WHI CCC	Use Only

Ancillary Manuscript Study /MS # Type:

Women's Health Initiative Virtual Data Enclave (VDE) Intake Form

Information provided on this form will be reviewed by the Women's Health Initiative Clinical Coordinating enter (WHI CCC) to confirm the feasibility of your proposed use of the Virtual Data Enclave (VDE). Please ittee (ASC)

provide a copy of the study or manuscript proposal(s) approved by the WHI Ancillary Study Commor Publications and Presentations (P&P) Committee.		
<u>Gen</u>	<u>eral</u>	
1.	Today's Date:	
2.	Title of and MS or AS number of proposal(s) (as approved by the ASC or P&P Committee):	
3.	Principal Investigator:	
	Institution:	
	Address:	
	Phone:	
	Fax:	
	Email:	
4.	Grants Administrator (or administrative contact):	
	Phone:	
	Fax:	
	Email:	
5.	Sponsoring WHI PI:	
6.	Proposed project period (mm/dd/yy): to	

Data and Software

7. The WHI Investigator Datasets which are currently available on the WHI website (whiops.org) are available to all users in the VDE. If you are requesting access to any Medicare Data, you should also request access to WHI enrollment dates under Confidential WHI Data. Please indicate which of the following additional datasets you requesting to use:

Medicare Data*	Confidential WHI Data
 ☐ MedPar ☐ Outpatient ☐ Carrier B ☐ Durable Medical Equipment (DME) ☐ Home Health ☐ Hospice ☐ LILAC-related Medicare Data 	☐ Geocoded addresses ☐ Other geographical data (e.g., zipcode) ☐ Calendar dates Please specify for what events(s) (e.g., WHI enrollment, birthday):

^{*}If requesting access to any Medicare data, please also request access to WHI enrollment dates under Confidential WHI data.

1 3/2024

8.	Will you need to provide the CCC with additional data files for your analyses in the VDE? □ No
	☐ Yes - Please detail the type and size of each data file that you will provide to the CCC:
9.	The following statistical software is installed in the VDE: Statistical Analysis System (SAS), STATA and R. The CCC cannot install other software in the VDE. You may provide programming code files to the CCC for use with one of the available software packages. Will you need to provide the CCC with code files(s). \square No
	☐ Yes - Please detail the type and size of the code file(s) that you will provide to the CCC:
10.	Which statistical software do you plan to use for the majority of your work? □ SAS □ STATA □ R
11.	Expectations of Users: The majority of the datasets available to users are stored as SAS datasets or tab-delimited ASCII files, however, from within SAS it is possible to export datasets into another format such as STATA. We assume that VDE users will have basic SAS programming skills and are able to perform most file manipulation tasks in the SAS environment. Do you meet these basic requirements?? \[\subseteq \text{No} \] \[\subseteq \text{Yes} \]

Study Operations and Logistics

After confirming the feasibility of your proposed use of the VDE, the WHI CCC will provide you with the following depending on which datasets you will use:

1. For non-Medicare data access: The WHI Data Use Agreement (DUA) and the WHI VDE Access Agreement

Or

2. For Medicare Data Access: The WHI Data Use Agreement (DUA) and Medicare DUA.

To initiate use of the VDE, you must provide the following to the CCC:

- The relevant signed agreements
- Documentation of IRB approval from your institution for the full study/manuscript

The WHI CCC will:

- Obtain approval from its IRB to provide VDE access to you for your study
- Prepare a remote access account, user identifier and password
- Provide instructions on the use of the VDE

3/2024

You may request that files you create in the VDE to be transferred to you after your VDE analyses are complete (see the VDE User Guide for details). Before transferring the files, the CCC will review them for compliance with confidentiality restrictions and conformance with your study proposal or manuscript. Standard access covers the confidentiality review of a total file size of 500GB. Charges may be necessary for the review of additional data.

Ouestions/Comments

Please note any questions or comments you have about your use of the VDE:

Please return this form to Lindsey Bull at lmbull@WHI.org

3/2024