

11/18/2015

**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 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 _____ having a principal place of business at _____ ("User"), 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 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. FHCRC 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 FHCRC through an electronic means known as the Virtual Data Enclave created and maintained by FHCRC.

1.3 FHCRC 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,

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Durable Medical Equipment, Denominator file, and Part D files. The investigator will be granted access via the Virtual Data Enclave (VDE) to the CMS data 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 FHCRC 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 FHCRC.

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 FHCRC 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 FHCRC'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 FHCRC, the NHLBI, and the DHHS CMS.

3.7. No Identification of Individual Identities. User and User Principal Investigator agree that

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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 FHCRC 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 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. Access to the Data is protected by an NIH Certificate of Confidentiality which will be utilized by FHCRC 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. FHCRC 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 FHCRC and its suppliers and contributors of data from and be responsible for any liability for, and will defend FHCRC and its suppliers and contributors of data from any claims, costs, damages or expenses, including attorneys’

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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 FHCRC 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 FHCRC: Fred Hutchinson Cancer Research Center
1100 Fairview Avenue North - Mailstop J5-110
Seattle, Washington 98109-1024
Attn: Vice President, Industry Relations and Business Development
E-mail: niki@fredhutch.org

With a copy to: Women's Health Initiative
1100 Fairview Avenue North – Mailstop M3-A410
Seattle, WA 98109-1024
Attn: Claudia Smith
E-mail: csmith@whi.org

If to User: _____

Attn: _____
E-mail: _____

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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 RESEARCH CENTER

By: _____

Patrick Shelby, PhD
Name

Director, Technology Management, Business

Development & Industry Relations
Title

Date: _____

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 19098, 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: _____

DATA USE AGREEMENT

DUA # RSCH-2017-51309

(AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA CONTAINING INDIVIDUAL IDENTIFIERS)

CMS agrees to provide the User with data that reside in a CMS Privacy Act System of Records as identified in this Agreement. In exchange, the User agrees to pay any applicable fees; the User agrees to use the data only for purposes that support the User's study, research or project referenced in this Agreement, which has been determined by CMS to provide assistance to CMS in monitoring, managing and improving the Medicare and Medicaid programs or the services provided to beneficiaries; and the User agrees to ensure the integrity, security, and confidentiality of the data by complying with the terms of this Agreement and applicable law, including the Privacy Act and the Health Insurance Portability and Accountability Act. In order to secure data that reside in a CMS Privacy Act System of Records; in order to ensure the integrity, security, and confidentiality of information maintained by the CMS; and to permit appropriate disclosure and use of such data as permitted by law, CMS and National Heart, Lung, and Blood Institute enter into this agreement to comply with the following specific paragraphs. (Requestor)

1. This Agreement is by and between the Centers for Medicare & Medicaid Services (CMS), a component of the U.S. Department of Health and Human Services (HHS), and National Heart, Lung, and Blood Institute, hereinafter termed "User." (Requestor)
2. This Agreement addresses the conditions under which CMS will disclose and the User will obtain, use, reuse and disclose the CMS data file(s) specified in section 5 and/or any derivative file(s) that contain direct individual identifiers or elements that can be used in concert with other information to identify individuals. This Agreement supersedes any and all agreements between the parties with respect to the use of data from the files specified in section 5 and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any grant award or other prior communication from the Department of Health and Human Services or any of its components with respect to the data specified herein. Further, the terms of this Agreement can be changed only by a written modification to this Agreement or by the parties adopting a new agreement. The parties agree further that instructions or interpretations issued to the User concerning this Agreement or the data specified herein, shall not be valid unless issued in writing by the CMS point-of-contact or the CMS signatory to this Agreement shown in section 20.
3. The parties mutually agree that CMS retains all ownership rights to the data file(s) referred to in this Agreement, and that the User does not obtain any right, title, or interest in any of the data furnished by CMS.
4. The User represents, and in furnishing the data file(s) specified in section 5 CMS relies upon such representation, that such data file(s) will be used solely for the following purpose(s).

Name of Study/Project

Women's Health Initiative and CMS Data Linkage Full Study

CMS Contract No. *(If applicable)*

The User represents further that the facts and statements made in any study or research protocol or project plan submitted to CMS for each purpose are complete and accurate. Further, the User represents that said study protocol(s) or project plans, that have been approved by CMS or other appropriate entity as CMS may determine, represent the total use(s) to which the data file(s) specified in section 5 will be put.

The User agrees not to disclose, use or reuse the data covered by this agreement except as specified in an Attachment to this Agreement or except as CMS shall authorize in writing or as otherwise required by law, sell, rent, lease, loan, or otherwise grant access to the data covered by this Agreement. The User affirms that the requested data is the minimum necessary to achieve the purposes stated in this section. The User agrees that, within the User organization and the organizations of its agents, access to the data covered by this Agreement shall be limited to the minimum amount of data and minimum number of individuals necessary to achieve the purpose stated in this section (i.e., individual's access to the data will be on a need-to-know basis).

5. The following CMS data file(s) is/are covered under this Agreement.

File	Years(s)	System of Record
MBSF (base, chronic conditions, cost & use)	2014-2015	
MBSF (other chronic conditions)	2014-2015	
MedPAR (ss/lis/snf)	2015	
IP, OP, Carrier, HHA, Hospice, SNF, DME	2015	
Part D Event, PtD Drug & Plan Characteristics	2006-2015	
PtD Prescriber Characteristics	2014-2015	
PtD Formulary File	2010-2015	
SSN to BENE_ID Crosswalk	2017	
Reuse Under DUA #19098		
Denominator	1991-2007	
see last page for additional file listings		

6. The parties mutually agree that the aforesaid files(s) (and/or any derivative file(s)), including those files that directly identify individuals or that directly identify bidding firms and/or such firms' proprietary, confidential or specific bidding information, and those files that can be used in concert with other information to identify individuals, may be retained by the User until ONE YEAR, hereinafter known as the "Retention Date." The User agrees to notify CMS within 30 days of the completion of the purpose specified in section 4 if the purpose is completed before the aforementioned retention date. Upon such notice or retention date, whichever occurs sooner, the User agrees to destroy such data. The User agrees to destroy and send written certification of the destruction of the files to CMS within 30 days. The User agrees not to retain CMS files or any parts thereof, after the aforementioned file(s) are destroyed unless the appropriate Systems Manager or the person designated in section 20 of this Agreement grants written authorization. The User acknowledges that the date is not contingent upon action by CMS.

The Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon notice of termination by User, CMS will cease releasing data from the file(s) to the User under this Agreement and will notify the User to destroy such data file(s). Sections 3, 4, 6, 8, 9, 10, 11, 13, 14 and 15 shall survive termination of this Agreement.

7. The User agrees to establish appropriate administrative, technical, and physical safeguards to protect the confidentiality of the data and to prevent unauthorized use or access to it. The safeguards shall provide a level and scope of security that is not less than the level and scope of security requirements established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III--Security of Federal Automated Information Systems (<http://www.whitehouse.gov/omb/circulars/a130/a130.html>) as well as Federal Information Processing Standard 200 entitled "Minimum Security Requirements for Federal Information and Information Systems" (<http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf>); and, Special Publication 800-53 "Recommended Security Controls for Federal Information Systems" (<http://csrc.nist.gov/publications/nistpubs/800-53-Rev2/sp800-53-rev2-final.pdf>). The User acknowledges that the use of unsecured telecommunications, including the Internet, to transmit individually identifiable, bidder identifiable or deducible information derived from the file(s) specified in section 5 is prohibited. Further, the User agrees that the data must not be physically moved, transmitted or disclosed in any way from or by the site indicated in section 17 without written approval from CMS unless such movement, transmission or disclosure is required by a law.

8. The User agrees to grant access to the data to the authorized representatives of CMS or DHHS Office of the Inspector General at the site indicated in section 17 for the purpose of inspecting to confirm compliance with the terms of this agreement.

9. The User agrees not to disclose direct findings, listings, or information derived from the file(s) specified in section 5, with or without direct identifiers, if such findings, listings, or information can, by themselves or in combination with other data, be used to deduce an individual's identity. Examples of such data elements include, but are not limited to geographic location, age if > 89, sex, diagnosis and procedure, admission/discharge date(s), or date of death.

The User agrees that any use of CMS data in the creation of any document (manuscript, table, chart, study, report, etc.) concerning the purpose specified in section 4 (regardless of whether the report or other writing expressly refers to such purpose, to CMS, or to the files specified in section 5 or any data derived from such files) must adhere to CMS' current cell size suppression policy. **This policy stipulates that no cell (e.g. admittances, discharges, patients, services) 10 or less may be displayed.** Also, no use of percentages or other mathematical formulas may be used if they result in the display of a cell 10 or less. By signing this Agreement you hereby agree to abide by these rules and, therefore, will not be required to submit any written documents for CMS review. If you are unsure if you meet the above criteria, you may submit your written products for CMS review. CMS agrees to make a determination about approval and to notify the user within 4 to 6 weeks after receipt of findings. CMS may withhold approval for publication only if it determines that the format in which data are presented may result in identification of individual beneficiaries.

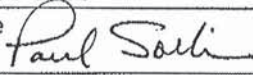
10. The User agrees that, absent express written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement to do so, the User shall not attempt to link records included in the file(s) specified in section 5 to any other individually identifiable source of information. This includes attempts to link the data to other CMS data file(s). A protocol that includes the linkage of specific files that has been approved in accordance with section 4 constitutes express authorization from CMS to link files as described in the protocol.
11. The User understands and agrees that they may not reuse original or derivative data file(s) without prior written approval from the appropriate System Manager or the person designated in section 20 of this Agreement.
12. The parties mutually agree that the following specified Attachments are part of this Agreement:

DUA Attachment B

13. The User agrees that in the event CMS determines or has a reasonable belief that the User has made or may have made a use, reuse or disclosure of the aforesaid file(s) that is not authorized by this Agreement or another written authorization from the appropriate System Manager or the person designated in section 20 of this Agreement, CMS, at its sole discretion, may require the User to: (a) promptly investigate and report to CMS the User's determinations regarding any alleged or actual unauthorized use, reuse or disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by CMS, submit a formal response to an allegation of unauthorized use, reuse or disclosure; (d) if requested by CMS, submit a corrective action plan with steps designed to prevent any future unauthorized uses, reuses or disclosures; and (e) if requested by CMS, return data files to CMS or destroy the data files it received from CMS under this agreement. The User understands that as a result of CMS's determination or reasonable belief that unauthorized uses, reuses or disclosures have taken place, CMS may refuse to release further CMS data to the User for a period of time to be determined by CMS.

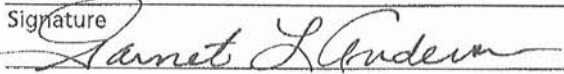
The User agrees to report any breach of personally identifiable information (PII) from the CMS data file(s), loss of these data or disclosure to any unauthorized persons to the CMS Action Desk by telephone at (410) 786-2580 or by e-mail notification at cms_it_service_desk@cms.hhs.gov within one hour and to cooperate fully in the federal security incident process. While CMS retains all ownership rights to the data file(s), as outlined above, the User shall bear the cost and liability for any breaches of PII from the data file(s) while they are entrusted to the User. Furthermore, if CMS determines that the risk of harm requires notification of affected individual persons of the security breach and/or other remedies, the User agrees to carry out these remedies without cost to CMS.

14. The User hereby acknowledges that criminal penalties under §1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine not exceeding \$10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law. The User further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i) (3)) may apply if it is determined that the Requestor or Custodian, or any individual employed or affiliated therewith, knowingly and willfully obtained the file(s) under false pretenses. Any person found to have violated sec. (i)(3) of the Privacy Act shall be guilty of a misdemeanor and fined not more than \$5,000. Finally, the User acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the User, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted. Under such circumstances, they shall be fined under Title 18 or imprisoned not more than 10 years, or both; but if the value of such property does not exceed the sum of \$1,000, they shall be fined under Title 18 or imprisoned not more than 1 year, or both.
15. By signing this Agreement, the User agrees to abide by all provisions set out in this Agreement and acknowledges having received notice of potential criminal or administrative penalties for violation of the terms of the Agreement.
16. On behalf of the User the undersigned individual hereby attests that he or she is authorized to legally bind the User to the terms this Agreement and agrees to all the terms specified herein.

Name and Title of User <i>(typed or printed)</i> Paul Sorlie, Chief of Epidemiology Branch		
Company/Organization National Heart, Lung, and Blood Institute		
Street Address 6701 ROCKLEDGE DR, RKL2 BG RM 10210		
City Bethesda	State MD	ZIP Code 20817
Office Telephone <i>(Include Area Code)</i> (301) 435-0456	E-Mail Address <i>(If applicable)</i> sorliep@nhlbi.nih.gov	
Signature 		Date May 25, 2017

17. The parties mutually agree that the following named individual is designated as Custodian of the file(s) on behalf of the User and will be the person responsible for the observance of all conditions of use and for establishment and maintenance of security arrangements as specified in this Agreement to prevent unauthorized use. The User agrees to notify CMS within fifteen (15) days of any change of custodianship. The parties mutually agree that CMS may disapprove the appointment of a custodian or may require the appointment of a new custodian at any time.

The Custodian hereby acknowledges his/her appointment as Custodian of the aforesaid file(s) on behalf of the User, and agrees to comply with all of the provisions of this Agreement on behalf of the User.

Name of Custodian <i>(typed or printed)</i> Garnet Anderson, PhD, Principal Investigator, Women's Health Initiative Clinical Coordinating Center		
Company/Organization Fred Hutchinson Cancer Research Center		
Street Address 1100 Fairview Ave N		
City Seattle	State WA	ZIP Code 98109-1024
Office Telephone <i>(Include Area Code)</i> 206-667-4699	E-Mail Address <i>(If applicable)</i> garnet@whi.org	
Signature 		Date 5/25/2017

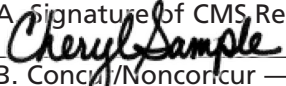

18. The disclosure provision(s) that allows the discretionary release of CMS data for the purpose(s) stated in section 4 follow(s). (To be completed by CMS staff.) PA03-RES

19. On behalf of _____ the undersigned individual hereby acknowledges that the aforesaid Federal agency sponsors or otherwise supports the User's request for and use of CMS data, agrees to support CMS in ensuring that the User maintains and uses CMS's data in accordance with the terms of this Agreement, and agrees further to make no statement to the User concerning the interpretation of the terms of this Agreement and to refer all questions of such interpretation or compliance with the terms of this Agreement to the CMS official named in section 20 (or to his or her successor).

Typed or Printed Name		Title of Federal Representative	
Signature			Date
Office Telephone (Include Area Code)		E-Mail Address (If applicable)	

20. The parties mutually agree that the following named individual will be designated as point-of-contact for the Agreement on behalf of CMS.

On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Name of CMS Representative (typed or printed)			
Cheryl Sample			
Title/Component			
Health Insurance Specialist, Div. of Data Information & Dissemination, DDSG, OEDA			
Street Address			Mail Stop
7500 Security Boulevard			B2-29-04
City	State	ZIP Code	
Baltimore	MD	21244	
Office Telephone (Include Area Code)		E-Mail Address (If applicable)	
410-786-7185		cheryl.sample@cms.hhs.gov	
A. Signature of CMS Representative			Date
			08/03/2017
B. Concur/Nonconcur — Signature of CMS System Manager or Business Owner			Date
Andrew Shatto, CMS Privacy Board Chair 			06/15/2017
Concur/Nonconcur — Signature of CMS System Manager or Business Owner			Date
Concur/Nonconcur — Signature of CMS System Manager or Business Owner			Date

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0734. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: Reports Clearance Officer, Baltimore, Maryland 21244-1850.

File	Year(s)	System of Record
Continued Reuse Under DUA #19098		
MedPAR	1991-2014	
IP, SNF	2013-2014	
OP, HHA, Hospice, Carrier	1991-2014	
DME	1994-2014	
MBSF	1998-2013	
XREF – Cross Reference	2013-2015	
New Data		
IP, OP, Carrier, HHA, Hospice, SNF, DME	2016	
MBSF (base)	2016	

Research Identifiable Files

DUA #: RSCH-2017-51309

Attachment B


This attachment supplements the above-referenced Data Use Agreement (DUA) between the Centers for Medicare and Medicaid Services and the User (as set forth in the DUA). Upon execution by both parties, to the extent this Attachment is inconsistent with any terms in the DUA, this Attachment modifies and overrides the DUA.

A-1. Use of Data: Users may disseminate research findings on providers or suppliers (including individual physicians) using original or derived information from the files specified in Section 5 of the DUA provided all findings are limited to patient de-identified data that conform with the HIPAA Privacy Rule's definition of de-identified data at 45 CFR 164.514(b).

A-2. Disclosure of Findings: Nothing in the DUA, including but not limited to Section 9, prohibits Users from discussing or reporting on specific providers or suppliers (including individual physicians) in a manner consistent with A-1.



For: Centers for Medicare & Medicaid Services



For: DUA Data Requestor

Paul Sorlie
Chief of Epidemiology Branch
National Heart, Lung, and Blood Institute

DATA USE AGREEMENT UPDATE TO EXISTING DATA USE AGREEMENT

EXISTING DUA # 51309

AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA

This agreement is needed as part of the review of your data request to ensure compliance with the requirements of the Privacy Act, and must be completed prior to the release or use of specified data files.

1. Requestor Organization

Fred Hutchinson Cancer Research Center

2. Name of Study/Project

Women's Health Initiative and CMS Data Linkage Full Study

CMS Contract Number *(if applicable)*

3. The following additional CMS data files(s) are being requested under this Agreement.

File	Year(s)	System of Record <i>(to be completed by CMS Staff)</i>
MBSF Base Segment	2006, 2007	
IP, OP, SNF, HOSPICE, HHA, CARRIER, DMERC	2016	
PDE (option 1 Actual IDs); Drug, Prescriber, Plan Char	2016	
Part D Formulary File	2010, 2016	
MedPAR (SS/LS/SNF)	2014, 2016	
X Walk: SSN to BENE ID	2018	
	SEE PAGE 2	

4. On behalf of the user the undersigned individual hereby attests that he or she is authorized to legally bind the user to the terms of the existing agreement and agrees to all the terms specified therein.

Type or Print Name of Requesting Individual

Pothur Srinivas

Signature

P.R. Srinivas

Date

2/21/2018

5. On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Type or Print Name and Title of CMS Representative

Cheryl Sample

Signature

Cheryl Sample

Date

03/13/2018

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

MBSF Base Segment 2012, 2016

MBSF Chronic Conditions, Cost & Utilization,
Other Chronic or Potentially Disabling Conditions 2016

DATA USE AGREEMENT UPDATE TO EXISTING DATA USE AGREEMENT

EXISTING DUA # 51309

AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA

This agreement is needed as part of the review of your data request to ensure compliance with the requirements of the Privacy Act, and must be completed prior to the release or use of specified data files.

1. Requestor Organization

National Heart Lung and Blood Institute

2. Name of Study/Project

Women's Health Initiative and CMS Data Linkage Full Study

CMS Contract Number (if applicable)

3. The following additional CMS data files(s) are being requested under this Agreement.

File	Year(s)	System of Record <i>(to be completed by CMS Staff)</i>
Inpatient, Outpatient (Cohort Specific)	2017 Q1- Q3	
MBSF Base Segment (Cohort Specific)	2017 Q1 - Q3	
SSN to Bene ID crosswalk	2018	

4. On behalf of the user the undersigned individual hereby attests that he or she is authorized to legally bind the user to the terms of the existing agreement and agrees to all the terms specified therein.

Type or Print Name of Requesting Individual

Pothur Srinivas

Signature

P.R. Srinivas

Date

07/10/18

5. On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Type or Print Name and Title of CMS Representative

Cheryl Sample

Signature

Cheryl Sample

Date

08/01/2018

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

DATA USE AGREEMENT UPDATE TO EXISTING DATA USE AGREEMENT

EXISTING DUA # 51309

AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA

This agreement is needed as part of the review of your data request to ensure compliance with the requirements of the Privacy Act, and must be completed prior to the release or use of specified data files.

1. Requestor Organization NATIONAL HEART LUNG AND BLOOD INSTITUTE
2. Name of Study/Project Women's Health Initiative and CMS Data Linkage Full Study
CMS Contract Number (if applicable)

3. The following additional CMS data files(s) are being requested under this Agreement.

File	Year(s)	System of Record <i>(to be completed by CMS Staff)</i>
Inpatient, Outpatient, SNF	2017 Q4	
Hospice, Home Health, Carrier	2017 Q4	
DMERC, MBSF (base)	2017 Q4	
SSN to Bene ID crosswalk	2018	

4. On behalf of the user the undersigned individual hereby attests that he or she is authorized to legally bind the user to the terms of the existing agreement and agrees to all the terms specified therein.

Type or Print Name of Requesting Individual Pothur Srinivas	
Signature 	Date 5/8/18

5. On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Type or Print Name and Title of CMS Representative Vivian Rogers, Health Insurance Specialist, Div of Data & Information Dissemination, DDSG, OEDA		
Signature 	Date	05/23/2018
Signature of CMS System Manager or Business Owner <input type="checkbox"/> Concur <input type="checkbox"/> Nonconcur	Date	System Name
Signature of CMS System Manager or Business Owner <input type="checkbox"/> Concur <input type="checkbox"/> Nonconcur	Date	System Name
Signature of CMS System Manager or Business Owner <input type="checkbox"/> Concur <input type="checkbox"/> Nonconcur	Date	System Name

DATA USE AGREEMENT UPDATE TO EXISTING DATA USE AGREEMENT

EXISTING DUA # RSCH-2017-51309

AGREEMENT FOR USE OF CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) DATA

This agreement is needed as part of the review of your data request to ensure compliance with the requirements of the Privacy Act, and must be completed prior to the release or use of specified data files.

1. Requestor Organization

Fred Hutchinson Cancer Research Center

2. Name of Study/Project

Women's Health Initiative and CMS Data Linkage Full Study

CMS Contract Number *(if applicable)*

3. The following additional CMS data files(s) are being requested under this Agreement.

File	Year(s)	System of Record <i>(to be completed by CMS Staff)</i>
MBSF base (2018 qtrly and annual refresh)	2017-2018	
MBSF (chronic cond, other chronic cond, cost & use)	2017	
MedPAR (ss/ls/snf)	2017	
IP, OP (2018 qtrly and annual refresh)	2017-2018	
Carrier, HHA, Hospice, SNF, DME	2017	
See next page for additional file listings...		

4. On behalf of the user the undersigned individual hereby attests that he or she is authorized to legally bind the user to the terms of the existing agreement and agrees to all the terms specified therein.

Type or Print Name of Requesting Individual

Pothur Srinivas

Signature

P.R. Srinivas

Date

01/10/19

5. On behalf of CMS the undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

Type or Print Name and Title of CMS Representative

Cheryl Sample

Signature

Cheryl Sample

Date

03/05/2019

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

Signature of CMS System Manager or Business Owner

Concur Nonconcur

Date

System Name

File	Year(s)	System of Record
Continued from first page...		
Part D Event (option 1)	2017	
PtD Characteristics (Drug, Prescriber)	2017	
PtD Formulary File	2017	
Plan Characteristics	2017	
SSN to BENE_ID Crosswalk	2019-2020	