VAPORHCS Institutional Review Board

IRQ Appendix M – Coordinating Center of Multi-site Research

**VAPORHCS PI Name:** **Date:**

**Study/Project ID#:**

This appendix should be completed if this is a multi-site research study for which the VAPORHCS PI is the PI of the overall study and/or VAPORHCS is the Coordinating Center for the study.

Identify the **pages** of the **protocol** (or protocol appendix) which address the following:

1. An explanation of how you will assure that all sites have the most current version of the protocol, consent form and HIPAA authorization:
2. The method to ensure that all changes to the protocol, consent form, and HIPAA authorization are communicated to engaged sites and local approvals have been obtained:
3. The method for ensure that all required approvals are obtained at each local IRB prior to study initiation:
4. The method to ensure that all sites will appropriately safeguard VA data:
5. The method to ensure that all sites will be informed of Serious Adverse Events which may affect the study and/or study events and/or that all noncompliance is reported in accordance with VHA Directive 1058.01:
6. The method to ensure that all local site investigators will conduct the study appropriately:

**Engagement**: An institution is considered “engaged” in human subjects research if the institution or its employees does any of the following:

* Receive/administer the funding,
* Intervene or interact for research purposes with any human subjects,
* Manipulate the environment for research purposes,
* Obtain informed consent, or
* Obtain for research purposes identifiable private information and/or identifiable biological specimens.
1. List each institution engaged in human subjects research for this study, and identify which components of the protocol will be conducted at each site.
2. Provide the Federalwide Assurance number for each institution:
3. Has IRB approval been obtained for each site?

[ ]  Yes [ ]  No

If “yes,” include with this study submission, copies of the IRB approvals for each participating site.

If “no,” please submit copies of the IRB approvals for the other sites as soon as they are obtained.

1. Please identify the page(s) that discuss the method to ensure that the Directors for sites which are **not** engaged, but where research will take place, are notified about the research:
2. Using the above definition of “engaged”, please also identify the pages which address how local Directors and/or site investigators are informed if engagement of their site is no longer required: