# Appendix A: Statement of Work (SOW)

Note: This is a simple SOW template intended to be broadly applicable to various CRADAs at VA. Your project may vary. For questions, you may contact your local Non-Profit Corporation, OGC STAR Attorney, or the Technology Transfer Specialist (TTS) assigned to your VAMC.

## Project Title

## Key Personnel

Department of Veterans Affairs (“VA”)

* Primary Investigator:
* Researcher #1
* Researcher #2

Collaborator (“Collaborator”)

* Collaborator Employee #1
* Collaborator Employee #2

## Background

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

## Objective and Specific Aims

Define the purpose of this study and include a corresponding list of objectives and specific aims. These will be expanded upon in the “Research Design and Methods” section below.

Objective #1:

Specific Aim #1:

Specific Aim #2:

Objective #2:

Specific Aim #1:

## Research Design and Methods

Give an overview of the study (participants, design, timeline, methods, analysis), including detail for each objective and specific aim defined above.

Will Veterans be recruited? If so, what is the method of recruitment?

## Responsibilities

Provide a list of specific responsibilities that both VA personnel and the collaborator are expected to carry out as part of the work. For example, describe the work and support that you and your VAMC will provide. If you plan to hire new study staff to accomplish the work, please specify. Then describe the work and support that the company will provide. You can use bullet points.

VA:

Collaborator:

## Local Reporting

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

## Information Security and Privacy

Will data be collected from Veterans? If so, specify what types of data, whether data will leave VA, how it will leave VA, and whether it will be de-identified or retain identifiers.

If the Collaborator will receive any VA data, include the following statements:

VA retains all ownership rights and responsibilities to any VA data provided to the Collaborator, which is the Confidential Information of VA. Except as VA shall authorize in writing, Collaborator shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to any VA data provided under this Agreement to any third party.

Collaborator shall use appropriate safeguards to protect any VA data 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 any VA 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.

All 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, any 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.

If data is to be de-identified, consider including a description of the de-identification process used, as well as the following statement: All VA data collected and shared with Collaborator will be de-identified according to Safe Harbor Requirements, as defined by Section 164.514(b)(2) of the HIPAA Privacy Rule.

## Presentations and Publications

Who will draft the presentation? What is the expected timeline?

Authorship shall be determined by mutual agreement of Collaborator, VA and Principal Investigator in accordance with customary scientific practices.

***SIGNATURE PAGE FOLLOWS***

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| **U.S. Department of Veterans Affairs**By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Primary InvestigatorDate: **Concur/Non-Concur** (If required by your research protocol)By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_VHA Information Security System Officer (ISSO)Date:By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_VHA Privacy Officer (PO)Date: | **Collaborator**By: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_NAME: TITLE: Date:  |