

Appendix

VHA IE Health Care Collaboration Playbook

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Statement of Work (SOW):

The Statement of Work serves as the *first* document to tell the “story” of the intended collaboration VHA works with a collaborator(s) on developing this document, uncovering details including the project title, background, scope, and goals. Project Managers and Signatories from both VHA and the collaborator(s) must be named in this document, with contact information included. This will become increasingly critical as conversations progress, allowing each party the ability to easily contact the other. A well and appropriately developed SOW should give the uninformed reader an accurate idea of the work being proposed.

Key considerations:

A critical portion of the SOW is aligning the desired collaboration to VHA’s mission and priorities. This also provides a space to think critically on the collaboration and understand if there is a need for the resources the collaborator(s) look to provide. Alignment to key VHA priorities or focus areas can further tell the “story” when seeking approval and reveal impact to VHA. SOWs must be approved by the Office of General Counsel (OGC), where the determination of the mechanism to proceed (CRADA, MOA, etc.) will be established.

VHA:IE Statement of Work
[Project Title]

[Collaborator] Point of Contact:

Name
Title
Address
Email
Phone Number

[Collaborator] Signatory:

Name
Title

VHA IE Point of Contact/Project Manager:

Name
Title
Address
Email
Phone Number

VHA IE Signatory:

(Choose one)

Ryan Vega, MD
Director, VHA Innovation Ecosystem
or
Kristopher “Kit” Teague
Deputy Director, VHA Innovation Ecosystem

[Collaborator] Overview

Background (Who and What)

What problem does this collaboration aim to solve? 2-3 sentences leading into the roles/responsibilities of each individual collaborator. What is each VHA bringing to the table? The collaborator?

Pro tip: The average, uninformed reader should have a gist of the work to be accomplished after reading this section. Tell the compelling story.

Scope (Where, When, How)

Give specific examples of any “tools,” “materials,” and/or “resources.”

Clearly define “space.” Whose is it? Where is it? How will Veterans/employees access it?

If data is being shared, what kind? Is it de-identified?

How will Veterans/staff access this project or be invited/included/enrolled (where applicable)?

What resources from VHA will be required for this collaboration to be successful? The collaborator?

Any pertinent timelines, necessary approvals/consents/etc? Funds?

Goals

What is the value proposition of this collaboration? What does VHA receive as a result of this collaboration? What does the collaborator receive? How is this in line with our Mission? How does this benefit Veterans? (If this aligns with a specific VHA:IE priority or focus, **highlight that here**)

How will you tell the story of this collaborations’ success both internally and externally? *Example opportunities for VHA IE: Our mission is to enable the discovery and spread of health care innovations within VHA that exceed expectations, restore hope, and builds trust within the Veteran community – and to imbed innovation as a core fabric of VHA, build a collaborative innovation community, and deliver a repeatable process for scaling innovation.*

Cooperative Research and Development Agreement (CRADA)

A Cooperative Research and Development Agreement allows VHA to work with a collaborator(s) on the development of innovative solutions at a local facility or across the entire VHA enterprise. With a CRADA, VHA may “accept, retain, and use funds, personnel, services, facilities, intellectual property, equipment or other resources from the collaborator(s).” Also, VHA may “provide personnel, services, facilities, intellectual property, equipment, or other resources, *excluding funds,*” if the collaboration is consistent with VHA’s mission. CRADAs must be approved by the OGC.

Key considerations:

Monies cannot be transferred **to** a collaborator under a CRADA. VHA can, however, accept funds under a CRADA. If VA looks to disburse funds for a collaboration, it must go through the acquisition and procurement channels. If the collaboration involves research in any shape, form, or fashion, it must undergo a layered review process by the Office of Research and Development.



Cooperative Research and Development Agreement

Between

U.S. Department of Veteran Affairs (“VA”)
Veterans Health Administration Innovation Ecosystem (“VHA:IE”)
810 Vermont Avenue NW
Washington, D.C. 20420

And

[enter name of partner + full address]

[TITLE]

This is a Cooperative Research and Development Agreement (CRADA or Agreement) between [name of partner], and the US Department of Veterans Affairs (VA) Veterans Health Administration Innovation Ecosystem (VHA:IE). When referred to independently or collectively, [name of partner] (“Partner”) and the VA/VHA:IE, locally are referred to as the “Parties” or “Party” as appropriate.

1. Program Overview

VHA:IE maintains an Innovation Partnerships Program to support teaming between VA and similar organizations to address shared challenges. The Innovation Partnerships Program focuses on tapping into and cultivating ideas from outside VA. The Partnership Program is where innovative ideas are co-developed between VHA:IE and external organizations that seek to explore mutual interests.

VHA:IE Partnerships are designed to allow VHA:IE to pool resources and ideas with partners to solve large, complex, and shared problems. The program enables more agile research, ad-hoc discussions, and quick course corrections as ideas mature or fail to come to fruition. This is an alternative level of engagement with external organizations where VHA:IE contributes to finding solutions that otherwise could not be resolved or discovered alone.

[Partner Overview]

2. Authority

This Agreement is supported by 15 U.S.C. § 3710(a) and VHA Directive 1098 “VHA Public-Private Partnerships.”

This agreement is for the [name of Partner] to provide [] .

3. CRADA Overview

The scope of this project is memorialized in Appendix A (attached).

4. Expenses

Each Party shall bear its own costs, risks, and liabilities incurred by it arising out of its obligations and efforts under this CRADA. Nothing in the agreement obligates either Party to expend funds on behalf of the other Party.

5. Confidentiality

5.1 The Parties may anticipate the need to exchange Confidential Information to fulfill their requirements under this Agreement. Confidential Information means scientific, business, or financial information so marked or otherwise identified by notification, provided that the information is not:

- (a) publicly known or available from public sources; or
- (b) Any information that, after disclosure to the recipient Party is published or becomes known publicly or otherwise becomes part of the public domain, through no fault of the recipient Party; or
- (c) made available by its owner to others without a confidentiality obligation; or
- (d) already known by the receiving Party, or independently created or compiled by the receiving Party without reference to or use of information provided under this CRADA; or
- (e) related to potential hazards or cautionary warnings associated with the production, handling, or use of the subject matter of the SOW.

At times the Parties may either be the recipient or the provider of such Confidential Information.

5.2 Each Party shall keep Confidential Information of each other in strict confidence and shall use Confidential Information only for the purposes described under this Agreement and to the extent consistent with applicable legal authorities. Recipient Party shall treat Confidential Information as it would its own Confidential Information and take all reasonable precautions to prevent the unauthorized use, disclosure, dissemination, or publication such information.

5.3 Each Party represents that any Confidential Information that it discloses is not information known to be the proprietary information of any third party.

5.4 VA is subject to various confidentiality and disclosure laws, including but not limited to the Privacy Act, 5 U.S.C. § 552a; Freedom of Information Act, 5 U.S.C. § 552; 38 U.S.C. §§ 5701, 5705, and 7332. Additionally, VA employees are bound by the Federal Trade Secrets Act, 18 U.S.C. § 1905, which prohibits them from disclosing confidential and proprietary information disclosed to them in the conduct of their official duties. Nothing in this Agreement bars disclosures to Congress pursuant to an oversight request, or to an authorized official of an executive agency or the Department of Justice that are essential to reporting a substantial violation of law. Requests for disclosure of Confidential Information will be handled in accordance with 5 U.S.C. § 552, E.O. 12600, and VA regulations, in particular VA's procedures for disclosure of business information, 38 C.F.R. 1.558.

6. Publicity; use of name; press releases

Any press releases issued by either Party concerning this CRADA or any resulting relationship to be carried out hereunder, will be subject to prior approval of the other subject to VA and other federal laws and regulations as may be pertinent.

By entering into this Agreement, neither Party shall state or imply that the other Party or any of its organizational units or employees endorse any product or services of another Party. Where publicity references VA, publicity will be accompanied by a disclaimer that no VA endorsement is intended. The Parties shall provide proposed press releases related to this CRADA to each other for review and comment at least five (5) business days before release. Any Party may disclose the title of this Agreement to the public without the approval of the other Parties. The Partner may use VA's logo, seals, flags, and other symbols only pursuant to a written determination by VA that the proposed use by the Partner advances the aims, purposes and mission of the Department. VA approval is not guaranteed.

7. General

7.1 This CRADA shall become effective upon the date of the last signature below, continuing through _____.

7.2 Nothing in this CRADA shall be deemed or implied to create a joint venture or legal partnership of any kind between the Parties. No Party shall have the right to contract on behalf of or bind the other Party or make any commitment, representation or warranty for or on behalf of the other Party.

7.3 This CRADA does not restrict either Party from collaborating with any other third parties in the areas specified in this Agreement.

7.4 All notices, requests, consents and other communications hereunder shall be deemed to have been duly given if delivered or mailed first class, postage prepaid, or by commercial courier to each Party at the address first given above.

7.5 This CRADA may not be assigned or otherwise transferred by any Party, in whole or in part, without the express prior written consent of the other Party, which shall not be unreasonably withheld. No provision of this CRADA may be waived or modified except by a written statement executed by all Parties.

7.6 If any term, provision, covenant, or condition of this CRADA is held to be invalid or unenforceable by a court of competent jurisdiction, it is to that extent deemed omitted and the remainder of this CRADA shall continue in full force and effort.

7.7 This Agreement may be terminated with 30 days' written notice sent to the authorized representative of the non-terminating Party.

7.8 This Agreement is the entire agreement between Parties hereto which supersedes all prior agreements, written or oral, relating to the subject matter hereof. Amendments may only be executed per the terms and conditions in ¶10, *infra*. There are no agreements, warranties (express or implied), liabilities (negligence or otherwise), or understandings other than those written or specified in this CRADA.

Nothing contained herein shall commit either Party to perform any specific obligation whatsoever, including but not limited to, research development effort or provide specific educational services, but merely indicates the Parties' intention to enter into separate agreements. This Agreement shall not be construed as granting any rights to any third party based on any third party beneficiary or otherwise. This CRADA may not be transferred without the express consent of both Parties hereto.

8. Intellectual Property:

This Agreement does not contemplate the creation, transfer, license or sale of any intellectual property as a result of performance of this Agreement. Any such creation, transfer, license or sale of intellectual property shall only be done in accordance with a separate written agreement between the parties.

9. Injuries or Harm:

The liability, if any, of the United States for injury or loss of property, or personal injury or death shall be governed exclusively by the provisions of the Federal Tort Claims Act.

10. Amendments:

Amendments must be bilaterally executed in writing, signed by authorized representatives of both parties. No oral or unilateral amendments will be effective. Only terminations done in accordance with the terms of this agreement may be done unilaterally. This Agreement may be modified only by a written instrument executed by an authorized signatory for each Party. Any project statement of work may be modified by mutual written consent of the Parties.

11. Notices:

All notices shall be in writing and signed by an authorized representative of the notifying Party. Parties shall send notices by registered or certified mail by U.S. Postal Service with return receipt, or by an express/overnight commercial delivery service, with delivery prepaid. Notices shall be properly addressed to the Parties at the addresses provided below or to any other address designated in writing by the receiving Party.

Project managers for this agreement are as follows:

VHA:IE: [to be completed by VHA:IE]

Name

Title

Physical Address

Phone number

Email address

[Partner]:

Name

Title

Physical Address

Phone number

Email address



IN WITNESS WHEREOF, this CRADA has been executed by the duly authorized representatives of the Parties on the day, month and year first written above.

[name of partner]

SIGNED BY:

Typed Name:

Title:

Date:

VHA Innovation Ecosystem (VHA:IE)

SIGNED BY:

Typed Name: Kristopher "Kit" Teague

Title: Deputy Director, VHA Innovation Ecosystem

Date:



Appendix A

(Once reviewed/approved by OGC, the Statement of Work should be added here)

Memorandum of Agreement (MOA)

A Memorandum of Agreement establishes the relationship between VA and a collaborator and details the agreed upon objective(s) and responsibilities. MOAs are commonly used when collaborators identify an overlap in mission, i.e., both parties are looking at solutions for the same illness, patient population, emerging tech, problem area, etc. This type of agreement outlines clear objectives the collaboration is looking to accomplish and, typically, methods to measure success. MOAs outline a collaboration and can be used with or without the exchange of funds.

Memorandum of Agreement (MOA) for Donations

A Memorandum of Agreement for donations also establish the relationship between VA and an entity that wishes to donate. Again, it details the agreed upon objective(s) and responsibilities for both VHA and the donor. The MOA for donations outlines clear objectives in what the donation is looking to accomplish and, only where appropriate, methods to measure success towards those ends.

Memorandum of Understanding (MOU)

A Memorandum of Understanding details the area(s) of collaboration between VA and the collaborators(s) and usually has a “Responsibilities” section. They are a more informal, non-committal type of agreement. MOUs are generally recognized as binding, even if no legal claim could be based on the rights and obligations within them. Most MOUs have flexible term limits and include clauses that allow extensions, typically ranging from 1 to 5 years.

Key Considerations:

MOUs and MOAs have the same legal boiler plate language about term(s), amendment(s), renegeing, and scope change that collaborators need to agree on, but MOUs are typically broader in scope, less binding, and build in less accountability measures. MOUs must be approved by the OGC. MOAs are more formal than a verbal agreement, but not as formal as a contract. MOAs and MOUs have the same legal boiler plate language about term(s), amendment(s), renegeing, and scope change that collaborators need to agree on, but MOAs are typically more specific in scope, are more formal, and can lay the groundwork for further collaboration. MOAs must be approved by the OGC.



MEMORANDUM OF AGREEMENT

Between

United States Department of Veterans Affairs

And

NGO Name

I. PURPOSE:

This Memorandum of Agreement (MoA) is entered into between the U.S. Department of Veterans Affairs (VA or Department), **insert address**, and **NGO Name, insert address**, individually referred to as a “Party” and collectively referred to as the “Parties.” This MoA sets forth a structure in which both entities will work in a mutually beneficial manner to advance and improve the quality of life for our Nation’s Veterans.

NGO Name will provide the following services and in-kind gifts to the Department in an effort to help the Secretary [achieve goals, aims, programs, missions, etc.—summarize/describe the end result of the P3].

Authorities:

- (1) The Secretary or his delegatee has the authority to accept gifts, bequests, or devises of all kinds that would benefit Veterans, agency medical/domiciliary facilities, the Secretary’s authority to administer the laws under his jurisdiction, or that would enhance his ability to provide services or benefits, codified under 38 U.S.C. § 8301.
- (2) The Secretary or his delegatee has the authority to accept gifts or donations of all kinds for the alteration, acquisition, expansion, or construction of medical facilities, codified under 38 U.S.C. §§ 8103, 8104.
- (3) The Secretary can and has delegated that authority to subordinate agency officials and employees under 38 U.S.C. § 512.
- (4) The Secretary may coordinate programs and efforts to provide and to enhance benefits with state, local, and private entities, codified under 38 U.S.C. § 523.
- (5) The Department has statutory charges to conduct outreach regarding Veterans and eligible beneficiaries under 38 U.S.C. § 6301 *et seq et inter alia*.

II. BACKGROUND:

Department of Veterans Affairs

VA’s mission is to fulfill President Lincoln’s promise, “[t]o care for him who shall have borne the battle and for his widow, and his orphan” by serving and honoring the men and women who are America’s Veterans in accordance with Federal law. The Secretary of the VA has identified four

priorities in advancing this mission: 1) Customer Service, 2) Mission Act Implementation, 3) Electronic Health Record Management, and 4) Business Systems Transformation. The Department has identified these priorities throughout the Veterans Benefits Administration, Veterans Health Administration, National Cemetery Administration, Staff Offices, and constituent-specific offices.
[Tailor according to aims and germane business unit]

NGO Name

NGO Name is insert boilerplate text that describes the NGO.

III. OBJECTIVES:

The Department and NGO Name have a shared goal to insert a simplified version of your purpose from above (goal) of this partnership. This partnership will be mutually beneficial as the Parties work together through a set of objectives to achieve this goal. This MoA sets forth a framework of intent and cooperation between the Parties to achieve the following objective(s):

1. Insert objective #1 of this partnership that supports VA's mission, goals, priorities, objectives, and/or strategies. [consider the number of objectives, drafting accordingly]

IV. RESPONSIBILITIES:

Department of Veterans Affairs: [or appropriate staff/business unit/office name]

1. VA will insert what you are committing VA to do in this partnership.
[include other ancillary VA responsibilities in the subject area]

NGO Name:

1. NGO Name will insert what the NGO is committing to do in this partnership.

V. PERFORMANCE MEASURES

[If applicable—can we develop metrics or criteria to judge effect or success?]

The Department and NGO Name seek to increase access to, and enhance services to Veterans and their families through this partnership. The ability to quantitatively and qualitatively capture objective performance through metrics that demonstrate the impact of this partnership is critical. Therefore, the Parties agree to use the following metrics to capture and record objective performance through related outcomes, outputs, measurables, and/or impacts, as appropriate:

1. Insert metric #1 of this partnership that captures and records appropriate quantitative or qualitative outcomes, outputs, measurables, and/or impacts. [Expected ROI or Result?]



VI. POINTS OF CONTACT:

DEPARTMENT OF VETERANS
AFFAIRS

Bus. Unit/Office

VA POC Name

Title

Department of Veterans Affairs

Address 1

Address 2

City, State Zip Code

Phone Number

Email Address

NGO NAME

NGO POC Name

Title

NGO Name

Address 1

Address 2

City, State Zip Code

Phone Number

Email Address

VII. LIMITATIONS:

(a) For the purposes of this MoA, a partnership is a voluntary, collaborative, working relationship between VA and **NGO Name**. The term partnership does not imply that VA and **NGO Name** are jointly liable for either Party's obligations. Neither party is responsible for debts, contractual obligations, or conduct, tortious or otherwise, of the other Party. This MoA shall not be construed to create a joint venture, agency, employment, or any other relationship between VA and **NGO Name**. This MoA does not authorize the expenditure or reimbursement of any funds. This MoA does not create a binding contractual obligation, obligate either Party to expend appropriations or other monies or enter into any contract or other obligation, or create any rights between the Parties. Should any exchange of funds or resources be necessary, the Parties will first enter into a supplemental binding instrument.

(b) **NGO Name** will not use this MoA to sell or promote any products or services.

(c) **NGO Name** will not use the name of the VA or any of its components, except in factual publicity and with prior written approval of VA. Factual publicity includes announcements of dates, times, locations, purposes, agendas, speakers, and fees, if any, involved with activities or events. Such factual publicity shall not imply that the involvement of VA serves as an endorsement of the general policies, activities, or products of **NGO Name**. Where the publicity references the VA, publicity will be accompanied by a disclaimer to the effect that no VA endorsement is intended. **NGO Name** may use VA's logo, seals, flags, and other symbols only pursuant to a written determination by VA that the proposed use by **NGO Name** advances the aims, purposes, and mission of the Department. VA approval is not guaranteed.

(d) VA will not use, and has obtained no ownership interests in **NGO's** names, logos, and/or trademarks (the Marks). VA will obtain **NGO Name's** prior written approval to use the Marks.

(e) This Agreement is not intended to be an exclusive arrangement. The relationship established in

this Agreement in no way limits VA or **NGO Name** from establishing similar relationships with any other entity.

(f) This Agreement does not represent any endorsement by VA of the general policies, activities, or products of **NGO Name**.

(g) Any publicity released by either Party concerning this MoA, the services or supports provided within, or any resulting outcomes, will be subject to prior approval of the other Party.

(h) Each Party shall bear its own costs, risks, and liabilities incurred by it arising out of its obligations and efforts under this MoA. One Party cannot commit the other to any cost, expense, or obligation without the prior written consent of that Party.

(i) This MoA may not be assigned or otherwise transferred by any Party, in whole or in part, without the prior written consent of the other Party, which shall not be unreasonably withheld.

(j) VA and **NGO Name** will only disclose data to one another as permitted under applicable federal law.

(k) With regards to any copyrighted materials created during the performance of this agreement, **NGO Name** will grant to VA (the Government), and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government.

NOTE: THE LIABILITY, IF ANY, OF THE UNITED STATES FOR INJURY OR LOSS OF PROPERTY, OR PERSONAL INJURY OR DEATH SHALL BE GOVERNED EXCLUSIVELY BY THE PROVISIONS OF THE FEDERAL TORT CLAIMS ACT. THIS AGREEMENT IS SUBJECT ONLY TO FEDERAL LAW.

VIII. DURATION, AMENDMENT, REVIEW, TERMINATION, DISPUTES:

- A. This MoA will have a Period of Performance of one (1) year, followed by X consecutive option years, subject to the availability of appropriated funds. [adapt POP as needed]
- B. Amendments must be bilaterally executed in writing, signed by authorized representatives of both Parties. No oral or unilateral amendments will be effective. Only terminations done in accordance with the terms of this agreement may be done unilaterally.
- C. Should disagreement arise as to the interpretation of the provisions of this agreement that cannot be resolved between the Parties' POCs, the area(s) of disagreement will be reduced to writing by each Party and presented to the authorized officials on both sides for resolution. If settlement cannot be reached at this level, the disagreement will be raised to the next level in accordance with the Parties' procedures for final resolution.
- D. This agreement may only be terminated in writing with XX days' notice sent from the authorized representative of the terminating Party to the authorized representative of the other Party. In no case will any oral termination be effective nor will any termination attempted outside these stated requirements.



VA INNOVATION Ecosystem

IX. APPROVALS:

Department of Veterans
Affairs
[Office/Business Unit]

NGO Name

By:

By:

NAME

NAME

POSITION

POSITION

Department of Veterans
Affairs
[Office/Business Unit]

NGO Name

Date: _____

Date: _____

Attachments/Appendices [If exhibits or attachments are needed—to be incorporated by reference as though fully set forth in the main document]

MOA Template: Donations

MEMORANDUM OF AGREEMENT

Between

United States Department of Veterans Affairs

And

NGO Name

I. PURPOSE:

This Memorandum of Agreement (MoA) is entered into between the U.S. Department of Veterans Affairs (VA or Department), **insert address**, and **NGO Name, insert address**, individually referred to as a “Party” and collectively referred to as the “Parties.” This MoA sets forth a structure in which both entities will work in a mutually beneficial manner to advance and improve the quality of life for our Nation’s Veterans.

NGO Name will provide the following services and in-kind gifts to the Department in an effort to help the Secretary [achieve goals, aims, programs, missions, etc. — summarize/describe the end result of the P3].

Authorities:

- (1) The Secretary or his delegatee has the authority to accept gifts, bequests, or devises of all kinds that would benefit Veterans, agency medical/domiciliary facilities, the Secretary’s authority to administer the laws under his jurisdiction, or that would enhance his ability to provide services or benefits, codified under 38 U.S.C. § 8301.
- (2) The Secretary or his delegatee has the authority to accept gifts or donations of all kinds for the alteration, acquisition, expansion, or construction of medical facilities, codified under 38 U.S.C. §§ 8103, 8104.
- (3) The Secretary can and has delegated that authority to subordinate agency officials and employees under 38 U.S.C. § 512.
- (4) The Secretary may coordinate programs and efforts to provide and to enhance benefits with state, local, and private entities, codified under 38 U.S.C. § 523.
- (5) The Department has statutory charges to conduct outreach regarding Veterans and eligible beneficiaries under 38 U.S.C. § 6301 *et seq et inter alia*.

II. BACKGROUND:

Department of Veterans Affairs

VA's mission is to fulfill President Lincoln's promise, "[t]o care for him who shall have borne the battle and for his widow, and his orphan" by serving and honoring the men and women who are America's Veterans in accordance with Federal law. The Secretary of the VA has identified four priorities in advancing this mission: 1) Customer Service, 2) Mission Act Implementation, 3) Electronic Health Record Management, and 4) Business Systems Transformation. The Department has identified these priorities throughout the Veterans Benefits Administration, Veterans Health Administration, National Cemetery Administration, Staff Offices, and constituent-specific offices. [Tailor according to aims and germane business unit]

NGO Name

NGO Name is insert boilerplate text that describes the NGO.

III. OBJECTIVES:

The Department and NGO Name have a shared goal to insert a simplified version of your purpose from above (goal) of this partnership. This partnership will be mutually beneficial as the Parties work together through a set of objectives to achieve this goal. This MoA sets forth a framework of intent and cooperation between the Parties to achieve the following objective(s):

1. Insert objective #1 of this partnership that supports VA's mission, goals, priorities, objectives, and/or strategies. [consider the number of objectives, drafting accordingly]

IV. RESPONSIBILITIES:

Department of Veterans Affairs: [or appropriate staff/business unit/office name]

1. VA will insert what you are committing VA to do in this partnership. [include other ancillary VA responsibilities in the subject area]

NGO Name:

1. NGO Name will insert what the NGO is committing to do in this partnership.



V. PERFORMANCE MEASURES:

[If applicable — can we develop metrics or criteria to judge effect or success?]

The Department and **NGO Name** seek to increase access to, and enhance services to Veterans and their families through this partnership. The ability to quantitatively and qualitatively capture objective performance through metrics that demonstrate the impact of this partnership is critical. Therefore, the Parties agree to use the following metrics to capture and record objective performance through related outcomes, outputs, measurables, and/or impacts, as appropriate:

1. **Insert metric #1 of this partnership that captures and records appropriate quantitative or qualitative outcomes, outputs, measurables, and/or impacts.**
[Expected ROI or Result?]

VI. POINTS OF CONTACT:

DEPARTMENT OF VETERANS
AFFAIRS

Bus. Unit/Office
VA POC Name
 Title
Department of Veterans Affairs
 Address 1
 Address 2
 City, State Zip Code
 Phone Number
 Email Address

NGO NAME
NGO POC Name
 Title
NGO Name
 Address 1
 Address 2
 City, State Zip Code
 Phone Number
 Email Address

VII. LIMITATIONS:

(a) For the purposes of this MoA, a partnership is a voluntary, collaborative, working relationship between VA and **NGO Name**. The term partnership does not imply that VA and **NGO Name** are jointly liable for either Party’s obligations. Neither party is responsible for debts, contractual obligations, or conduct, tortious or otherwise, of the other Party. This MoA shall not be construed to create a joint venture, agency, employment, or any other relationship between VA and **NGO Name**. This MoA does not authorize the expenditure or reimbursement of any funds. This MoA does not create a binding contractual obligation, obligate either Party to expend appropriations or other monies or enter into any contract or other obligation, or create any rights between the Parties. Should any exchange of funds or resources be necessary, the Parties will first enter into a supplemental binding instrument.

- (b) **NGO Name** will not use this MoA to sell or promote any products or services.
- (c) **NGO Name** will not use the name of the VA or any of its components, except in factual publicity and with prior written approval of VA. Factual publicity includes announcements of dates, times, locations, purposes, agendas, speakers, and fees, if any, involved with activities or events. Such factual publicity shall not imply that the involvement of VA serves as an endorsement of the general policies, activities, or products of **NGO Name**. Where the publicity references the VA, publicity will be accompanied by a disclaimer to the effect that no VA endorsement is intended. **NGO Name** may use VA's logo, seals, flags, and other symbols only pursuant to a written determination by VA that the proposed use by **NGO Name** advances the aims, purposes, and mission of the Department. VA approval is not guaranteed.
- (d) VA will not use, and has obtained no ownership interests in **NGO's** names, logos, and/or trademarks (the Marks). VA will obtain **NGO Name's** prior written approval to use the Marks.
- (e) This Agreement is not intended to be an exclusive arrangement. The relationship established in this Agreement in no way limits VA or **NGO Name** from establishing similar relationships with any other entity.
- (f) This Agreement does not represent any endorsement by VA of the general policies, activities, or products of **NGO Name**.
- (g) Any publicity released by either Party concerning this MoA, the services or supports provided within, or any resulting outcomes, will be subject to prior approval of the other Party.
- (h) Each Party shall bear its own costs, risks, and liabilities incurred by it arising out of its obligations and efforts under this MoA. One Party cannot commit the other to any cost, expense, or obligation without the prior written consent of that Party.
- (i) This MoA may not be assigned or otherwise transferred by any Party, in whole or in part, without the prior written consent of the other Party, which shall not be unreasonably withheld.
- (j) VA and **NGO Name** will only disclose data to one another as permitted under applicable federal law.
- (k) With regards to any copyrighted materials created during the performance of this agreement, **NGO Name** will grant to VA (the Government), and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to



reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government.

NOTE: THE LIABILITY, IF ANY, OF THE UNITED STATES FOR INJURY OR LOSS OF PROPERTY, OR PERSONAL INJURY OR DEATH SHALL BE GOVERNED EXCLUSIVELY BY THE PROVISIONS OF THE FEDERAL TORT CLAIMS ACT. THIS AGREEMENT IS SUBJECT ONLY TO FEDERAL LAW.

VIII. DURATION, AMENDMENT, REVIEW, TERMINATION, DISPUTES:

- A. This MoA will have a Period of Performance of one (1) year, followed by X consecutive option years, subject to the availability of appropriated funds. [adapt POP as needed]
- B. Amendments must be bilaterally executed in writing, signed by authorized representatives of both Parties. No oral or unilateral amendments will be effective. Only terminations done in accordance with the terms of this agreement may be done unilaterally.
- C. Should disagreement arise as to the interpretation of the provisions of this agreement that cannot be resolved between the Parties' POCs, the area(s) of disagreement will be reduced to writing by each Party and presented to the authorized officials on both sides for resolution. If settlement cannot be reached at this level, the disagreement will be raised to the next level in accordance with the Parties' procedures for final resolution.
- D. This agreement may only be terminated in writing with XX days' notice sent from the authorized representative of the terminating Party to the authorized representative of the other Party. In no case will any oral termination be effective nor will any termination attempted outside these stated requirements.

IX. APPROVALS:

Department of Veterans
Affairs
[Office/Business Unit]

NGO Name

By:

By:

NAME

NAME

POSITION

POSITION

Department of Veterans
Affairs
[Office/Business Unit]

NGO Name

Date: _____

Date: _____

Attachments/Appendices [If exhibits or attachments are needed—to be incorporated by reference as though fully set forth in the main document]

Data Use Agreement (DUA)

A Data Use Agreement governs data sharing between VHA IE and its collaborators and establishes how information is protected and how it may be used by collaborators. In this collaboration agreement, VHA IE sets rules and limitations on the use, storage, transfer, disposal, access, control, etc., of shared data. HIPAA allows VHA, as a covered entity, to use and disclose a limited data set (LDS) for research without obtaining an authorization or a waiver of authorization. VHA may disclose an LDS to a collaborator who is not a covered entity when a DUA is in place. Four types of DUAs exist: DUA with a Federal Entity; DUA with a non-Federal Entity; DUA for LDS with a Federal entity; DUA for LDS with a non-Federal entity.

Key considerations:

This agreement is used when VHA IE establishes criteria for the use, disclosure, storage, processing, and disposal of data. Other agreements beyond a DUA may include data protection, so consider the provisions accompanied with the data sharing in question.

DUA with Federal Entities (without Limited Data Set)

DATA USE AGREEMENT WITH FEDERAL ENTITIES

FOR DATA FROM THE

DEPARTMENT OF VETERANS AFFAIRS (VA),
VETERANS HEALTH ADMINISTRATION INNOVATION ECOSYSTEM (VHA IE)

TO THE

<INSERT NAME OF FEDERAL ENTITY>

FOR

<INSERT PROJECT NAME>

Purpose:

This Agreement establishes the terms and conditions under which the Department of Veterans Affairs, Veterans Health Administration Innovation Ecosystem (VHA IE) will provide, and <INSERT NAME OF FEDERAL ENTITY> will use VHA individually identified information/VHA protected health information (VHA III/PHI).

References and Authorities:

- *The Privacy Act of 1974, 5 U.S.C. § 552a, as amended*
- *The Health Insurance Portability and Accountability Act of 1994, Pub. L. 104-191*
- *Standards for Privacy of Individually Identifiable Health Information and Security Standards for the Protection of Electronic Protected Health Information (HIPAA Privacy and HIPAA Security Rules), 45 C. F. R. §§ 160, 164.*
- *Federal Information Processing Standards (FIPS) Publication 140-2, "Security Requirements for Cryptographic Modules," May 25, 2001*
- *The HITECH Act, Pub. L. 109-1*
- *System of Records Notice (SORN) <INSERT VHA SORN NUMBER>, <INSERT NAME OF VHA DATABASE and (DATE and FEDERAL REGISTRY CITATION NUMBER)>*
- *System of Records Notice (SORN) <INSERT FEDERAL ENTITY SORN NUMBER>, <INSERT NAME OF FEDERAL ENTITY DATABASE and (DATE and FEDERAL REGISTRY CITATION NUMBER)>*

TERMS OF THE AGREEMENT:

1. This Agreement is by and between VHA IE and the <INSERT NAME OF FEDERAL ENTITY>

2. This Agreement supersedes any and all agreements between the parties with respect to the transfer and use of data for the purpose described in this agreement, and pre-empts and overrides any instructions, directions, agreements, or other understanding in or pertaining to



any other prior communication with respect to the data and activities covered by this Agreement.

3. The VHA IE will transfer to <INSERT NAME OF FEDERAL ENTITY PROGRAM OFFICE RECEIVING INFORMATION>, through <DESCRIBE SECURE MEANS OF TRANSFER>, any and all related data for:

- <INSERT PURPOSE>

- <INSERT ADDITIONAL PURPOSE>.

VHA III/PHI to be transferred from VHA IE to the <INSERT NAME OF FEDERAL ENTITY> may include, but is not limited to: **VHA HANDBOOK 1080.01 November 20, 2013 APPENDIX E E-2**

- **<NAME DATA ELEMENTS>**

4. VHA will retain ownership of the original data and the Federal agency will receive a copy. Data transferred under this agreement becomes the property of <INSERT NAME OF FEDERAL ENTITY>. The data shall be treated by <INSERT NAME OF FEDERAL ENTITY> in the same manner as other individually identifiable information maintained under the Privacy Act by <INSERT NAME OF FEDERAL ENTITY>. The data will be incorporated into <INSERT NAME OF FEDERAL ENTITY> Privacy Act Systems of Records (SOR) “<INSERT NAME OF FEDERAL ENTITY DATABASE>” (<INSERT SORN NUMBER OF FEDERAL ENTITY DATABASE>). The following named individuals are designated as Technical Representatives of VHA, and the <INSERT NAME OF FEDERAL ENTITY>, who will arrange for transfer of the VHA III via <DESCRIBE SECURE MEANS OF TRANSFER> to the <INSERT NAME OF FEDERAL ENTITY> for their use. The <INSERT NAME OF FEDERAL ENTITY> Technical Representative will be responsible for complying with all conditions of use and for establishment and maintenance of security arrangements to prevent unauthorized use or disclosure of the data provided under this agreement. <INSERT NAME OF FEDERAL ENTITY> agrees to notify VHA within 15 days of any change of circumstances affecting the ability of the <INSERT NAME OF FEDERAL ENTITY> to comply with terms of this agreement.

Technical Representative for <INSERT NAME OF FEDERAL ENTITY>:

<INSERT NAME, PHONE NUMBER AND EMAIL OF FEDERAL ENTITY TECHNICAL REPRESENTATIVE>

Technical Representative for VHA:

<INSERT NAME, PHONE NUMBER AND EMAIL OF VHA TECHNICAL REPRESENTATIVE>

5. The following named individuals are designated as their agencies' Points of Contact for performance with the terms of the Agreement. All questions of interpretation or compliance with the terms of this Agreement should be referred to the officials named below.

Point-of-Contact on behalf of <INSERT NAME OF FEDERAL ENTITY>:

<INSERT NAME, PHONE NUMBER AND EMAIL OF FEDERAL ENTITY POC>

Point-of-Contact on behalf of VHA IE:

<INSERT NAME, PHONE NUMBER AND EMAIL OF VHA POC>

6. The VHA III provided to <INSERT NAME OF FEDERAL ENTITY> under this Agreement will be covered by the Privacy Act SOR “<INSERT SORN NAME>” Although <INSERT NAME OF FEDERAL ENTITY> will own the copy of VHA III/ PHI transferred under this Agreement, it agrees not to disclose the VHA III/ PHI to any person outside the <INSERT NAME OF FEDERAL ENTITY> except as required by law. pursuant to a Freedom of Information Act (FOIA) request, as authorized by Federal statute or regulation, <INSERT VHA SORN NAME AND NUMBER> or pursuant to a court order from a court of competent jurisdiction.

7. <INSERT NAME OF FEDERAL ENTITY PROGRAM OFFICE> will provide appropriate administrative, technical, and physical safeguards to ensure the confidentiality and security of the data covered by this Agreement and to prevent unauthorized use or access to it. As a component of a federal agency, <INSERT NAME OF FEDERAL ENTITY PROGRAM OFFICE> will conform to the applicable Federal Information Processing Standards (FIPS) and Special Publications developed by the National Institute of Standards and Technology and, the common information security laws and regulations, such as the Federal Information Security Management Act (FISMA). The use of unsecured telecommunications, including the Internet, to transmit individually-identifiable or deducible information derived from VHA III/ PHI covered by this Agreement is prohibited, unless VHA and <INSERT NAME OF FEDERAL ENTITY> agree to transmit any data in an encrypted form which meets the encryption requirements of FIPS 140-2.

8. In the event <INSERT NAME OF FEDERAL ENTITY> as the data owner determines or reasonably believes that an unauthorized disclosure of the data shared in this Agreement has occurred, <INSERT NAME OF FEDERAL ENTITY> will follow all appropriate breach protocols as required by Federal law. developed under FISMA and statutory protocols under <INSERT THE CORRECT AUTHORITY i.e., HIPAA, HITECH, and title 38 OR THE OMB REQUIREMENTS ON ALL FEDERAL AGENCIES>, which include but are not limited to the following: (1) Immediately notifying its Privacy Officer/Chief Information Officer of the potential breach; (2) Working with its breach response program to investigate and assess the nature and scope of the breach and taking all appropriate actions; (3) Identifying all individuals involved who are the subject of the breach; and (4) Providing all necessary notifications to the individuals involved as required by <INSERT APPROPRIATE LANGUAGE FROM ABOVE> and [INSERT NAME OF FEDERAL ENTITY] policy. [INSERT NAME OF FEDERAL ENTITY] will immediately notify VHA of any identified potential breaches and will share findings of the breach investigation and remediation activities with VHA in a timely manner. After notification of a breach, VHA may request [INSERT NAME OF FEDERAL ENTITY] perform a security and privacy compliance assessment to ensure adequate processes are in place for the protection of the data. [INSERT NAME OF FEDERAL ENTITY] agrees to share all findings from the security and privacy compliance assessment with VHA.

9. Authority for VHA IE to share this data for the purpose indicated is under this Agreement are as follows: HIPAA Privacy Rule provision <45 CFR INSERT LEGAL CITATION>, the Privacy Act is [INSERT LEGAL CITATION OR ROUTINE USE FROM THE APPLICABLE PRIVACY ACT SYSTEM OF RECORD] and 38 USC 5701(b)(3) <IF THIS STATUTE IS APPLICABLE> and 38 USC 7332 <INSERT LEGAL CITATION, IF THIS STATUTE IS APPLICABLE>.

10. The terms of this Agreement can be changed only by a written modification of the agreement by the agency signatories (or their designated representatives) to this Agreement or by the parties adopting a new agreement in place of this Agreement.

11. This Agreement may be terminated by either party, at any time, and for any reason upon 30 days written notice from the terminating party to the other party.



12. On behalf of VHA and <INSERT NAME OF FEDERAL ENTITY>, each undersigned individual hereby attests that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

<INSERT NAME OF FEDERAL ENTITY SIGNER> Date
<INSERT TITLE OF FEDERAL ENTITY SIGNER>
<INSERT PROGRAM OFFICE OF FEDERAL ENTITY>
<INSERT NAME OF FEDERAL ENTITY>

Ryan Vega, MD Date
Director
VHA Innovation Ecosystem
Veterans Health Administration

Concur/Non-Concur:

Signature Date
<INSERT NAME OF VHA FACILITY/PROGRAM OFFICE ISO>

Concur/Non-Concur:

Signature Date
<INSERT NAME OF VHA FACILITY/PROGRAM OFFICE PRIVACY OFFICER>

DUA with Non-Federal Entities (No Limited Data Sets)

DATA USE AGREEMENT WITH FEDERAL ENTITIES

FOR DATA FROM THE

DEPARTMENT OF VETERANS AFFAIRS (VA),
VETERANS HEALTH ADMINISTRATION INNOVATION ECOSYSTEM (VHA IE)

TO THE

<INSERT NAME OF NON-FEDERAL ENTITY>

FOR

<INSERT PROJECT NAME>

Purpose:

This Agreement establishes the terms and conditions under which the VHA Innovation Ecosystem (VHA IE) will provide, and <INSERT ENTITY NAME>, its contractors and agents, will use VHA IE data <PROVIDE DESCRIPTION OF PROJECT INCLUDING TYPE OF DATA AND HOW IT WILL BE USED>.

TERMS OF THE AGREEMENT:

1. This Agreement is by and between <INSERT ENTITY NAME>, its contractors and agents (hereafter the "Requestor") and the VHA Innovation Ecosystem (hereafter the "VHA IE"), a component of the U.S. Department of Veterans Affairs.
2. This Agreement supersedes any and all agreements between the parties with respect to the transfer and use of data for the purpose described in this agreement, and preempts and overrides any instructions, directions, agreements, or other understanding in or pertaining to any other prior communication with respect to the data and activities covered by this Agreement.
3. <SELECT ONE> VHA IE retains all ownership rights and responsibilities to the original and derivative data file(s) provided to the Requestor under this Agreement. <OR> VHA IE will retain ownership of the original data and <INSERT ENTITY NAME> will receive a copy. Data transferred under this agreement becomes the property of <INSERT ENTITY NAME>.
4. Upon completion of the project, or at the request of VHA IE after making an ownership decision, the Requestor will securely return or destroy, at VHA IE option, all data gathered, created, received or processed.
5. <INSERT NAME OF OFFICIAL AND ENTITY> will be responsible for the observance of all conditions of use and for establishment and maintenance of appropriate administrative, technical and physical security safeguards to prevent unauthorized use and to protect the confidentiality of the data. The Requestor agrees to notify the VHA IE within fifteen (15) days of any change in the named Requestor.
6. VHA IE will ensure the secure transfer of the data to <INSERT NAME OF OFFICIAL AND ENTITY>. The method of transfer will be: <INSERT METHOD OF TRANSFER>.

7. The following named individuals are designated as their agencies' Points of Contact for performance of the terms of the Agreement. All questions of interpretation or compliance with the terms of this Agreement should be referred to the VHA IE official named below.

VHA's Point-of-Contact on behalf of VHA IE

Name:

Title:

Telephone:

Points-of-Contact on behalf of <INSERT NON-FEDERAL ENTITY NAME>

Name:

Title:

Telephone:

8. [INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA], the requesting entity must provide the following information:
9. <DESCRIBE WHERE THE DATA WILL BE STORED:>
10. <DESCRIBE MEANS OF ACCESSING DATA AND ACCESS AUDIT METHODS:>
11. <PROVIDE DATE OF PROJECT COMPLETION:>
12. [INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA] Except as VHA IE shall authorize in writing, <insert requesting entity name>, its contractors and agents, shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the VHA IE data covered by this Agreement to any person or entity outside the Requestor and its team of subcontractors performing the Project. Without limitation to any other provision of this Agreement, the Requestor agrees not to disclose, display or otherwise make available any company proprietary information to any third party, in any form, except to public health officials or as required by law. VHA IE will clearly indicate in writing any information that is considered to be trade secret or confidential business information.
13. [INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA] <INSERT ENTITY NAME>, its contractors and agents, shall establish appropriate administrative, technical, procedural, and physical safeguards in accordance with VA Handbook 6500, to protect VA data confidentiality and to prevent unauthorized access to the data provided by VHA IE. If co-mingling must be allowed to meet the requirements of the business/research need, the Requestor must ensure that VHA IE's information is returned to the VHA IE or destroyed in accordance with VA's sanitization requirements. VHA IE reserves the right to conduct onsite inspections of Requestor's IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA requirements.

14. All VHA IE data and derivative data must be stored in an encrypted partition on the Requestor's or its contractors' /subcontractors' information system hard drive using FIPS 140-2 validated software. (See <http://csrc.nist.gov/groups/STM/cmvp/validation.html> for a complete list of validated cryptographic modules). The application must be capable of key recovery and a copy of the encryption key(s) must be stored in multiple secure locations. FIPS 140-2 (or current version) compliant / NIST validated encryption will be used to secure VHA IE data stored on any portable drives, IT components, disks, CDs / DVDs.
15. Data must not be physically moved or transmitted from the site without first obtaining prior written approval from the information owner and the data being encrypted prior to said move or transmission.
16. **[INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA]** All electronic storage media used on non-VA leased or owned IT equipment that is used to store, process, or access VA sensitive information must have all VA sensitive information removed, cleared, sanitized, or destroyed in accordance with VA policies and procedures upon the earlier of: (1) completion or termination of the agreement, or (2) disposal or return of the IT equipment by the Requestor or any person acting on behalf of the Requestor.
17. **[INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA]** VHA IE reserves the right to allow authorized representatives of VHA IE and the VA Inspector General to be granted access to premises where the data are kept by the Requestor for the purpose of confirming that the Requestor is in compliance with all requirements associated with this agreement.
18. **[INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA]** If a Requestor's employee, contractor, or agent becomes aware of the theft, loss or compromise of any device used to transport, access or store VHA IE information or data, such employee, agent, or contractor must immediately report the incident to his or her supervisor. Should any security incident or event involve VHA IE data (i.e. the theft, loss, compromise, or destruction of any device used to transport, access, or store VHA data) covered by this agreement, or the incident places VHA IE data at risk of loss, unauthorized access, misuse or compromise, the Requestor will notify the VHA IE Point-of-Contact by phone or in writing within one hour of detection. The Requestor will provide details of the security event, the potential risk to VHA IE data, and the actions that have been or are being taken to remediate the issue. The Requestor will also provide VHA IE with a written closing action report once the security event or incident has been resolved. VHA IE will follow this same notification process should a security event occur within the VHA IE's boundary involving Requestor provided data. Designated points of contact will follow established incident response and reporting procedures, determine whether the incident warrants escalation, and comply with established escalation requirement for responding to security incidents.
19. **[INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA]** The Requestor's employees, contractors and agents must provide evidence of completion (or initiation) of background investigation prior to granting access to VA or VHA IE information systems.
20. **[INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA]** The Requestor's employees, contractors and agents must complete VA's Security and Privacy Awareness training and sign VA's National Rules of Behavior. 15. In the event VHA IE determines or has a reasonable cause to believe that the Requestor disclosed or may have used or disclosed any part of the data other than as authorized by this Agreement or other written authorization from the person designated in item number 5 of this Agreement, VHA IE in its sole discretion may require the Requestor to: (a) promptly investigate and report to /VHA IE the Requestor's determinations regarding any alleged or actual unauthorized use or disclosure, (b) promptly

resolve any problems identified by the investigation; (c) if requested by VHA IE, submit a formal response to an allegation of unauthorized disclosure; and (d) if requested, return VHA IE's data files to the Data Owner. If VHA IE reasonably determines or believes that unauthorized disclosures of Data Owner's data in the possession of Requestor have taken place, the VHA IE may refuse to release further data to the Requestor for a period of time to be determined by VHA IE, or may terminate this Agreement.

21. In the event VHA IE determines or has a reasonable cause to believe that the Requestor disclosed or may have used or disclosed any part of the data other than as authorized by this Agreement or other written authorization from the person designated in item number 5 of this Agreement, VHA IE in its sole discretion may require the Requestor to: (a) promptly investigate and report to VHA IE the Requestor's determinations regarding any alleged or actual unauthorized use or disclosure, (b) promptly resolve any problems identified by the investigation; (c) if requested by VHA IE, submit a formal response to an allegation of unauthorized disclosure; and (d) if requested, return VHA IE's data files to the Data Owner. If VHA IE reasonably determines or believes that unauthorized disclosures of Data Owner's data in the possession of Requestor have taken place, the VHA IE may refuse to release further data to the Requestor for a period of time to be determined by VHA IE, or may terminate this Agreement.
22. Access to the VHA IE data shall be restricted to authorized <insert Entity name> employees, contractors, agents and officials who require access to perform their official duties in accordance with the uses of the information as authorized in this Agreement. Such personnel shall be advised of: (1) the confidential nature of the information; (2) safeguards required protecting the information; and (3) the administrative, civil and criminal penalties for noncompliance contained in applicable Federal laws. The Requestor agrees to limit access to, disclosure of and use of all data provided under this Agreement. The Requestor agrees that access to the data covered by this Agreement shall be limited to the minimum number of individuals who need the access to the Information Owner's data to perform this Agreement.
23. <INSERT ENTITY NAME>, its contractors or agents, will protect the privacy and confidentiality of any individually identifiable information contained in the data consistent with the Privacy Act of 1974, and, to the extent applicable, standards promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 38 U.S.C. 5701(f), and other applicable laws, regulations, and policies. The Requestor may provide data access to appropriate employees, contractors, and other authorized Requestors. Except as may be required in a public health emergency to protect life and health of individuals and populations, and for authorized follow-up activities described herein, the Requestor will not attempt to identify the individuals whose records are contained in the data provided under this agreement or link these data with other data sources for identification purposes.
24. The information provided may not be disclosed or used for any purpose other than as outlined in this Agreement. If the Requestor wishes to use the data and information provided by VHA IE under this Agreement for any purpose other than those outlined in this Agreement, the Requestor shall make a written request to VHA IE describing the additional purposes for which it seeks to use the data. If VHA IE determines that the Requestor's request to use the data and information provided hereunder is acceptable, VHA IE shall provide the Requestor with written approval of the additional use of the data.



25. The Requestor hereby acknowledges that criminal penalties under § 1106(a) of the Social Security Act (42 U.S.C. § 1306(a)) may apply to disclosures of information that are covered by § 1106 and that are not authorized by regulation or by Federal law. The Requestor further acknowledges that criminal penalties under the Privacy Act (5 U.S.C. § 552a(i)(1)) may apply if it is determined that the Requestor, or any individual employed or affiliated therewith, knowingly and willfully discloses VHA IE's data. Finally, the Requestor acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the Requestor, or any individual employed or affiliated therewith, has taken or converted to his own use data file(s), or received the file(s) knowing that they were stolen or converted.
26. Authority for VHA IE to share this data for the purpose indicated is under the HIPAA Privacy Rule, is <INSERT LEGAL CITATION> under the Privacy Act is <INSERT LEGAL CITATION OR ROUTINE USE FROM THE APPLICABLE PRIVACY ACT SYTEM OF RECORD> and under 38 USC 5701 <INSERT LEGAL CITATION> and 38 USC 7332 <INSERT LEGAL CITATION, IF THIS STATUTE IS APPLICABLE>.
27. <INSERT ENTITY NAME> will ensure that its contractors and agents abide by the terms and conditions of this agreement. The VA or VHA IE may request verification of compliance.
28. The terms of this Agreement can be changed only by a written modification to the agreement by the agency signatories (or their designated representatives) to this Agreement or by the parties adopting a new agreement in place of this Agreement.
29. This Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Upon such notice, VHA IE will notify the Requestor to destroy or securely return such data at Requestor's expense using the same procedures stated in the above paragraph of this section.
30. On behalf of both parties the undersigned individuals hereby attest that he or she is authorized to enter into this Agreement and agrees to all the terms specified herein.

<INSERT NAME OF ENTITY SIGNER> Date
<INSERT TITLE OF ENTITY SIGNER>
<INSERT PROGRAM OFFICE OF ENTITY>
<INSERT NAME OF ENTITY>

<INSERT NAME OF VHA SIGNER> Date
<INSERT TITLE OF VHA SIGNER>
VHA Innovation Ecosystem

Concur/Non-Concur:

Signature and Date
<INSERT NAME OF VHA PROGRAM OFFICE ISO>

Concur/Non-Concur:

Signature and Date
<INSERT NAME OF VHA PROGRAM OFFICE PRIVACY OFFICER>

DUA for Limited Data Sets with Federal Entities

DATA USE AGREEMENT

FOR DATA FROM THE

DEPARTMENT OF VETERANS AFFAIRS (VA),
VETERANS HEALTH ADMINISTRATION INNOVATION ECOSYSTEM (VHA IE)

TO THE

<INSERT NAME OF FEDERAL ENTITY>

FOR

<INSERT PROJECT NAME>

This Data Use Agreement (Agreement) is entered into as of this ____ day of _____, <INSERT YEAR>, by and between the Department of Veterans Affairs (VA) Veterans Health Administration Innovation Ecosystem (VHA IE) (“Covered Entity”), and <INSERT FEDERAL ENTITY NAME> (“Data Requestor”). WHEREAS, the Covered Entity and the Data Requestor are committed to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations of Title 45 Code of Federal Regulations (CFR) Parts 160 and 164 (“HIPAA Privacy Rule”); and WHEREAS, the purpose of this Agreement is to satisfy the obligations of the Covered Entity under the HIPAA Privacy Rule, and to ensure the integrity and confidentiality of information disclosed by the Covered Entity to the Data Requestor under this Agreement (“Data”) in the form of a Limited Data Set, as defined by the HIPAA Privacy Rule at 45 CFR § 164.514(e); and WHEREAS, the parties acknowledge and recognize that the Data will not be disclosed to the Data Requestor until the parties execute this Agreement pursuant to 45 CFR § 164.514(e)(4)(ii).

TERMS OF THE AGREEMENT:

1. All provisions of this Agreement that apply to the Data Requestor also apply to any employee, contractor, subcontractor, or other agent of the Data Requestor. The Data Requestor will ensure that its employees, contractors, subcontractors and other agents abide by the terms and conditions of this Agreement. The Covered Entity may request verification of compliance.
2. The Data Requestor will use the Data provided by the Covered Entity under this Agreement to <PROVIDE BRIEF DESCRIPTION OF PROJECT INCLUDING TYPE OF DATA AND HOW IT WILL BE USED>. The specific VHA data-elements being provided to the Data Requestor to support these analyses, and specific data elements to be excluded from the limited data set are listed in Attachment A.
3. For the purpose described in paragraph 2, the Covered Entity will provide the Data Requestor with a Limited Data Set, defined by the HIPAA Privacy Rule as Protected Health

Information (PHI) from which the following direct identifiers of the individual have been removed: names, addresses (other than town or city, state, or zip code), phone numbers, fax numbers, e-mail addresses, Social Security Numbers, medical record numbers, health plan numbers, account numbers, certificate and/or license numbers, vehicle identifiers or serial numbers, device identifiers or serial numbers, web universal resource locators, internet protocol address numbers, biometric identifiers, and full-face photographic images and any comparable images. The Covered Entity and the Data Requestor acknowledge and affirm that a Limited Data Set does not meet the standard for de-identified information as provided by the HIPAA Privacy Rule and is therefore still subject to its requirements.

4. The following named individuals are designated as their agency's Point-of-Contact (POC) for performance of the terms of the Agreement. The Data Requestor agrees to notify the Covered Entity within fifteen (15) calendar days of any change in the named contact.

Point-of-Contact on behalf of VHA IE:

<INSERT NAME, PHONE NUMBER AND EMAIL OF FEDERAL ENTITY POC>

Point-of-Contact on behalf of <FEDERAL ENTITY>:

<INSERT NAME, PHONE NUMBER AND EMAIL OF POC>

5. The VHA PHI/III provided to <INSERT NAME OF FEDERAL ENTITY> under this Agreement will be covered by the Privacy Act SOR <INSERT SOR NAME>. Although <INSERT NAME OF FEDERAL ENTITY> will own the copy of VHA III/PHI transferred under this Agreement, it agrees not to disclose the VHA III/PHI to any person outside the <INSERT NAME OF FEDERAL ENTITY> except pursuant to a Freedom of Information Act (FOIA) request, as authorized by Federal statute or regulation, <INSERT VHA SORN NAME AND NUMBER> or pursuant to a court order from a court of competent jurisdiction.
6. **[TO BE MODIFIED FOR SPECIFIC AGREEMENT]** The parties mutually agree that any derivative data, analyses, or findings created from the Data may be retained by the Data Requestor. The Data Requestor agrees to share any findings or outcomes from the analysis of the Data with the Covered Entity at no charge and with no conditions.
7. The Data Requestor agrees that it will not identify, contact, or attempt to identify or contact the individuals whose information is contained in the Data. The Data Requestor also agrees that it will not link or attempt to link the Data with other data sources for such purposes.
8. The Data Requestor shall establish appropriate administrative, technical, procedural, and physical safeguards in accordance with the HIPAA Privacy Rule and the common information security laws and regulations, such as the Federal Information Security Management Act (FISMA) and Federal Information Processing Standards (FIPS), to protect VA data confidentiality and to prevent unauthorized access to, or use or disclosure of, the Data.
 - (a) Data will be <INSERT MEANS OF SECURE TRANSMISSION OF DATA> by the Covered Entity to <INSERT FEDERAL ENTITY POINT OF CONTACT> at <INSERT FEDERAL ENTITY NAME AND ADDRESS>. The Data Requestor agrees to store all data received from the Covered Entity in a physically secure space. Pursuant to the Covered Entity's requirements for information security, the data once received by the Data Requestor will reside on dedicated equipment isolated from all other information systems and will not be comingled with any other data. Access to the Data Requestor site in order to review the data will be made available to predetermined VA staff for inspection/audit at all times during standard business hours.
 - (b) The Data Requestor agrees that the Data will be stored in an encrypted partition on the Data Requestor's information system hard drive using Federal Information Processing Standards (FIPS) 140-2 validated software. (See

<http://csrc.nist.gov/groups/STM/cmvp/validation.html> for a complete list of validated cryptographic modules). The application must be capable of key recovery and a copy of the encryption key(s) must be stored in multiple secure locations. FIPS 140-2 (or current version) compliant / NIST validated encryption will be used to secure the Covered Entity's data stored on any portable drives, IT components, disks, compact disk (CDs) / optical disk storage (DVDs). (c) The Data Requestor agrees that the Data provided under the Agreement will not be physically moved or transmitted from the Data Requestor's site without first obtaining prior written approval from the Covered Entity, and without the data being encrypted prior to said move or transmission.

9. The Data Requestor will grant authorized representatives of the Covered Entity, VA OI&T, and the VA Inspector General access to premises where the Data are kept by the Data Requestor for the purpose of confirming that the Data Requestor is in compliance with all security and data use requirements prescribed by this Agreement. The Data Requestor will be notified 60 days in advance of a need to review the premises where the Data are kept. If the review is in response to a data breach by the Data Requestor, the 60-day notice requirement will be waived.
10. If a Data Requestor's employee, contractor, subcontractor, or agent becomes aware of the theft, loss, or compromise of any device used to transport, access, or store the Data, or of the theft, loss, or other unauthorized access, use, or disclosure of any of the Data, such employee, contractor, subcontractor, or agent must immediately report the incident to his or her supervisor. Should any security incident or event involve the Data (i.e. the theft, loss, or other unauthorized access, use, or disclosure of any of the Covered Entity's data or the destruction of any device used to transport, access, or store such data), the Data Requestor will notify the VHA POC along with VA OI&T Information Security Officer (ISO) by phone or in writing within one (1) hour of detection. The VHA POC will contact VHA's Privacy Officer. The Data Requestor will provide details of the security event, the potential risk to the individuals whose information is contained in the Data, and the actions that have been or are being taken by the Data Requestor to remediate the incident or event. The Data Requestor will also provide the Covered Entity with status updates upon request and a written closing action report once the security event or incident has been resolved.
11. Access to the Data shall be restricted to authorized employees, contractors, subcontractor, and agents of the Data Requestor requiring access to perform their official duties as authorized by this Agreement. The Data Requestor shall inform such personnel of: (1) the confidential nature of the information; (2) safeguards required to protect the information; (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws; and (4) that their actions can lead to the immediate termination of this Agreement by the Covered Entity. The Data Requestor agrees to limit access to, disclosure of, and use of Data provided under this Agreement to the minimum number of individuals needing access to the data provided by the Covered Entity to perform their duties as authorized by this Agreement.
12. In the event that the Covered Entity suspects or determines that the Data Requestor accessed, used, or disclosed any part of the Data other than as authorized by this Agreement or other written authorization from the person designated in Paragraph 4 of this Agreement, the Covered Entity in its sole discretion may require the Data Requestor to:
 - (a) Promptly investigate and report to the Covered Entity the Data Requestor's determinations regarding any alleged or actual unauthorized use or disclosure;

- (b) Promptly resolve any problems identified by the investigation;
 - (c) Submit a formal response to an allegation of unauthorized disclosure; and
 - (d) Return the Data to the Covered Entity.
13. Further, if the Covered Entity suspects or determines that the Data in the possession of the Data Requestor has been accessed, used, or disclosed other than as authorized by this Agreement, the Covered Entity in its sole discretion may suspend further releases of the data to the Data Requestor or may terminate this Agreement in its entirety.
 14. The Data Requestor hereby acknowledges that criminal penalties under § 1106(a) of the Social Security Act (42 U.S.C. § 1306(a)), including a fine imprisonment not exceeding 5 years, or both, may apply to disclosures of information covered by § 1106 and not authorized by regulation or by Federal law. Finally, the Data Requestor acknowledges that criminal penalties may be imposed under 18 U.S.C. § 641 if it is determined that the Data Requestor, or any individual employed or affiliated therewith, embezzles, steals, purloins, or knowingly converts to his use or the use of another, or without authority, sells, conveys, or disposes of any Data provided under this Agreement.
 15. This Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Once this Agreement is terminated, the Data Requestor has no legal authority to access, use, disclose, or retain the Data. Upon termination of the Agreement, the Data Requestor must, at its own expense, destroy or return the limited data set in accordance with Paragraph 9.
 16. All questions of interpretation or compliance with the terms of this Agreement should be referred to the Covered Entity's official named in Paragraph 4 (or his or her successor).
 17. Authority for the Covered Entity to disclose this data to the Data Requestor for the purpose indicated is provided by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, 45 CFR 164.514(e). The Privacy Act and 38 USC §§ 5701 and 7332 do not apply, as a Limited Data Set is not considered individually identifiable under these statutes.
 18. This Agreement supersedes any and all previous agreements related to this project. The terms of this Agreement can only be changed by written modification to this Agreement or adoption of a new agreement in place of this Agreement.
 19. On behalf of both parties, the undersigned individuals hereby attest that he or she is authorized to enter into this Agreement and agrees to all of the terms specified herein.



<INSERT NAME OF FEDERAL ENTITY SIGNER> Date
<INSERT TITLE OF FEDERAL ENTITY SIGNER>
<INSERT PROGRAM OFFICE OF FEDERAL ENTITY>
<INSERT NAME OF FEDERAL ENTITY>

<INSERT NAME OF VHA SIGNER> Date
<INSERT TITLE OF VHA SIGNER>
Veterans Health Administration Innovation Ecosystem

Concur/Non-Concur:
<INSERT NAME OF VHA PROGRAM OFFICE ISO>

Signature and Date

Concur/Non-Concur:
<INSERT NAME OF VHA PROGRAM OFFICE PRIVACY OFFICER>

Signature and Date

DUA for Limited Data Set with Non-Federal Entities

DATA USE AGREEMENT FOR A LIMITED DATA SET WITH A NON-FEDERAL ENTITY FOR DATA FROM THE

DEPARTMENT OF VETERANS AFFAIRS (VA),
VETERANS HEALTH ADMINISTRATION INNOVATION ECOSYSTEM (VHA IE)

TO THE

<INSERT NAME OF NON-FEDERAL ENTITY>

FOR

<INSERT PROJECT NAME>

This Data Use Agreement (Agreement) is entered into as of this ____ day of _____, <INSERT YEAR>, by and between the Department of Veterans Affairs (VA) Veterans Health Administration (VHA), Innovation Ecosystem (VHA IE) ("Covered Entity"), and <INSERT NON-FEDERAL ENTITY NAME> ("Data Requestor"). WHEREAS, the Covered Entity and the Data Requestor are committed to comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations of Title 45 Code of Federal Regulations (CFR) Parts 160 and 164 ("HIPAA Privacy Rule"); and WHEREAS, the purpose of this Agreement is to satisfy the obligations of the Covered Entity under the HIPAA Privacy Rule, and to ensure the integrity and confidentiality of information disclosed by the Covered Entity to the Data Requestor under this Agreement ("Data") in the form of a Limited Data Set, as defined by the HIPAA Privacy Rule at 45 CFR § 164.514(e); and WHEREAS, the parties acknowledge and recognize that the Data will not be disclosed to the Data Requestor until the parties execute this Agreement pursuant to 45 CFR § 164.514(e)(4)(ii).

TERMS OF THE AGREEMENT:

1. All provisions of this Agreement that apply to the Data Requestor also apply to any employee, contractor, subcontractor, or other agent of the Data Requestor. The Data Requestor will ensure that its employees, contractors, subcontractors and other agents abide by the terms and conditions of this Agreement. The Covered Entity may request verification of compliance.
2. The Data Requestor will use the Data provided by the Covered Entity under this Agreement to <PROVIDE BRIEF DESCRIPTION OF PROJECT INCLUDING TYPE OF DATA AND HOW IT WILL BE USED>. The specific VHA IE data-elements being provided to the Data Requestor to support these analyses, and specific data elements to be excluded from the limited data set are listed in Attachment A.
3. For the purpose described in paragraph 2, the Covered Entity will provide the Data Requestor with a Limited Data Set, defined by the HIPAA Privacy Rule as Protected Health Information from which the following direct identifiers of the Veteran have been removed:

names, addresses (other than town or city, state, or zip code), phone numbers, fax numbers, e-mail addresses, Social Security Numbers, medical record numbers, health plan numbers, account numbers, certificate and/or license numbers, vehicle identifiers or serial numbers, device identifiers or serial numbers, web universal resource locators, internet protocol address numbers, biometric identifiers, and full-face photographic images and any comparable images. The Covered Entity and the Data Requestor acknowledge and affirm that a Limited Data Set does not meet the standard for de-identified information as provided by the HIPAA Privacy Rule and is therefore still subject to its requirements.

4. The following named individuals are designated as their agency's Point-of-Contact (POC) for performance of the terms of the Agreement. The Data Requestor agrees to notify the Covered Entity within fifteen (15) calendar days of any change in the named contact.

Point-of-Contact on behalf of <INSERT NAME OF NON-FEDERAL ENTITY>:
<INSERT NAME, PHONE NUMBER AND EMAIL OF NON-FEDERAL ENTITY POC>

Point-of-Contact on behalf of VHA IE:
<INSERT NAME, PHONE NUMBER AND EMAIL OF VHA POC>

5. <SELECT ONE > VHA IE retains all ownership rights and responsibilities to the original and derivative data file(s) provided to the Requestor under this Agreement. <OR> VHA IE will retain ownership of the original data and <INSERT ENTITY NAME> will receive a copy. Data transferred under this agreement becomes the property of <INSERT ENTITY NAME>.
6. The Data Requestor has no rights in the Data other than to use the Data for the purpose described in paragraph 2 for the duration of this Agreement and will not use the Data for any purpose other than as outlined in this Agreement, unless such use is required by law. If the Data Requestor wishes to use the Data for any purpose other than as specified in this Agreement, the Data Requestor shall first provide a written request to the Covered Entity describing the additional purpose for which it seeks to use the data. The Data Requestor may not use the information for the additional purpose unless the Covered Entity provides the Data Requestor with written approval of the additional use.
7. [TO BE MODIFIED FOR SPECIFIC AGREEMENT] The parties mutually agree that any derivative data, analyses, or findings created from the Data may be retained by the Data Requestor. The Data Requestor agrees to share any findings or outcomes from the analysis of the Data with the Covered Entity at no charge and with no conditions.
8. The Data Requestor agrees that it will not identify, contact, or attempt to identify or contact the individuals whose information is contained in the Data. The Data Requestor also agrees that it will not link or attempt to link the Data with other data sources for such purposes.
9. The Data provided may not be used or disclosed by the Data Requestor for any purpose other than as outlined in this Agreement or as otherwise required by law. If the Data Requestor wishes to use the Data provided by the Covered Entity under this Agreement for any purpose other than those outlined in this Agreement, the Data Requestor shall make a written request to the Covered Entity describing the additional purposes for which it seeks to use the data. If the Covered Entity determines that the Data Requestor's request to use the data and information provided hereunder is acceptable, the Covered Entity shall provide the Data Requestor with written approval of the additional use of the data. Data will <INSERT MEANS OF SECURE TRANSMISSION OF DATA> by the Covered Entity to <INSERT NON-FEDERAL ENTITY POINT OF CONTACT> at <INSERT NON-FEDERAL ENTITY NAME AND ADDRESS>.



VA INNOVATION Ecosystem

10. [INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA], the requesting entity must provide the following information:
<DESCRIBE WHERE THE DATA WILL BE STORED:>
<DESCRIBE MEANS OF ACCESSING DATA AND ACCESS/AUDIT METHODS:>
<PROVIDE DATE OF PROJECT COMPLETION:>
11. [INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA] Except as VHA IE shall authorize in writing, <insert requesting entity name>, its contractors and agents, shall not disclose, release, reveal, show, sell, rent, lease, loan, or otherwise grant access to the VHA IE data covered by this Agreement to any person or entity outside the Requestor and its team of subcontractors performing the Project. Without limitation to any other provision of this Agreement, the Requestor agrees not to disclose, display or otherwise make available any company proprietary information to any third party, in any form, except to public health officials in connection with the purposes established herein or as otherwise required under the Freedom of Information Act (FOIA), or other Federal law. VHA will clearly indicate in writing any information that is considered to be trade secret or confidential business information.
12. [INSERT IF VHA RETAINS OWNERSHIP OF THE DATA] <INSERT ENTITY NAME>, its contractors and agents, shall establish appropriate administrative, technical, procedural, and physical safeguards in accordance with VA Handbook 6500, to protect VA data confidentiality and to prevent unauthorized access to the data provided by VHA. If co-mingling must be allowed to meet the requirements of the business/research need, the Requestor must ensure that VHA IE's information is returned to the VHA IE or destroyed in accordance with VA's sanitization requirements. VHA IE reserves the right to conduct onsite inspections of Requestor's IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA requirements. All VHA IE data and derivative data must be stored in an encrypted partition on the Requestor's or its contractors/subcontractors information system hard drive using FIPS 140-2 validated software. (See <http://csrc.nist.gov/groups/STM/cmvp/validation.html> for a complete list of validated cryptographic modules). The application must be capable of key recovery and a copy of the encryption key(s) must be stored in multiple secure locations. FIPS 140-2 (or current version) compliant / NIST validated encryption will be used to secure VHA IE data stored on any portable drives, IT components, disks, CDs / DVDs. Data must not be physically moved or transmitted from the site without first obtaining prior written approval from the information owner and the data being encrypted prior to said move or transmission.
13. [INSERT IF VHA RETAINS OWNERSHIP OF THE DATA] All electronic storage media used on non-VA leased or owned IT equipment that is used to store, process, or access VA sensitive information must have all VA sensitive information removed, cleared, sanitized, or destroyed in accordance with VA policies and procedures upon the earlier of: (1) completion or termination of the agreement, or (2) disposal or return of the IT equipment by the Requestor or any person acting on behalf of the Requestor.
14. [INSERT IF VHA RETAINS OWNERSHIP OF THE DATA] VHA IE reserves the right to allow authorized representatives of VHA IE and VA's Inspector General to be granted access to premises where the data are kept by the Requestor for the purpose of confirming that the Requestor is in compliance with all requirements associated with this agreement.
15. [INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA] If a Requestor's employee, contractor, or agent becomes aware of the theft, loss or compromise of any device used to

transport, access or store VHA IE information or data, such employee, agent, or contractor must immediately report the incident to his or her supervisor. Should any security incident or event involve VHA IE data (i.e. the theft, loss, compromise, or destruction of any device used to transport, access, or store VHA IE data) covered by this agreement, or the incident places VHA IE data at risk of loss, unauthorized access, misuse or compromise, the Requestor will notify the VHA IE Point-of-Contact by phone or in writing within one hour of detection. The Requestor will provide details of the security event, the potential risk to VHA IE data, and the actions that have been or are being taken to remediate the issue. The Requestor will also provide VA with a written closing action report once the security event or incident has been resolved. VA will follow this same notification process should a security event occur within VA's boundary involving Requestor provided data. Designated points of contact will follow established incident response and reporting procedures, determine whether the incident warrants escalation, and comply with established escalation requirement for responding to security incidents.

16. [INSERT IF VHA IE RETAINS OWNERSHIP OF THE DATA] The Requestor's employees, contractors and agents must provide evidence of completion (or initiation) of background investigation prior to granting access to VA or VHA IE information systems.
17. [INSERT IF THE VHA IE RETAINS OWNERSHIP OF THE DATA] The Requestor's employees, contractors and agents must complete VA's Security and Privacy Awareness training and sign VA's National Rules of Behavior.
18. The Data Requestor shall establish appropriate administrative, technical, procedural, and physical safeguards in accordance with the HIPAA Privacy Rule, to protect VA data confidentiality and to prevent unauthorized access to, or use or disclosure of, the Data.
19. The Data Requestor will grant authorized representatives of the Covered Entity, VA OI&T, and the VA Inspector General access to premises where the Data are kept by the Data Requestor for the purpose of confirming that the Data Requestor is in compliance with all security and data use requirements prescribed by this Agreement. The Data Requestor will be notified 60 days in advance of a need to review the premises where the Data are kept. If the review is in response to a data breach by the Data Requestor, the 60-day notice requirement will be waived.
20. Access to the Data shall be restricted to authorized employees, contractors, subcontractor, and agents of the Data Requestor requiring access to perform their official duties as authorized by this Agreement. The Data Requestor shall inform such personnel of: (1) the confidential nature of the information; (2) safeguards required to protect the information; (3) the administrative, civil, and criminal penalties for noncompliance contained in applicable Federal laws; and (4) that their actions can lead to the immediate termination of this Agreement by the Covered Entity. The Data Requestor agrees to limit access to, disclosure of, and use of Data provided under this Agreement to the minimum number of individuals needing access to the Covered Entity's data to perform their duties as authorized by this Agreement.
21. In the event that the Covered Entity suspects or determines that the Data Requestor accessed, used, or disclosed any part of the Data other than as authorized by this Agreement or other written authorization from the person designated in Paragraph 4 of this Agreement, the Covered Entity in its sole discretion may require the Data Requestor to:
 - a. promptly investigate and report to the Covered Entity the Data Requestor's determinations regarding any alleged or actual unauthorized use or disclosure;
 - b. promptly resolve any problems identified by the investigation;

- c. submit a formal response to an allegation of unauthorized disclosure; and
 - d. return the Data to the Covered Entity.
22. Further, if the Covered Entity suspects or determines that the Data in the possession of the Data Requestor has been accessed, used, or disclosed other than as authorized by this Agreement, the Covered Entity in its sole discretion may suspend further releases of the data to the Data Requestor or may terminate this Agreement in its entirety.
 23. The Data Requestor hereby acknowledges that criminal penalties under § 1106(a) of the Social Security Act (42 U.S.C. §1106(a)), including a fine not exceeding \$10,000 or imprisonment not exceeding 5 years, or both, may apply to disclosures of information covered by §1106 and not authorized by regulation or by Federal law. Finally, the Data Requestor acknowledges that criminal penalties may be imposed under 18 U.S.C. §641 if it is determined that the Data Requestor, or any individual employed or affiliated therewith, embezzles, steals, purloins, or knowingly converts to his use or the use of another, or without authority, sells, conveys, or disposes of any Data provided under this Agreement.
 24. This Agreement may be terminated by either party at any time for any reason upon 30 days written notice. Once this Agreement is terminated, the Data Requestor has no legal authority to access, use, disclose, or retain the Data. Upon termination of the Agreement, the Data Requestor must, at its own expense, destroy or return the limited data set in accordance with paragraph 9.
 25. All questions of interpretation or compliance with the terms of this Agreement should be referred to the Covered Entity's official named in Paragraph 7 (or his or her successor).
 26. Authority for the Covered Entity to disclose this data to the Data Requestor for the purpose indicated is provided by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, 45 CFR 164.514(e). The Privacy Act and 38 USC §§ 5701 and 7332 do not apply, as a Limited Data Set is not considered individually identifiable under these statutes.
 27. This Agreement supersedes any and all previous agreements related to this project. The terms of this Agreement can only be changed by written modification to this Agreement or adoption of a new agreement in place of this Agreement.
 28. On behalf of both parties, the undersigned individuals hereby attest that he or she is authorized to enter into this Agreement and agrees to all of the terms specified herein.

<INSERT NAME OF ENTITY SIGNER> Date
<INSERT TITLE OF ENTITY SIGNER>
<INSERT PROGRAM OFFICE OF ENTITY>
<INSERT NAME OF ENTITY>

<INSERT NAME OF VHA SIGNER> Date
<INSERT TITLE OF VHA SIGNER>

Veterans Health Administration Innovation Ecosystem



Concur/Non-Concur:

<INSERT NAME OF VHA PROGRAM OFFICE ISO>

Signature and Date

Concur/Non-Concur:

<INSERT NAME OF VHA PROGRAM OFFICE PRIVACY OFFICER>

Signature and Date

**DATA ELEMENTS TO BE PROVIDED TO <INSERT NON-FEDERAL ENTITY NAME>
FOR < PROVIDE BRIEF DESCRIPTION OF PROJECT>**

The following identifiers **must be removed** from health information if the data are to qualify as a limited data set:

1. Names
2. Postal address information, other than town or city, state and Zip Code
3. Telephone Numbers
4. Fax numbers
5. Electronic mail addresses
6. Social security numbers
7. Medical record numbers
8. Health plan beneficiary numbers
9. Account numbers
10. Certificate/license numbers
11. Vehicle identifiers and serial numbers, including license plate numbers
12. Device identifiers and serial numbers
13. Web universal resource locators (URLs)
14. Internet protocol (IP) address numbers
15. Biometric identifiers, including fingerprints and voiceprints
16. Full-face photographic images and any comparable images

Note: The above data elements apply to the individual, the individual's relatives, employer, and household members.

<INSERT LIST OF DATA ELEMENTS TO BE PROVIDED>

Business Associate Agreement (BAA)

A Business Associate Agreement allows individual or entity ‘business associates’ to access protected health information to perform functions, activities, or services on behalf of VHA. The agreement documents a Business Associate’s responsibility to safeguard protected health information (PHI) used by or disclosed by VHA according to the HIPAA Security, Privacy, and Data Breach Notification Rules.

Key considerations:

A Business Associate *must* protect the data according to HIPAA.

BUSINESS ASSOCIATE AGREEMENT

BETWEEN

THE DEPARTMENT OF VETERANS AFFAIRS VETERANS HEALTH ADMINISTRATION
INNOVATION ECOSYSTEM (VHA IE)

AND

<COMPANY/ORGANIZATION>

Whereas, **<COMPANY/ORGANIZATION>** (Business Associate) provides **<BRIEFLY DEFINE SERVICES (i.e., medical device, transcription, publishing, etc.)>** services to the Department of Veterans Affairs, Veterans Health Administration (Covered Entity); and Whereas, in order for Business Associate to provide **<BRIEFLY DEFINE SERVICES (i.e., medical device, transcription, publishing, etc.)>** services to Covered Entity, Covered Entity discloses to Business Associate Protected Health Information (PHI) and Electronic Protected Health Information (EPHI) pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104-191, 110 Stat. 1936 (1996), and its implementing regulations, 45 C.F.R. Parts 160, and 164 (“the HIPAA Privacy and Security Rules”); and Whereas, the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5, 123 Stat. 115 (2009), pursuant to Title XIII of Division A and Title IV of Division B, called the Health Information Technology for Economic and Clinical Health (HITECH) Act, provides modifications to the HIPAA Privacy and Security Rules; and Whereas, Department of Veterans Affairs, Veterans Health Administration is a “Covered Entity” as that term is defined in the HIPAA implementing regulations, 45 C.F.R. § 160.103; and Whereas, **<COMPANY/ORGANIZATION>**, including its employees, officers, contractors, subcontractors, or any other agents, as a recipient of PHI from Covered Entity in order to **provide <BRIEFLY DEFINE SERVICES (i.e., medical device, transcription, publishing, etc.)>** services to Covered Entity, is a “Business Associate” of Covered Entity as that term is defined in the HIPAA implementing regulations, 45 C.F.R. § 160.103; and Whereas, pursuant to the Privacy and Security Rules, all Business Associates of Covered Entities must agree in writing to certain mandatory provisions regarding the Use and Disclosure of PHI; and Whereas, the purpose of this Agreement is to comply with the requirements of the Privacy and Security Rules, including, but not limited to, the Business Associate Agreement requirements at 45 C.F.R. §§ 164.308(b), 164.314(a), 164.410, 164.502(e), and 164.504(e), as may be amended.

NOW, THEREFORE, Covered Entity and Business Associate agree as follows:

1. Definitions. Unless otherwise provided in this Agreement, capitalized terms and phrases that are defined in the Privacy and Security Rules have the same meanings as set forth in the Privacy and Security Rules. When the phrase “Protected Health Information” and the abbreviation “PHI” are used in this Agreement, they include the phrase “Electronic Protected Health Information” and the abbreviation “EPHI.”

2. Ownership of PHI. PHI provided by Covered Entity to Business Associate and its contractors, subcontractors, or other agents, or gathered by them on behalf of Covered Entity under this Agreement is the property of Covered Entity.
3. Scope of Use and Disclosure by Business Associate of Protected Health Information. Unless otherwise limited herein, Business Associate may:
 - a. Make Uses and Disclosures of PHI that is disclosed to it by Covered Entity or received by Business Associate on behalf of Covered Entity as necessary to perform its obligations under this Agreement and all applicable agreements, provided that such Use or Disclosure would not violate the HIPAA Privacy Rule if made by Covered Entity and complies with Covered Entity's minimum necessary policies and procedures;
 - b. Use the PHI received in its capacity as a Business Associate of Covered Entity for its proper management and administration and to fulfill any legal responsibilities of Business Associate;
 - c. Make a Disclosure of the PHI in its possession to a third party for the proper management and administration of Business Associate or to fulfill any legal responsibilities of Business Associate; provided, however, that the Disclosure would not violate the HIPAA Privacy Rule if made by Covered Entity, or is Required by Law; and Business Associate has received from the third party written assurances that (a) the information will be held confidentially and used or further disclosed only for the purposes for which it was disclosed to the third party or as Required By Law, (b) the third party will notify Business Associate of any instances of which it becomes aware in which the confidentiality of the information may have been breached, and (c) the third party has agreed to implement reasonable and appropriate steps to safeguard the information;
 - d. Engage in Data Aggregation activities, consistent with the HIPAA Privacy Rule; and
 - e. De-identify any and all PHI created or received by Business Associate under this Agreement, provided that the de-identification conforms to the requirements of the HIPAA Privacy Rule.
4. Obligations of Business Associate. In connection with its Use or Disclosure of PHI, Business Associate agrees that it will:
 - a. Consult with Covered Entity before making the Use or Disclosure whenever Business Associate is uncertain whether it may make a particular Use or Disclosure of PHI in performance of this Agreement;
 - b. Ensure any employee, officer, contractor, subcontractor, or other agent of Business Associate who has access to PHI receives at a minimum annual privacy and security awareness training that conforms to the requirements of Covered Entity;

- c. Develop and document policies and procedures and use reasonable and appropriate safeguards to prevent use or disclosure of PHI other than as provided by this Agreement;
- d. To the extent practicable, mitigate any harmful effect of a Use or Disclosure of PHI by Business Associate in violation of this Agreement that is known or, by exercising reasonable diligence, should have been known to Business Associate;
- e. Maintain a system or process to account for any Security Incident, Privacy Incident, or Use or Disclosure of PHI not authorized by this Agreement of which Business Associate becomes aware;
- f. Notify Covered Entity within 24 hours of Business Associate's discovery of any incident which may potentially be a data breach, including a HIPAA Electronic Transactions and Code Sets, Privacy, Security or Standard Identifier Incident, or Use or Disclosure of PHI, whether secured (PHI which has been destroyed or in the alternative has been rendered unreadable, unusable, or undecipherable through methodology specified by the Department of Health and Human Services in guidance issued under § 13402(h)(2) of the HITECH Act) or unsecured (PHI not secured through the use of a technology which renders it unusable, unreadable, or indecipherable through such methodology), not provided for by this Agreement and promptly provide a report to Covered Entity within ten (10) business days of the notification;
 - i. An incident is any physical, technical, or personal activity or event that, a reasonable person believes, increases risk of inappropriate or unauthorized use or disclosure of PHI or causes Covered Entity to be considered non-compliant with the HIPAA Privacy and Security Rules;
 - ii. A breach, as defined in 45 C.F.R. § 164.402, is an unauthorized acquisition, access, use, or disclosure of PHI in a manner not permitted under the HIPAA Privacy Rule which compromises the security or privacy of the PHI by posing a significant risk of financial, reputational, or other harm to the individual;
 - iii. A breach, consistent with 45 C.F.R. § 164.410(a)(2), will be treated as discovered as of the first day on which such breach is known to Business Associate or, by exercising reasonable diligence, would have been known to Business Associate, or any employee, officer, contractor, subcontractor, or other agent of Business Associate;
 - iv. Notification will be made by Business Associate to the Director, Health Information Governance, by email at VHABAAIssues@va.gov, of any HIPAA Electronic Transactions and Code Sets, Privacy, Security or Standard Identifier Incident, or Use or Disclosure of PHI not provided for by this Agreement; and

- v. A written report of the incident, submitted to the Director, Health Information Governance within ten (10) business days after initial notification, will document the following:
 - a) The identification of each individual whose PHI has been, or is reasonably believed by Business Associate, to have been, accessed, acquired, used, or disclosed during the breach;
 - b) A brief description of what occurred, including the date of the breach and the date of the discovery of the breach (if known);
 - c) A description of the types of secured and/or unsecured PHI that was involved;
 - d) A description of what is being done to investigate the breach, to mitigate further harm to individuals, and the reasonable and appropriate safeguards being taken to protect against future breaches; and
 - e) Any other information described in 45 C.F.R. § 164.404(c);
- vi. This report should be documented as a letter and sent to:
Director, Health Information Governance
Department of Veterans Affairs – Veterans Health Administration
Office of Informatics and Analytics (10P2C)
810 Vermont Avenue NW
Washington, DC 20420
- g. Implement administrative, physical, and technical safeguards and controls for the PHI that Business Associate receives, maintains, or transmits on behalf of Covered Entity, including policies, procedures, training, and sanctions, in compliance with Federal Information Security Management Act (FISMA), Pub. L. No. 107-347, 116 Stat. 2946 (2002); the HIPAA Privacy and Security Rules, 45 C.F.R. Parts 160, 162, and 164; standards and guidance from the Office of Management and Budget and the National Institute of Standards and Technology; Federal Records Act requirements, National Archives and Records Administration regulations, to include applicable records retention schedules, and other laws, regulations, and policies pertaining to safeguarding VA Sensitive Data;
- h. Require contractors, subcontractors, or other agents to whom Business Associate provides PHI received from Covered Entity to agree to the same restrictions and conditions that apply to Business Associate pursuant to this Agreement, including implementation of administrative, physical, and technical safeguards and controls, including policies, procedures, training, and sanctions, in compliance with the above-referenced legal authorities;
- i. Obtain satisfactory written assurances from contractors, subcontractors, or other agents to whom Business Associate provides PHI received from Covered Entity that the contractors, subcontractors, or other agents agree to the same restrictions and conditions that apply to Business Associate pursuant to this Agreement;

- j. If Business Associate maintains PHI in a Designated Record Set or Privacy Act System of Records, within ten (10) business days of receiving a written request from Covered Entity:
 - i. Make available PHI in the Designated Record Set or System of Records necessary for Covered Entity to respond to individuals' requests for access to PHI about them that is not in the possession of Covered Entity;
 - ii. Incorporate any amendments or corrections to the PHI in the Designated Record Set or System of Records in accordance with the Privacy Act and the HIPAA Privacy Rule; and
 - iii. Maintain the information necessary to document the disclosures of PHI sufficient to make an accounting of those disclosures as required under the Privacy Act, 5 U.S.C. § 552a, and the HIPAA Privacy Rule, and within ten (10) business days of receiving a request from Covered Entity, make available the information necessary for Covered Entity to make an accounting of Disclosures of PHI about an individual in the Designated Record Set or System of Records;
- k. Utilize only contractors, subcontractors, or other agents who are physically located within a jurisdiction subject to the laws of the United States and ensure that no contractor, subcontractor, or agent maintains, processes, uses, or discloses PHI received from Covered Entity in any way that will remove the PHI from such jurisdiction. Any modification to this provision must be approved by Covered Entity in advance and in writing;
- l. Provide satisfactory assurances that the confidentiality, integrity, and availability of the PHI provided by Covered Entity under this Agreement are reasonably and appropriately protected;
- m. Upon completion or termination of the applicable contract(s) or agreement(s), return and/or destroy, at Covered Entity's option, the PHI gathered, created, received, or processed during the performance of the contract(s) or agreement(s). No data will be retained by Business Associate, or contractor, subcontractor, or other agent of Business Associate, unless retention is required by law and specifically permitted by Covered Entity. As deemed appropriate by and under the direction of Covered Entity, Business Associate shall provide written assurance that all PHI has been returned to Covered Entity or destroyed by Business Associate. If immediate return or destruction of all data is not possible, Business Associate shall notify Covered Entity and assure that all PHI retained will be safeguarded to prevent unauthorized Uses or Disclosures;
- n. Be liable to Covered Entity for any civil or criminal penalties imposed on Covered Entity under the HIPAA Privacy and Security Rules in the event of a violation of the Rules as a result of any practice, behavior, or conduct by Business Associate;

- o. Make available to Covered Entity its practices, policies and procedures, for the purpose of determining compliance with this Agreement and underlying agreements; and
 - p. Make available to the Secretary of Health and Human Services Business Associate's internal practices, books, and records, including policies and procedures, relating to the Use or Disclosure of PHI for purposes of determining Covered Entity's compliance with the Privacy and Security Rules, subject to any applicable legal privileges.
5. Obligations of Covered Entity. Covered Entity agrees that it:
- a. Has obtained or will obtain from Individuals any consents, authorizations, and other permissions necessary or required by laws applicable to Covered Entity for Business Associate and Covered Entity to fulfill their obligations under this Agreement;
 - b. Will promptly notify Business Associate in writing of any restrictions on the Use and Disclosure of PHI about Individuals that Covered Entity has agreed to that may affect Business Associate's ability to perform its obligations under this Agreement; and
 - c. Will promptly notify Business Associate in writing of any change in, or revocation of, permission by an Individual to use or disclose PHI, if such change or revocation may affect Business Associate's ability to perform its obligations under this Agreement;
6. Material Breach and Termination.
- a. Termination for Cause. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:
 - i. Provide an opportunity for Business Associate to cure the breach or end the violation;
 - ii. Terminate this Agreement and underlying contract(s) if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity; or
 - iii. Immediately terminate this Agreement and underlying contract(s) if cure is not possible; or
 - iv. If Business Associate has breached a material term of this Agreement and neither termination nor cure is feasible, report the violation to the Secretary of Health and Human Services.
 - b. Termination Upon Review. This Agreement may be terminated by Covered Entity, if appropriate, upon review as defined in Section 12 of this Agreement.
 - c. Automatic Termination. This Agreement will automatically terminate upon completion of the Business Associate's duties under all underlying agreements or by mutual written agreement to terminate underlying agreements.
 - d. Effect of Termination. Termination of this Agreement will result in cessation of activities by Business Associate involving PHI under this Agreement.
7. Amendment. Business Associate and Covered Entity agree to take such action as is necessary to amend this Agreement for Covered Entity to comply with the requirements of the Privacy and Security Rules or other applicable law.
8. No Third Party Beneficiaries. Nothing expressed or implied in this Agreement is intended to confer, nor shall anything herein confer, upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.



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9. Other Applicable Law. This Agreement does not and is not intended to abrogate any responsibilities of the parties under any other applicable law.
10. Effect of Agreement. With respect solely to the subject matter herein, the terms and conditions in a National Business Associate Agreement, executed by the Director, Health Information Governance, or a designated representative, will supersede any local business associate agreement between Business Associate and a component of VHA. The parties also agree that a National Business Associate Agreement, unless itself modified by the parties, will control and cannot be superseded, modified, or nullified by any local business associate agreement.
11. Effective Date. This Agreement shall be effective on the last signature date below.
12. Review Date. The provisions of this Agreement will be reviewed by Covered Entity every two years from Effective Date to determine the applicability of the agreement based on the relationship of the parties at the time of review.

Department of Veterans Affairs Company/Organization
Veterans Health Administration

By:

Name:

Title:

Date:

Company/Organization

By:

Name:

Title:

Date: