**APPENDIX A**

**Statement of Work**

**Statement of Work (SOW)**

TITLE:

**PI:**

**Background:**

Give a rationale for the study. Explain why it is relevant to Veterans.

**Research Design**

Give a brief overview of the methods of the study (participants, design, methods, analysis). Specify how many veterans will be recruited at VABHS and the method of recruitment

**Work to be Accomplished:**

1. Describe the work/support that VA Boston will provide (you can use bullet points). If you plan to hire new study staff to accomplish the work, please specify.
2. Describe the work/support that the company will provide (you can use bullet points)

**Information security/privacy:**

Specify what type of data will be collected from the veterans, whether data will leave VA, how it will leave VA and whether it will be de-identified or retain identifiers.

**Local Reporting:**

Include information about plans for local reporting of adverse events, serious adverse events and unanticipated problems.

**Include the following statements regarding data:**

VHA retains all ownership rights and responsibilities to the original VABHS data file(s) provided to the Sponsor, coordinating center and/or study PI (Recipient). The Recipient may use original data and any data determined to be derived data. Derived data will become the property of the Recipient. Except as VHA shall authorize in writing, the Recipient, its contractors and agents, shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the VHA’s original data covered by this Agreement to any person or entity outside the Recipient and its team of subcontractors performing the Project.

Recipient shall use appropriate safeguards to protect the information from misuse, or inappropriate disclosure and to prevent any use or disclosure of the information other than as provided in this Agreement, or as otherwise acquired by law or regulation. Access to the Data shall be restricted to authorized employees, contractors, subcontractors, and agents of the Recipient requiring access to perform their official duties, as authorized by this Agreement.

Any VA data must be used, stored, and secured according to the requirements of the VA Handbook 6500, other applicable VA and VHA requirements, and as described in the approved research protocol.

For the purpose of this Agreement, VA data will not be shared outside the VA other than as permitted by this agreement and permitted within the protocol for which the data have been requested. A separate copy of VA data may not be created by the Recipient in any way. Data cannot be physically moved or transmitted from the Recipient without first obtaining prior written approval from the VA Facility providing the data and the data being transmitted securely prior to said move or transmission.