**Women’s Health Initiative (WHI)**

**Data and Material Transfer and Use Agreement**

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| **This Data and Material Transfer and Use Agreement must be signed by an authorized representative of the Recipient prior to obtaining specimens and/or data for use in an approved WHI Research Project.** |

This Data and Material Transfer and Use Agreement (the “Agreement”), entered into on the last date of signature on this Agreement (the “Effective Date”), is between the Fred Hutchinson Cancer Research Center ("FHCRC"), a non-profit organization having its principal place of business at 1100 Fairview Avenue North, Seattle Washington, 98109 on behalf of the Women’s Health Initiative (“WHI”) and [**institution name**] having a principal place of business at [**institution address**] (“Recipient”), each of which is a “Party” and together are the “Parties.” This Agreement governs an arrangement through which FHCRC, through WHI, shall make available the Material and/or the Data described below to Recipient and Recipient Principal Investigator.

In consideration of the mutual promises and covenants contained herein, the Parties agree as follows:

**Article 1 - Background**

1.1 The Women’s Health Initiative (WHI) investigators, with support from the National Heart, Lung, and Blood Institute (NHLBI), have collected clinical data and biologic specimens from the participants in the WHI, its extension and ancillary studies. FHCRC serves as the WHI Clinical Coordinating Center (WHI CCC).

1.2 Specific clauses will be added to address Research Project-specific relationships and definitions including but not limited to clinical trial agreements and the names and reference numbers of studies.

1.3 Recipient through Recipient Principal Investigator has an approved WHI Research Project pursuant to which he/she wishes to obtain and use the Material(s) and/or a Data and FHCRC may transfer the Material(s) and/or the Data under this Agreement.

**Article 2 – Definitions**

2.1 Research Project means the research study (as approved by WHI and the NHLBI Project Office) under WHI reference number **\_\_\_\_\_\_\_** entitled “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_” and incorporated into this Agreement by reference. No modifications to the original proposal will be valid without WHI’s prior review and approval.

2.2 WHI Investigator is Garnet Anderson, PhD.

2.3 Recipient Principal Investigator is **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**.

2.4 Data means: A list of WHI Common IDs linked to the results of specimen tests associated with WHI **AS#**. The investigator will be granted online access to the WHI website for the purpose of downloading additional datasets for **AS#** study subjects. These datasets may include: Clinical data (data, and associated records, collected and recorded from WHI subjects through periodic examinations and follow-up contacts conducted in the WHI), Demographic Data (the subset of data consisting of the age, race/ethnicity, education and income of WHI subjects), Laboratory Data (data derived from analyses of blood samples and products thereof collected and prepared in the WHI), and Other Data (such as dietary, psychosocial, etc.). This Data will contain no individual identifiers as set forth in 45 CFR 164.514(e)(2). No individual identifiers will be provided to Recipient or Recipient Principal Investigator.

2.5 Material or Materials mean(s) blood, tissue and urine samples and products thereof, including serum, plasma, buffy coat, and extracted DNA and RNA, collected and prepared in the WHI and approved for the purposes of this research project by WHI. The Materials will be coded with unique identifiers. Materials include any and all progeny, clones, isolated or purified cell populations, derivatives, and modifications to any of the Materials which are substantially based on or incorporate a substantial element of the original Materials. The unique identifier and label will contain no information about factors such as disease status, and will contain no personally identifying information.

**Article 3 - Use of Material and Data**

3.1. Use for Research Project. Recipient and Recipient Principal Investigator will use the Material and/or Data only in the performance of the Research Project and for no other use without the written approval of FHCRC and execution of an amendment to this Agreement.

3.2 Permitted Users. The Material and/or Data will be used solely by Recipient Principal Investigator and those under his/her direct supervision.

3.3 No Transfer. Except as specifically provided herein, neither Recipient nor Recipient Principal Investigator will distribute or transfer the Material and/or Data to any other investigator at the Recipient or to any third party for any reason, without the prior written consent of an authorized representative of FHCRC.

3.4 No Commercial Use. Recipient Principal Investigator will not use the Material and/or Data in any research that is subject to consulting or licensing obligations to any for-profit organizations.

3.5 Use under Suitable Containment. Recipient and Recipient Principal Investigator agree to use the Materials under suitable containment conditions.

3.6 Data Security. Recipient agrees to establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Data and to prevent unauthorized use or access to it.

3.7 Recipient’s Responsibility to follow Data Security Best Practices. Recipient is aware of computer and data security best practices and will follow them for receipt, storage and use of Data and Resultant Data. An example of best practice guidelines can be found in <http://www.ncbi.nlm.nih.gov/projects/gap/pdf/dbgap_2b_security_procedures.pdf>.

3.8 No Human or Diagnostic Use. Recipient Principal Investigator will not use the Material in any manner on human subjects or the Material and or Data for any diagnostic purpose.

3.9 No Identification of Individual Identities. Recipient and Recipient Principal Investigator agree that the Material and/or Data will not be used, either alone or in conjunction with any other information in any effort whatsoever to establish the individual identities of any of the participants from whom the Material and/or Data were obtained.

**Article 4 - Confidentiality**

Recipient and Recipient Principal Investigator agree to maintain the confidentiality of any information received from FHCRC that is marked “Confidential” (“Confidential Information”). If Recipient or Recipient Principal Investigator is required by law to disclose such Confidential Information, including without limitation by discovery, subpoena or other legal or administrative process, Recipient and Recipient Principal Investigator agree to make reasonable efforts to provide FHCRC prompt advance notice of the required disclosure to permit FHCRC at its option and expense, to seek an appropriate protective order or waive the requirements under this Agreement. If no protective order or waiver is obtained and disclosure is legally required, such disclosure may be made but only to extent required.

**Article 5 - Term and Termination**

5.1 Term. The Agreement shall begin on the Effective Date and shall expire upon completion of the Research Project (the “Term”) unless earlier terminated pursuant to this Article 5.

5.2 Termination. Either Party may terminate this Agreement with or without cause at any time upon the receipt of thirty (30) days prior written notice pursuant to Section 11.4 (Notices) to the non-terminating Party.

5.3 Effect of Termination. Recipient and Recipient Principal Investigator agree to destroy the Data and all copies thereof upon termination of this Agreement, provided however that the Recipient Principal Investigator may retain one copy of the Data for archival purposes only. Recipient will provide prompt written notice of such destruction to FHCRC. At the request of FHCRC, unused Material received from FHCRC will be promptly returned or destroyed. Recipient Principal Investigator agrees to promptly provide FHCRC with the Penultimate and Final Reports (as defined in Article 7 below).

5.4 Survival of Obligations. The rights and obligations that would, by their nature, survive expiration or termination of this Agreement or that have accrued prior to termination shall survive expiration or termination of this Agreement.

**Article 6 – Intellectual Property**

1. Data and Material. The Material and Data are and remain the property of FHCRC.
2. Research inventions. FHCRC makes no claim to rights in any intellectual property Recipient develops through use of the Material, and/or Data that are developed without conceptual contribution from FHCRC. Recipient is free to file patent application(s) claiming inventions made by the Recipient through the use of the Material and/or Data, but agrees to notify FHCRC upon filing a patent application claiming Modifications or methods of use of the Material. No rights are provided by either Party to the other under any patent applications, trade secrets or other proprietary rights of a Party.
3. Government Rights in Intellectual Property**.** The Parties recognize that Intellectual Property or other proprietary information may arise from research sponsored in whole or in part by agencies of the federal government. The Parties hereto agree that any such development covered by this Agreement may be limited under the provisions of 35 USC §§200-212, and regulations and rules promulgated thereunder and the Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources as set forth in 64 FR 72090, December 23, 1999. Any right granted in this Agreement that is greater than that permitted under Public Law 96-517 or 98-620 shall be subject to modification as may be required to conform to the provisions of that statute.

**Article 7 – Reporting**

Recipient’s Resulting Data to be Provided to WHI Investigators. Prior to release of analytic data by the WHI, Recipient agrees to provide the WHI CCC with a report (“Penultimate Report”) containing all data derived by Recipient from any data and/or Material provided to Recipient for the performance of the Research Project. In addition, at the time of the primary publication of the Research Project, Recipient agrees to provide the WHI CCC with a report (“Final Report”) containing a final analytic dataset (i.e., the data of the Penultimate Report in its final, fully curated form). Recipient agrees that the WHI may distribute the data in the Penultimate and Final Reports to qualified scientific investigators requesting access through established WHI procedures and completing a signed agreement comparable to this Agreement. Recipient will provide the Penultimate and Final Reports in the precise electronic formats specified by WHI.

**Article 8 - Disclaimer of Representations and Warranties**

No Warranty. ReCipient and ReCipient Investigator acknowledge that the materials and/or DATA are experimental in nature and may have hazardous properties. fhcrc MAKES NO REPRESENTATIONS NOR EXTENDS ANY WARRANTIES, express or implied, as to any matter whatsoever including, without limitation, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE. Without limitation of the foregoing generality, nothing contained herein shall be construed as extending any representation or warranty, express or implied, with respect to the research conducted USING THE material and/or DATA or the results to be obtained hereof or that use of the material and/or Data WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT.

**Article 9 - Compliance with Laws, Regulations and Institutional Policies**

9.1 Compliance. Recipient and Recipient Principal Investigator will comply with all applicable laws, rules and regulations including, without limitation, all applicable current governmental regulatory requirements, concerning the use of the Material, including NIH guidelines.

9.2 Compliance with Recipient Institutional Policies and Procedures. Recipient and Recipient Principal Investigator represent that the conditions for use of the Material and/or Data have been approved by the Recipient’s Institutional Review Board (IRB), or equivalent body, in accordance with applicable law including but not limited to 45 CFR Part 46 and 21 CFR Parts 50 and 56.

**Article 10 – Hold Harmless**

Hold Harmless and Indemnification. To the extent permitted by applicable law, Recipient will indemnify and hold harmless FHCRC and its suppliers and contributors of specimens from and be responsible for any liability for, and will defend FHCRC and its suppliers and contributors of specimens and/or data from any claims, costs, damages or expenses, including attorneys’ fees, resulting from or arising out of any injury, damage or loss in any way relating to Recipient’s or Recipient Principal Investigator’s possession and use of the Materials and/or Data, except for any such claims or damages (including attorneys’ fees) arising out of gross negligence, recklessness, or willful misconduct of FHCRC and/or its suppliers and contributors of specimens and/or data.

**Article 11 - Miscellaneous**

11.1 Amendments. Amendments to this Agreement must be made in writing and signed by authorized representatives of both Parties.

11.2 Assignment. The Agreement shall be binding on the Parties hereto and upon their respective heirs, administrators, successors and permitted assigns. This Agreement may not be assigned by either Party or by operation of law without the prior written consent of an authorized individual of the other Party.

11.3 Independent Parties. The Parties to this Agreement are independent contractors and not agents of the other. This Agreement shall not constitute a partnership or joint venture, and neither Party may be bound by the other to any contract, arrangement or understanding except as specifically stated herein.

11.4 Notices. Formal notices required or permitted hereunder shall be given in writing. Written notices may be delivered personally, sent by a nationally recognized courier service or by first class mail, or transmitted electronically by facsimile (“fax”) or e-mail. All notices or communications required or permitted hereunder shall be deemed to have been given (a) if by personal delivery to the proper address and with receipt acknowledged, on the date of such delivery; (b) if by overnight courier service to the proper address and with receipt acknowledged, on the second business day following deposit if delivered; (c) if transmitted electronically, with confirmed transmission, on the next business day following such transmission; or (d) if mailed, postage prepaid first-class certified or registered mail, return receipt requested, on the fifth business day after mailing, to the address designated below or to such other address as a Party may designate to the other Party in writing. Any notices shall be sent as follows:

If to FHCRC: Fred Hutchinson Cancer Research Center

1100 Fairview Avenue North - Mailstop J2-110

Seattle, Washington 98109-1024

Attn: Vice President, Business Development & Strategy

Fax: 206-667-4732

E-mail: MTA@fredhutch.org

With a copy to: Women’s Health Initiative

1100 Fairview Avenue North – Mailstop M3-A410

Seattle, WA 98109-1024

Attn: Helen Penor

Fax: 206-667-4142

E-mail: hpenor@whi.org

If to Recipient:

Attn:

Fax:

E-mail:

With a copy to:

Attn:

Fax:

E-mail:

11.5 Use of Name. Neither Party will use the other Party's name or logo in any advertising or other form of publicity without the prior written consent by an authorized individual of the other Party.

**Remainder of Page - Signature pages follow**

IN WITNESS WHEREOF, the Parties hereto have caused their duly authorized representatives to execute this Agreement as of the Effective Date.

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| **Fred Hutchinson Cancer** **Research CENTER**By:  Patrick Shelby, PhD  Director, Technology Management  Date | **Recipient INSTITUTION**By:  Print Name Title Date |

WHI Investigator and Recipient Principal Investigator, by affixing their signatures below, acknowledge that they have read and understood the terms of this Agreement.

**WHI Investigator Recipient Principal Investigator**

By: By:

Name: Garnet Anderson, PhD Name:

Title: WHI CCC Principal Investigator Title:

Date: Date: