

**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)  
 1,100 Serum (1,000 samples, plus 10% QC)  
 Budget estimate for 2 year study  
 Sample processing and delivery split evenly between years 1 and 2

**Personnel**

**Co-Investigator (0.60 Calendar Months (5% FTE) in Years 1 and 2)**

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 and 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 and 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 and 2)**

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
26%	34.5%

(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 1,100 serum samples and sending the aliquots in dry ice to the Specimen Processing Laboratory (SPL). In addition, Fisher will process the returned aliquots from SPL. 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	\$0.20	\$210
			<u>\$1,260</u>

**Year 1**

**Serum**

	#	Unit cost	
550 (500 samples, 50 QC)			
Pulling and shipping	550	\$2.00	\$1,100
Receiving/restoring returned aliquots (up to 7 returned/sample)	3850	\$0.20	\$770
			<u>\$1,870</u>

**Fisher total estimated cost for Year 1**

**\$3,130**

**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	\$0.206	\$216
			<u>\$1,298</u>

**Year 2**

**Serum**

	#	Unit cost	
550 (500 samples, 50 QC)			
Pulling and shipping	550	\$2.06	\$1,133
Receiving/restoring returned aliquots (up to 7 returned/sample)	3850	\$0.206	\$793
			<u>\$1,926</u>

**Fisher total estimated cost for Year 2**

**\$3,224**

**Shared Resource**

***Specimen Processing Lab (SPL) at Fred Hutchinson Cancer Research Center***

SPL 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 1,100 serum samples into one .25 ml aliquot (and up to seven 0.25 ml aliquots for each case/control for return to Fisher). Samples will be packed in dry ice and other appropriate packing material and shipped to the testing lab. Sample processing will be split evenly between years 1 and 2.

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**Year 1**

**Buffy Coat Full Extraction Samples**

	#	Unit cost	
525 (500 samples, 25 QC)			
Full Extraction & Aliquoting	525	\$29.00	\$15,225
Shipping to lab and returning samples to Fisher	525	\$1.00	\$525
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			\$15,750

**Serum**

	#	Unit cost	
550 (500 samples, 50 QC)			
Aliquoting	550	\$6.00	\$3,300
Shipping to lab and returning samples to Fisher	550	\$1.00	\$550
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			\$3,850

**SPL total estimated cost for Year 1**

**\$19,600**

**Year 2**

**Buffy Coat Full Extraction Samples**

	#	Unit cost	
525 (500 samples, 25 QC)			
Full Extraction & Aliquoting	525	\$29.87	\$15,682
Shipping to lab and returning samples to Fisher	525	\$1.03	\$541
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			\$16,223

**Serum**

	#	Unit cost	
550 (500 samples, 50 QC)			
Aliquoting	550	\$6.18	\$3,399
Shipping to lab and returning samples to Fisher	550	\$1.03	\$567
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			\$3,966

**SPL total estimated cost for Year 2**

**\$20,189**

**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)			
	2625	\$0.12	\$315

**Serum Labels**

	#	Unit cost	
8 labels per sample required, 550 samples x 8 labels = 4400 labels (1 for testing lab vials and up to 7 for vials returned to Fisher)			
	4400	\$0.12	\$528

**CDS total estimated cost for Year 1**

**\$843**

**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)	<b>#</b>	<b>Unit cost</b>	
	2625	\$0.1236	\$324

**Serum Labels**

8 labels per sample required, 550 samples x 8 labels = 4400 labels (1 for testing lab vials and up to 7 for vials returned to Fisher)	<b>#</b>	<b>Unit cost</b>	
	4400	\$0.1236	\$544

**CDS total estimated cost for Year 2** **\$868**

**NW Lipids Lab at the University of Washington**

In addition to the assays above, it is WHI quality control policy that the NW Lipids Lab performs assays on the 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	<b>#</b>	<b>Unit cost</b>	
	50	\$6.00	<b>\$300</b>

**Year 2**

Cholesterol testing on QC samples	<b>#</b>	<b>Unit cost</b>	
	50	\$6.18	<b>\$309</b>

**Inflation Rate**

3%

**Indirect Cost Rate**

Calculated at 76% of Modified Total Direct Costs; rate effective as of 9/11/17.