

Budget assumptions:

Sample size:

- 1,050 Buffy Coat DNA Full Extraction (1,000 samples, plus 5% QC)
- 1,050 Serum/Plasma (1,000 samples, plus 5% QC)

Budget estimate for 5 year study

Sample processing and delivery split evenly between years 1 and 2

Assumed scientific involvement in all 5 years

June 2026

DIRECT COSTS

		Year 1	Year 2	Year 3	Year 4	Year 5	Total
Personnel							
	Salary	25,764	21,449	13,066	13,458	13,862	87,599
	Fringe Benefits	8,138	6,622	3,698	3,809	3,924	26,191
Total Personnel		33,902	28,071	16,764	17,267	17,786	113,790
Purchased Services and Shared Resources							
25-Fisher BioServices Specimen Repository		2,651	2,731	0	0	0	5,382
75-BPB (Biospecimen Processing and Biorepository)		28,140	28,984	0	0	0	57,124
75-CDS Label Printing		567	584	0	0	0	1,151
25-ARDL at Uminn for QC Cholesterol Testing		425	438	0	0	0	863
Total Purchased Services and Shared Resources		31,783	32,737	0	0	0	64,520
Subtotal Direct		65,685	60,808	16,764	17,267	17,786	178,310
TOTAL DIRECT COSTS		65,685	60,808	16,764	17,267	17,786	178,310
Costs subject to indirect costs		65,685	60,808	16,764	17,267	17,786	178,310
On-site Indirect Costs (76% of direct costs)		49,921	46,214	12,741	13,123	13,517	135,516
TOTAL COSTS		115,606	107,022	29,505	30,390	31,303	313,826

		Year 1			Year 2			Year 3			Year 4			Year 5		
Title	ProjID	Cal Mos	Hrs/ Mth	ProjID	Cal Mos	Hrs/ Mth	ProjID	Cal Mos	Hrs/ Mth	ProjID	Cal Mos	Hrs/ Mth	ProjID	Cal Mos	Hrs/ Mth	
Co-Investigator	5.0%	0.60	9	5.0%	0.60	9	5.0%	0.60	9	5.0%	0.60	9	5.0%	0.60	9	
Programmer/Analyst	1.0%	0.12	2	1.0%	0.12	2	0.0%	0.00	0	0.0%	0.00	0	0.0%	0.00	0	
SRA	3.0%	0.36	5	0.0%	0.00	0	0.0%	0.00	0	0.0%	0.00	0	0.0%	0.00	0	
Study Data Coordinator	5.0%	0.60	9	5.0%	0.60	9	0.0%	0.00	0	0.0%	0.00	0	0.0%	0.00	0	
Project Coordinator	2.0%	0.24	3	2.0%	0.24	3	1.0%	0.12	2	1.0%	0.12	2	1.0%	0.12	2	
	16.0%	1.92	28	13.0%	1.56	23	6.0%	0.72	11	6.0%	0.72	11	6.0%	0.72	11	

Budget Justification for WHI Ancillary Study

SAMPLE

Fred Hutch Cancer Research Center Women's Health Initiative (WHI) Clinical Coordinating Center (CCC)

Budget assumptions:

Sample size:

- 1,050 Buffy Coat DNA Full Extraction (1,000 samples, plus 5% QC)
- 1,050 Serum (1,000 samples, plus 5% QC)

Budget estimate for 5 year study

Sample processing and delivery split evenly between years 1 and 2

Assumed scientific involvement in all 5 years

Personnel

Co-Investigator (0.60 Calendar Months (5% FTE) in Years 1-5)

The Co-Investigator will serve as Fred Hutch Investigator of the proposed study and will maintain communication with the CCC and the investigators of this ancillary study, provide scientific expertise, assist with facilitating the WHI ancillary study process, assist with data reporting, data analysis and manuscript preparation as appropriate.

Systems Analyst Programmer (0.12 Calendar Months (1% FTE) in Years 1-2)

The systems analyst will coordinate the implementation and execution of the specimen pull and subsequent receipt of results with appropriate CCC programming staff.

Statistical Research Associate (SRA) (0.36 Calendar Months (3% FTE) in Year 1)

The SRA will oversee the identification of cases based on matching factors specified in the study proposal, prepare a datafile with common IDs to allow study investigators to merge study lab data to existing covariate data and provide data file support as needed.

Study Data Coordinator (0.6 Calendar Months (5% FTE) in Years 1-2)

The study data coordinator will be responsible for the coordination of efforts between the CCC, Fisher BioServices, the Specimen Processing Lab (SPL), and the testing lab, coordinate the technical aspects of pulling, aliquoting and sorting samples, oversee issues of sample selection, sample availability, and quality control for both the samples and prepare technical documentation and reports, and receive lab results.

Project Coordinator (0.24 Calendar Months (2% FTE) in Years 1-2, 0.12 Calendar Months (1% FTE) in Years 3-5)

The project coordinator will be responsible for handling project-specific research support activities, coordinate CCC activities, monitor budgets and expenditures, submit IRB reports, assist in resolving study-related problems for this ancillary study and provide general administrative assistance.

Fringe Benefit Rates

Faculty	Staff
27.8%	34.6%

(Fringe benefits include FICA, medical and dental insurance, disability insurance, workmen's compensation, term life insurance, retirement, and state unemployment insurance. Holiday, sick leave, and other paid absences are considered a salary expense)

Purchased Services

Fisher BioServices

Fisher BioServices will be responsible for pulling 1,050 buffy coat samples and 1,050 serum samples and sending the aliquots in dry ice to the Biospecimen Processing and Biorepository (BPB). In addition, Fisher will process the returned aliquots from BPB. Sample processing will be split evenly between years 1 and 2.

Year 1

Buffy Coat Full Extraction Samples

	#	Unit cost	
525 (500 samples, 25 QC)			
Pulling and shipping	525	\$2.00	\$1,050
Receiving/restoring returned aliquots (2 returned/sample)	1050	\$0.21	\$221
			<u>\$1,271</u>

Year 1

Serum

	#	Unit cost	
525 (500 samples, 25 QC)			
Pulling and shipping	525	\$2.00	\$1,050
Receiving/restoring returned aliquots (up to 3 returned/sample)	1575	\$0.21	\$331
			<u>\$1,381</u>

Fisher total estimated cost for Year 1

\$2,651

Year 2

Buffy Coat Full Extraction Samples

	#	Unit cost	
525 (500 samples, 25 QC)			
Pulling and shipping	525	\$2.06	\$1,082
Receiving/restoring returned aliquots (2 returned/sample)	1050	\$0.216	\$227
			<u>\$1,309</u>

Year 2

Serum

	#	Unit cost	
525 (500 samples, 25 QC)			
Pulling and shipping	525	\$2.06	\$1,082
Receiving/restoring returned aliquots (up to 3 returned/sample)	1575	\$0.216	\$341
			<u>\$1,926</u>

Fisher total estimated cost for Year 2

\$2,731

Shared Resource

Biospecimen Processing and Biorepository (BPB) at Fred Hutchinson Cancer Research Center

BPB will be responsible for extracting DNA from 1,050 buffy coat samples and aliquoting the DNA into one daughter aliquot and two parent aliquots and realiquoting 1,050 serum samples into one 0.1mL sample and up to three 0.5 mL aliquots for each return to Fisher. They will ship the daughter aliquots on

dry ice to the testing labs and ship the remaining parent and daughter aliquots on dry ice back to Fisher for long-term storage. Sample processing will be split evenly between years 1 and 2.

Year 1**Buffy Coat Full Extraction Samples**

	#	Unit cost	
525 (500 samples, 25 QC)	525	\$41.00	\$21,525
Full Extraction & Aliquoting	525	\$3.00	\$1,575
Shipping to lab and returning samples to Fisher	525		<u>\$1,575</u>
			\$23,100

Serum

	#	Unit cost	
525 (500 samples, 25 QC)	525	\$6.60	\$3,465
Aliquoting	525	\$3.00	\$1,575
Shipping to lab and returning samples to Fisher	525		<u>\$1,575</u>
			\$5,040

BPB total estimated cost for Year 1**\$28,140****Year 2****Buffy Coat Full Extraction Samples**

	#	Unit cost	
525 (500 samples, 25 QC)	525	\$42.23	\$22,171
Full Extraction & Aliquoting	525	\$3.00	\$1,622
Shipping to lab and returning samples to Fisher	525		<u>\$1,622</u>
			\$23,793

Serum

	#	Unit cost	
525 (500 samples, 25 QC)	525	\$6.80	\$3,569
Aliquoting	525	\$3.00	\$1,622
Shipping to lab and returning samples to Fisher	525		<u>\$1,622</u>
			\$5,191

SPL total estimated cost for Year 2**\$28,984****Collaborative Data Services (CDS) at Fred Hutchinson Cancer Research Center**

Collaborative Data Services will provide printed labels for all specimen vials. The cost of this procedure is \$0.12 per label.

Year 1**Buffy Coat DNA Labels**

	#	Unit cost	
5 labels per sample required, 525 samples x 5 labels = 2625 labels (1 for testing lab vials, up to 2 for vials returned to Fisher, 2 procedural vials)	2,625	\$0.12	\$315

Serum Labels

	#	Unit cost	
4 labels per sample required, 525 samples x 4 labels = 2,100 labels			

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(1 for testing lab vials and up to 3 for vials returned to Fisher)	2,100	\$0.12	\$252
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CDS total estimated cost for Year 1			\$567
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Year 2

Buffy Coat DNA Labels

5 labels per sample required, 525 samples x 5 labels = 2625 labels (1 for testing lab vials, up to 2 for vials returned to Fisher, 2 procedural vials)	#	Unit cost	
	2625	\$0.1236	\$324

Serum Labels

4 labels per sample required, 525 samples x 4 labels = 2,100 labels (1 for testing lab vials and up to 3 for vials returned to Fisher)	#	Unit cost	
	2,100	\$0.1236	\$260

CDS total estimated cost for Year 2			\$584
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Advanced Research and Diagnostic Laboratory (ARDL) at the University of Minnesota

It is WHI quality control policy that the ARDL performs assays on the serum QC samples. Cholesterol will be tested on serum QC samples in Years 1 and 2. This is done to ensure the samples were properly handled during aliquoting and labeling

Year 1

Cholesterol testing on QC samples	#	Unit cost	
	50	\$8.50	\$425

Year 2

Cholesterol testing on QC samples	#	Unit cost	
	50	\$8.76	\$438

Inflation Rate

3%

Indirect Cost Rate

Calculated at 76% of Modified Total Direct Costs; rate effective as of December 9th, 2025.

Fred Hutch will comply with applicable law and guidance governing indirect cost rates upon award.

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:

- Assist with issues related to sample selection.
- 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 specimen pull mechanism for samples (creation of pull and integration of lab results into WHI database).
- Assist in data reporting as needed.

Study Data Coordinator responsibilities:

- Provide Fisher BioServices with a report of aliquot numbers of EDTA samples to pull.
- Coordinate transfer of samples from Fisher to the Specimen Processing Lab (SPL) and the testing lab.
- Coordinate the technical aspects of pulling and aliquoting EDTA samples.
- Oversee issues of sample selection, sample availability, aliquoting and quality control.
- Prepare/update 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.
- Perform initial quality control checks on lab results, transmit the QC reports to the PI, and summarize the QC results for the WHI Lab Working Group.

Project Coordinator responsibilities:

- Communication and meetings with study investigators and CCC staff.
- Budget monitoring and administrative assistance.
- 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 Biospecimen Processing and Biorepository (BPB) at Fred Hutchinson Cancer Center (Fred Hutch).
- Receive returned daughter samples and place in inventory for long-term storage.
- Pull QC samples.

Fred Hutch Collaborative Data Services (CDS) responsibilities:

- Prepare printed labels for all specimen vials.

Fred Hutch Biospecimen Processing and Biorepository (BPB) 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.

Advanced Research and Diagnostic Laboratory (ARDL) at the University of Minnesota – QC testing

- Receive quality control samples and test cholesterol.