Women's Health Initiative (WHI)
Virtual Data Enclave (VDE) for use of WHI and Medicare
Data Use Agreement

This VDE and Data Use Agreement must be signed by an authorized representative of the User Principal Investigator's Institution prior to obtaining data for use in an approved WHI Research Project.

This VDE Data Use Agreement (the "Agreement"), entered into on the last date of signature on this Agreement (the "Effective Date"), is between the Fred Hutchinson Cancer Center ("FHCC"), 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**] ("User"), each of which is a "Party" and together are the "Parties." This Agreement governs an arrangement through which FHCC, through WHI, shall make available the Data described below to User and User 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 from the participants in the WHI, its extension and ancillary studies. FHCC serves as the WHI Clinical Coordinating Center (WHI CCC). These data have been linked with additional data obtained from the Centers for Medicare & Medicaid Services (CMS).

1.2 User has requested access to these data maintained by FHCC through an electronic means known as the Virtual Data Enclave created and maintained by FHCC.

1.3 FHCC will permit User access to the data via the Virtual Data Enclave in accordance with certain terms and conditions outlined herein.

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 User Principal Investigator is _____.

2.4 Data means: A list of WHI Common IDs linked to the CMS data for WHI participants. CMS data includes the following Medicare files: MedPar, Outpatient, Home Health, Carrier, Hospice, Durable Medical Equipment, Denominator file, and Part D files. The investigator will be granted access via the Virtual Data Enclave (VDE) to the CMS date files associated with the approved Research Project, defined as either an approved WHI ancillary study (AS) or manuscript proposal (MS). The investigator will also be granted access to the WHI datasets developed under the WHI protocol or associated ancillary studies as required for approved for this AS or MS . These datasets 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.). These Data will contain no individual identifiers as set forth in 45 CFR 164.514(e)(2). No individual identifiers will be provided to User or User Principal Investigator.

Article 3 - Use of Data

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

3.2 Permitted Users. The Data will be used solely by User Principal Investigator and the analyst(s) (if any) under his/her direct supervision (listed on the final page of this agreement).

3.4 No Commercial Use. User Principal Investigator will not use the Data in any research that is subject to consulting or licensing obligations to any for-profit organizations without the prior written approval of FHCC.

3.5 Data Security. User agrees to establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality of the Data and to prevent unauthorized use, access to or viewing of it. For Data accessed via the VDE, these include:

Data may not be copied or stored at any location outside the VDE through FTP, email, or any other means.

Data may not be copied to any removable media such as a USB drive.

No creation of screen shots, either by Print Screen, photography, or any other means, is permitted.

No access to the Data will be permitted by anyone who has not signed this agreement.

The FHCC must review any resulting data files or tables containing the Data to ensure that no confidential data is contained within them before sending them to the User.

The User Principal Investigator will notify the FHCC's Office of the General Counsel (206-667-1224) immediately if they become aware of any unauthorized access to or use of the Data.

3.6 Compliance with DUA#51309. User Principal Investigator will review and agree to the participant confidentiality and data security requirements specified in Sections 4, 7, 9, and 14 outlined in the *Agreement for Use of CMS Data Containing Individual Identifiers* (DUA# 51309, attached hereto and incorporated herein by reference) between FHCC, the NHLBI, and the DHHS CMS.

3.7 No Identification of Individual Identities. User and User Principal Investigator agree that the 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 Data were obtained.

Article 4 - Confidentiality

User and User Principal Investigator agree to maintain the confidentiality of any information received from FHCC that is marked "Confidential" ("Confidential Information"). If User or User Principal Investigator is required by law to disclose such Confidential Information, including without limitation by discovery, subpoena or other legal or administrative process, User and User Principal Investigator agree to make reasonable efforts to provide FHCC prompt advance notice of the required

disclosure to permit FHCC at its option and expense, to seek an appropriate protective order or waive the requirements under this Agreement. Access to the Data is protected by an NIH Certificate of Confidentiality which will be utilized by FHCC to prevent disclosure of the Data. 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") or one year after the initiation of access, 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 Termination for Breach. FHCC may immediately terminate this Agreement and cancel User's access to and use of the Data in the event that the User, User Principal Investigator, or someone under the User Principal Investigator's supervision or control violates the terms of this Agreement.

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 - Compliance with Laws, Regulations and Institutional Policies

6.1 Compliance. User and User 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 Data, including NIH guidelines.

6.2 Compliance with User Institutional Policies and Procedures. User and User Principal Investigator represent that the conditions for use of the Data have been approved by the User'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 7 – Hold Harmless

To the extent permitted by applicable law, User will indemnify and hold harmless FHCC and its suppliers and contributors of data from and be responsible for any liability for, and will defend FHCC and its suppliers and contributors of 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 User's or User Principal Investigator's access to and use of the Data, except for any such claims or damages (including attorney's fees) arising out of gross negligence, recklessness, or willful misconduct of FHCC and/or its suppliers and contributors of data.

Article 8 - Miscellaneous

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

8.2 Assignment. The Agreement shall be binding on the Parties hereto and upon their respective 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.

8.3 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.

8.4 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 FHCC: Fred Hutchinson Cancer Center
1100 Fairview Avenue North - Mailstop J5-110
Seattle, Washington 98109-1024
Attn: MTA
E-mail: mta@fredhutch.org

With a copy to: Women's Health Initiative
1100 Fairview Avenue North – Mailstop M3-A410
Seattle, WA 98109-1024

If to User: _____
_____
_____
Attn: _____
E-mail: _____

With a copy to: _____
_____
_____
Attn: _____
E-mail: _____

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

FRED HUTCHINSON CANCER CENTER

By: _____

Patrick Shelby, PhD

Name

Director, Technology Management
Title

Date:_____ _____

USER INSTITUTION Title

Date:_____

By:_____

_____

Name

WHI Investigator, User Principal Investigator, and Collaborators, by affixing their signatures below, acknowledge that they have read and understood the terms of this Agreement, the attached CMS DUA #51309, and the U.S. Department of Justice Privacy Act of 1974 (http://www.justice.gov/opcl/privacy-act-1974). Include all collaborators, statisticians/analysts who will have access to the CMS data via the VDE under the direct supervision of the User.

WHI Investigator

By:_____

Name: Garnet Anderson, PhD

Title: WHI CCC Principal Investigator

Date:

User Principal Investigator

By: _____

Name: _____

Title: _____

Date: _____

Collaborator/ Statistician/Analyst

By: _____

Name: _____

Title: _____

Date: _____

Collaborator/Statistician/Analyst

By: _____

Name: _____

Title: _____

Date: _____

Collaborator/ Statistician/Analyst

By: _____

Name: _____

Title: _____

Date: _____