/doc/AS-Application-Procedures-Guide.pdf).

[ ]  WHI Sponsoring Investigator not required (as indicated in **Qx. 2**.)

WHI Sponsoring Investigator:

 Signature Date