

Statement of Work for WHI Ancillary Study**SAMPLE****Fred Hutch Cancer Research Center
Women's Health Initiative (WHI) Clinical Coordinating Center (CCC)****CCC Co-Investigator responsibilities:**

- Maintain communications between ancillary study (AS) investigators and the WHI CCC.
- Monitor and oversee CCC activities.
- Assist with data reporting, data analysis and manuscript preparation as appropriate.

Statistical Research Associate responsibilities:

- Select the cases and matched controls based on matching.
- Prepare a data file with participant common IDs to allow AS PI to download and merge with data from the WHI website for approved WHI paper proposals. This file will contain results and any data items necessary for the conduct of the study, such as case/control status and matching IDs.
- Assist in data reporting as needed.

Systems Analyst/Programmer responsibilities:

- Implement blood pull mechanism for samples (creation of pull and receipt of final data).
- Problem solve, as needed, when results are received.

Study Data Coordinator responsibilities:

- Provide Fisher BioServices with a report of samples to pull.
- Coordinate transfer of sample from Fisher to the Specimen Processing Lab (SPL) and the testing lab.
- Coordinate the technical aspects of pulling and aliquoting samples.
- Oversee issues of sample selection, sample availability, aliquoting and quality control.
- Prepare/update the detailed documentation about the study's biospecimen use.
- Prepare status reports to support the routine monitoring of SPL's progress on a study's samples.
- Receive lab results, prepare for loading into the WHI database.
- Perform initial quality control checks on lab results and summarize for the WHI Lab Working Group.

Project Coordinator responsibilities:

- Communication and meetings with study investigators and CCC staff.
- Budget Monitoring and assist in resolving study-related problems.
- Institutional Review Board (IRB) Reporting.

Fisher responsibilities:

- Pull samples as defined by report provided by the WHI-CCC.
- Pack all specimen aliquots in dry ice and other suitable packing material and ship to the Specimen Processing Lab (SPL) at Fred Hutchinson Cancer Research Center (FHCRF).
- Receive returned daughter samples and place in inventory for long-term storage.
- Pull QC samples.

FHCRF Collaborative Data Services (CDS) responsibilities

- Prepare printed labels for all specimen vials.

FHCRF Specimen Processing Lab (SPL) responsibilities:

- Receive parent aliquots from Fisher BioServices.
- Extract DNA from buffy coat samples and aliquot the DNA into one daughter aliquot and two parent aliquots.
- Realiquot serum samples from each parent sample.
- Pack daughter aliquots and ship to the testing lab.
- Pack parent aliquots and return to Fisher BioServices.

NW Lipids Lab – QC testing

- Receive quality control samples and test cholesterol.