

Local Site Investigator Application - VA Million Veteran Program (MVP)



VA Facility Name:

Please check to indicate application status:

Local Site Investigator Name:

Initial **Revised
Version #:**

Application Instructions

Date:

- The Local Site Investigator (LSI), the LSI's supervisor, and the ACOS/R&D, or Chief of Staff if the ACOS/R&D is the LSI, for a participating site must complete this form.
- Each section must contain a response. Please ensure all responses are consistent with the approved funded project Principal Investigator (PI)/Study Chair(SC) New Project Application and the model informed consent and HIPAA forms
- Other documents associated with this application as checked below should also be submitted electronically. Documents can be submitted in PDF or Microsoft Word format with the exception of the informed consent document. This document must be submitted in Microsoft Word. Please ensure the file name includes the name of the document, site, and date (e.g., 133.site.date)
- For ease of use, some of the fields have been locked for editing, and you will not be able to make changes to these sections. If you have any questions or concerns regarding these sections, please contact the MVP PIs, Mike Gaziano, MD, MPH or John Concato, MD, MPH.
- Submit this entire application to the PI/SC Study Team. The PI/SC Study Team will upload the signed application to the VA Central IRB secure SharePoint site after their review.

Contents of Application Package

Please check all documents included in this package:

- Local Site Investigator Application – VA Million Veteran Program (VA Central IRB Form 104a)
- Local Site Biosketches or CVs of Applicable Study Team Members (Merit Review or NIH Format)
- Local Study Team Conflict of Interest Determinations
- Local Informed Consent Form
- Local HIPAA Authorization

Please list below any other documentation included in this application:

PROTOCOL TITLE: Million Veteran Program

Section 1: Local Site Investigator General Information

Local Site Investigator (LSI) Name:

Academic Degrees:

Board Certifications:

Employment Status: *(Check all that apply)*

- VA Employee (Indicate VA percentage of time in 8ths _____)
- VA WOC
- Intergovernmental Personnel Act (IPA)
- Other (Specify) _____

VA Facility Name:

VA Station Number:

Phone:

VA Facility Address:

Fax:

E-mail:

1. Describe your qualifications to do the research detailed in the project and attach a copy of your biosketch (*Merit Review or NIH format*). Be specific in regard to your research experience.

2. Indicate below how many of the following you currently supervise as a PI, Study Chair, or LSI (*excluding this current application*.)

_____ **Open Research Projects**
 _____ **Participating Sites**

_____ **Project Team Members**
 _____ **Approximate Number of Active Project Participants**

3. Please list all project team members, including the Local Site Investigator, in the table below who will be involved in directing and/or conducting the project at this site. Attach a biosketch or CV of team members who will function in a medical or scientific capacity.

Project Team Member	Degrees	5% or More Effort? Yes/No	Project Role (<i>Specify or use project role key found in instructions for completing form</i>)	Access to Identifiable Participant Data? Yes/No	Date of Latest VA Human Subjects Training

Note: Additional project members may be added by inserting more rows in the table. If some project members are unknown at this time, they can be added at a later date through submission of an amendment.

4. Has your participation in this project and that of your project team been reviewed by your local Conflict of Interest Committee or in accordance with your local conflict of interest policies and procedures?

- Yes. The determinations of my local Conflict of Interest Committee or other local Conflict of Interest review are attached.
- Review is pending. Determinations will be forwarded upon completion of review. I understand no final decision regarding approval of this project can be made by the VA Central IRB until the local Conflict of Interest Committee determinations have been received and reviewed.

Section 2: Local Participating Site Overview

1. Where will the research project be conducted? (Check all that apply)

- VA Outpatient Clinic
 VA Clinician Office
 VA Laboratories
 Other (Specify):

2. What resources are available at your facility to treat emergencies resulting from project-related procedures, as well as any non-emergency or psychological referrals that may be required? (Check all that apply)

- Basic Life Support (BLS) trained personnel
 Advanced Cardiac Life Support (ACLS) trained personnel and crash cart
 Emergency drugs and supplies to stabilize participant until emergency personnel arrive
 Emergency response team within facility
 911 or other emergency response number
 Psychological counseling
 N/A
 Other Please explain:

If not all resources required to treat emergencies resulting from project-related procedures, as well as non-emergency or psychological referrals that may be required, are available at your facility, specify below your plan to handle emergencies requiring these resources.

3. If the project is not conducted at a medical facility, what medical facility and/or services will you use in an emergency? N/A

How much time does it take to get to the above-named medical facility from where the project is to be conducted?

4. Are there applicable state and local laws that differ from VA and other federal requirements concerning the conduct of research activities (e.g., who may serve as a legally authorized representative)? (Check with your local Research Office and or see instructions for completing this form)

- No
 Yes; please explain:

5. Are there any cultural, ethnic, religious, or other special characteristics of the community, or local issues that the VA Central IRB needs to consider in its review of the project?

- Unknown
- No
- Yes; please explain:

Section 3: Local Site Potential Risk/Benefit Analysis

1. Are there any additional risks to participants in this project at your site than what was described in the PI/SC Application? *(Note: Risks or harms can be physical, psychological, financial, social, or legal. They may also involve breaches of confidentiality and privacy.)*

- No
- Yes; please explain:

2. Are there any differences in anticipated benefits to participants or society at your site from what was described in the PI/SC Application?

- No
- Yes; please explain:

3. What is your plan for identifying any problems that arise during the conduct of this project at your site? *(e.g., How will you identify adverse events?)*

Due to the minimal risk nature of participating in the MVP program, and its lack of interventional strategies, no serious adverse events are expected. However, if participants are injured while actively participating in this program (having blood drawn, getting a health assessment) they will be treated immediately at the study visit by the VA Medical Center and the event reported to the PI/SC Study Team and the VA Central IRB in accordance with its reporting requirements.

4. How will you convey information, such as serious adverse events, to the Principal Investigator/Study Chair and/or to the VA Central IRB? *(e.g., encrypted e-mail, secure fax)*

All contacts regarding adverse events will be made via secure fax or encrypted email. Reports to the VA Central IRB will be made via their secure SharePoint Site.

Section 4: Local Site Human Participant Information

1. What is your planned or targeted enrollment at this site and what is your expected accrual rate *(e.g., number per month)*?

2. What populations at your site will be targeted for recruitment as participants? *Check all that apply.*

Males	<input checked="" type="checkbox"/>
Females	<input checked="" type="checkbox"/>
Inpatients	<input type="checkbox"/>
Outpatients	<input checked="" type="checkbox"/>
Other (Specify)	<input type="checkbox"/>

Note: In accordance with the approved study, only veterans may be enrolled at this time.

3. Will you target a specific race or ethnic group as participants? Yes No

4. What are the age ranges of participants? *Check all that apply.*

Young Adults (18-21)	<input type="checkbox"/>
Adults (22-65)	<input type="checkbox"/>
Seniors (Over 65)	<input type="checkbox"/>

Note: In accordance with the approved study, no one under the age of 18 may be enrolled at this time. If the legal age for an adult is not 18 in your local jurisdiction, please note this in the table above, next to the Young Adults check box.

5. In accordance with the approved study, the study does not require the enrollment of VA employees; students; individuals with impaired decision making capacity; pregnant women; economically and/or disadvantages persons; prisoners, illiterate or no English language proficiency, or terminally ill participants.

Do you plan to enroll any of these populations at this site?

- No
 Yes. If yes, please specify the population and justify the reason for enrollment. For pregnant women and prisoners, the applicable VA Central IRB Form 110, Vulnerable Population Supplement must be completed and attached to this application.

Section 5: Local Site Informed Consent

1. Who will conduct the consent discussion with the local site participants? *(Check all that apply)*

- Local Site Investigator
 Local Sub/Co-investigator
 Local Research Project Team Member (Specify who: _____)
 Other: *Please explain:*

2. Where will the informed consent process at this site take place? *(Check all that apply)*

- N/A
 In a private room
 In a waiting room
 In a group setting
 Other: *Please explain:*

3. How will you be sure there is sufficient opportunity or time for the participants to consider whether or not to consent? *(Check all that apply)*

- Participants will be allowed to take the unsigned consent form home for consideration prior to signing it.
 Participants will be allowed a waiting period of _____ (e.g., number of hour/days) to consider their decision.
 Other *Please explain:* The participants will have received a sample copy of the informed consent document without signature blocks prior to the study visit in a study visit appointment mailing. This will allow participants sufficient time to read over the document

and ask questions by calling the MVP Call Center. They will also be able to ask questions at the appointment.

4. Are there any differences in the steps taken at your site to minimize the possibility of coercion or undue influence from those described in the PI/SC Application?

- No
 Yes; please explain:

5. Will you or a member of your research team be obtaining informed consent from someone other than the participant?

- No
 Yes

6. What is the language of the participants you plan to enroll at this site?

- English
 Spanish. If your VA Facility has a large Spanish-speaking population of veterans, and you do not plan to recruit Spanish-speaking participants, please provide justification:
 Other:

7. Besides the Local Site Investigator and site-specific points of contact information, have you further modified the model informed consent document(s) provided by the Principal Investigator/Study Chair?

- Yes No

If yes, please provide justification for the changes:

Reminder: Please use the Microsoft Word track changes function to indicate modifications in the model informed consent document provided by the PI/SC. Submit BOTH tracked and untracked versions of the documents.

Section 6: Type of HIPAA Research Subject Authorization Being Requested at Local Site

Have you made any modifications to the model HIPAA authorization documents provided by the Principal Investigator/Study Chair?

- Yes No N/A

If yes, please provide justification and provide copies of the modified documents:

Section 7: Local Site Participant Recruitment Information

1. Who will be primarily responsible for recruiting potential participants at this site?

Recruitment of participants will occur centrally by research staff at the Massachusetts Veterans Epidemiology and Research Information Center (MAVERIC) housed at the Boston VA Medical Center.

2. How will initial contact with the participant be made? (e.g. local clinics, general populations, physician referrals, letters to prospective participants – Note: VA policy prohibits “cold calls” to potential VA research participants.)

MAVERIC will contact Veterans who are users of the primary care services at each of the participating sites per the methodology described in the approved PI/SC Application. Potential

participants will be identified for contact from the VA clinical care databases.

Individuals will be contacted by mail and informed about the study. If interested they can respond by mail or to a telephone hotline.

Once a study visit is arranged, participants are mailed a brief description of the study and the sample informed consent document. At the visit, the study is discussed and the consent process occurs.

3. Will you be using any of the following methods to recruit participants?

(Please check all that apply.)

- N/A
- Database for which participants have given prior permission to be contacted for research
- Personal contact with patients or students over whom you have direct/indirect oversight
- Referrals

4. Please indicate below the following types of recruitment materials that will be used at this site?

<input checked="" type="checkbox"/>	Only approved advertisements provided by the MVP PI team
<input type="checkbox"/>	Fliers
<input type="checkbox"/>	Newspaper
<input type="checkbox"/>	Letters
<input type="checkbox"/>	Websites
<input type="checkbox"/>	Television
<input type="checkbox"/>	Radio
<input type="checkbox"/>	Video
<input type="checkbox"/>	Audio
<input type="checkbox"/>	Customer Surveys
<input type="checkbox"/>	Other <i>(Please specify)</i>

Please note that ALL recruitment materials must be reviewed and approved by the VA Central IRB prior to being used as part of any recruitment activities.

5. Will Protected Health Information (PHI) be obtained directly from participants at this site?

- Yes No

If yes, describe the PHI obtained in terms of specific data elements/identifies *(e.g., name, address, phone numbers)*

PHI, including name, address, SSN, and dates will be collected centrally by MAVERIC prior to enrollment for recruitment purposes through an approved HIPAA Waiver of Individual Authorization. Once informed consent and HIPAA authorization are obtained at the study visit, the participant's PHI (including name, address, phone number and SSN) will be verified.

6. Will you be contacting participants from existing PHI?

- Yes No, not at this site.

Section 8: Local Site Payment to Participants

In accordance with the approved study, no compensation is being provided to participants. Does your site plan to provide any compensation?

No. Continue to Section 9.

Section 9: Biological Specimens

1. What is the type of specimen that will be collected under this study at this site:

Blood

2. Are there any differences in the measures you will take to minimize the potential for physical, psychological, financial, social, or legal harm from breaches in confidentiality and privacy resulting from participating in this aspect of the research project than those described in the PI/SC Application?

Yes

No

If yes, please describe:

Section 10: Local Site Privacy and Confidentiality

1. Are there any procedures concerning the collection of data which differ from those specified in the approved study?

No

Yes; please specify:

2. Will transmission of project research data project from this site to the VA Genomics Coordinating Center differ from how it is described in the approved study?

No

Yes; please specify:

3. Will the storage of project research data at this site differ from how it is described in the approved study?

No

Yes; please specify:

4. Will your plan for protecting project research data generated from this site differ from how it is described in the approved study?

No

Yes; please specify:

The local facility Information Security Officer (ISO) and Privacy Officer will be informed within one hour of any improper use, disclosure, or loss of data.

Section 11: Local Site Investigator Statement

1. As the Local Site Investigator for this project, I attest to the following:

- I reviewed the approved application for the study, Million Veteran Program, and have indicated on this application if I have made any changes in the model documents or in the approved procedures and methodology.
- I have adequate local resources and time to complete this project.
- All members of the local project team will be trained on applicable project procedures, to include informed consent procedures, and on all VA and other requirements pertaining to human participant protections as befits their roles and responsibilities prior to participating in the project.
- The project team has access to a population that will allow recruitment of the required number of participants.
- Our local VA facility has adequate resources to support the conduct of this project, including medical and psychological resources that participants might require as a consequence of their participation in the project.

2. I accept that I have responsibility for the following:

- Conducting the project according to all applicable requirements, including but not limited to VHA Handbook 1200.05, 38 CFR 16, FDA requirements, VA Central IRB requirements, and local policy and procedures.
- Not make any changes to the protocol, without prior VA Central IRB approval, except to eliminate immediate hazards to participants.
- Promptly reporting to the VA Central IRB, the local Institutional Official, and Principal Investigator/Study Chair any reportable activity as defined by VA and other requirements, as well as VA Central IRB policies and procedures.
- Cooperating with the Principal Investigator/Study Chair in the submission of all project amendments and continuing review reports.
- Following applicable requirements (e.g., information security) relevant to the conduct of the VA Central IRB-approved project and the maintenance of research records in accordance with the VA Records Control Schedule.

Local Site Investigator Signature

Date

Local Site Investigator Printed Name

Section 12: Local Site Investigator's Supervisor (Must be at least a Section or Department Chief)

I have reviewed this application as completed by the Local Site Investigator, who is under my supervision. I approve the conduct of the research by the Local Site Investigator, to include the use of any time and resources within this Department/Section/Facility, as specified in this application.

Supervisor

Date

Printed Name

Department/Section/Facility

Section 13: Review by Local Site Associate Chief of Staff for Research and Development (ACOS/R&D) at the Local Investigator's Site

Note: If the ACOS/R&D is the LSI, the Facility's Chief of Staff must complete this Section.

1. As the Associate Chief of Staff for Research and Development or Chief of Staff {Name of Local Facility}, I have reviewed this project, the local site project team qualifications, and site requirements. I have concluded that this facility is an acceptable site to conduct this project and I certify the following:

- The Local Site Investigator and the rest of the local site project team have the experience and training to conduct this research. All members of the project team have been appropriately credentialed, privileged, and have completed all required VA training in the protection of human participants and Good Clinical Practice.
- This facility has reviewed or is in the process of reviewing any potential conflicts of interest any of the project team members may have in accordance with our local policies and procedures. A summary of the determinations made and any management plans is either attached to this application or will be forwarded separately for review by the VA Central IRB.
- The local project team has access to a population that will allow recruitment of the required number of participants and the local project team has the time to complete the project.
- This project will not begin at this site until the LSI has received written approval to initiate the study in accordance with VHA Handbook 1200.01.
- This facility has adequate resources, including medical and psychological resources that participants might require as a consequence of their participation in the project, to support the functions of this site as detailed in the project.

2. I have considered whether or not there are state and local laws governing the proposed project. I have also considered whether there are any cultural, ethnic, religious, or special characteristics of the community, or other local issues that the VA Central IRB needs to consider in its review. I have the following comments regarding these local context issues: *(If none, so state)*

3. The Federalwide Assurance for our VA Facility is current and lists or will list the VA Central IRB as an IRB of Record for this facility. We have a current, approved Memorandum of Understanding (MOU) on file with the VHA Central Office Human Research Protections Program (HRPP) or will obtain one prior to this Local Site Investigator Application being considered by the VA Central IRB for approval.

ACOS/R&D or Chief of Staff Signature

Date

ACOS/R&D or Chief of Staff Printed Name

Phone Number: _____

E-mail Address: _____

Submission Instructions

1. Please review your entire application prior to submission and ensure the following:
 - All three required signatures have been obtained. For revisions, only the signature of the LSI is required. Ensure you include the version number and date for all revisions.
 - The attachments match with what you have indicated on the preceding page
 - Unnecessary page breaks have been removed and any formatting errors have been corrected
 - All sections of the application have been completed or marked "Not Applicable."
2. All Local Site Applications are to be submitted to Boston MAVERIC. They will then in turn forward all Local Site Investigator Applications to the VA Central IRB Administration Office.

For any other questions, please contact the VA Central IRB staff by e-mail at va.central.irb@va.gov or at the following toll-free number: 877-254-3130.