

For Internal Use Only

Study #: _____

Study Type: Ancillary Manuscript

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

To enable the Women's Health Initiative Clinical Coordinating Center (WHI CCC) both to confirm the feasibility of your proposed use of the Virtual Data Enclave (VDE) and to prepare and provide a quote for costs, please provide the following information, plus a copy of the study or manuscript proposal(s) approved by the WHI Ancillary Study Committee (ASC) or Publications and Presentations (P&P) Committee.

General

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: _____ Email: _____
Address: _____
Phone: _____
Fax: _____
4. Grants Administrator (or administrative contact): _____
Phone: _____
Fax: _____
Email: _____
5. Sponsoring WHI PI: _____
6. Proposed project period (mm/dd/yy): _____ to _____

Study Details

7. Access to the WHI data currently available on the WHI investigator web site is available through the VDE. Please indicate to which of the following additional data you seek access:

Confidential WHI Data

- Geocoded addresses
- Other geographical data (e.g., zipcode)
- Calendar dates
Please specify for what event(s) (e.g., WHI enrollment, birthdate): _____

8. Will you need the CCC to upload additional data into the VDE for your study?
- No
 - Yes - Please detail the type and size of each dataset that you need the CCC to upload:
9. The VDE includes the following software: Statistical Analysis System (SAS); STATA; and R. The CCC cannot add software to the VDE, but we may be able to transfer a copy of your programming code into your work space for use on one of the available software programs. Will you need the CCC to transfer your programming code?
- No
 - Yes - Please detail the type and size of the programming code file that you will provide to the CCC:

Study Operations, Logistics and Fees

After confirming the feasibility of your proposed use of the VDE, the WHI CCC will provide you with a cost quote, the WHI Data Distribution Agreement (DDA) and the WHI VDE Access Agreement. To initiate use of the VDE, you must provide the following to the CCC:

- A signed WHI DDA
- A signed WHI VDE Access Agreement
- Documentation of IRB approval from your institution for the full study/manuscript.
- A Purchase Order (PO) from your institution in the amount specified in the cost quote.

The WHI CCC will:

- Process the PO
- Obtain approval from its IRB to provide VDE access to you for your study
- Prepare a study-specific remote access account, user identifier and password

The base VDE access fee is \$3,014. This covers the creation and management of your VDE account and regulatory compliance for your study (e.g., CCC IRB review and approval).

You will deposit output files into a study-specific directory on the VDE server and request transmission of output files as needed. Before transmitting output files, the CCC will review them for compliance with confidentiality restrictions and conformance with your study proposal. This review will be done in about 2-3 days, depending on the size of the output data. The base access fee covers the confidentiality review of up to 32 Mb of output data. Additional charges may be necessary for studies requiring the review of additional data.

The base access fee does not cover statistical consulting or training on the use of the data or the statistical software.

Questions/Comments

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