**Department of Veterans Affairs**
**Office of Research and Development**

# Guidance on Pre-Award Requirements for Use of MVP Data and MVP Feasibility Request Process
**November 14, 2025**

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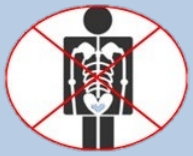
## Requirements and Limitations

The ***MVP Feasibility Request Process*** applies to new proposal submissions and to resubmissions.

**Researchers <u>MAY NOT:</u>**

**Recontact Participants**

**Request Biospecimens**



**Request Access to Medical Images**
Notes and reports generated from images can be accessed.

Requests may be denied if the requests are not consistent with MVP policy or insufficient information is included in the application.

Any person requiring access to individual level MVP data behind the VA firewall must have a VA appointment: VA paid, IPA, or WOC, and a VA network account.

Requests for data sources not currently available in the MVP Central Research Database, are subject to additional review, must meet MVP coded data standards and be limited to MVP participants.

MVP sample collection and processing is not currently CLIA certified, and resulting data cannot be used to make clinical decisions.

All analysis happens ***within MVP computing environments***. Only summary level results may leave the MVP computing environments.

Investigators on existing Cooperative Studies Program (CSP) projects cannot be granted MVP access by approval through their CSP project executive committee. If you would like to consider use of MVP data as part of the LOI submission to CSP, email MVPLOI@va.gov prior to submission.

# Introduction

The **Million Veteran Program (MVP)** is a national genetics research initiative of the Department of Veteran Affairs Office of Research and Development (ORD). MVP is a longitudinal cohort of over one million Veterans used to better understand how genes, lifestyle behaviors, and military exposures impact health and illness, and to bring personalized medicine to VA health care. Veterans who volunteer to join MVP provide access to their medical records, complete surveys, and provide a blood specimen.

MVP data access is available to VA researchers that meet Principal Investigator (PI) eligibility criteria and funding requirements, described below. Collaborative research teams with expertise in genomics, phenomics and data science, as appropriate, are encouraged.

The following guidance applies to new proposal submissions, including competitive renewals and supplementals, and to resubmissions, and specifically explains the MVP Feasibility Request Process. Please check with your Research and Development (R&D) office, VA funding portfolio[1], or local VA non-profit corporation (NPC) as appropriate for guidance or other instructions. **Currently funded VA and non-VA projects may not add MVP-specific aims.**

# VA Principal Investigator (PI) Requirements

1. PIs must be at a VA station with an active Federal wide Assurance (FWA).
2. ACOS confirmation of VA appointment and PI status is required as part of the VA Just-in-Time (JIT) process.
3. **VA 8ths requirements:**
    - **VA Funding**: The applicant PI and/or MPI (if applicable) must meet any eligibility requirements of the Actively Managed Portfolio, Broad Portfolio, and/or Request for Application (RFA) to which they are applying. All other personnel named on the application should meet all applicable eligibility requirements.
    - **Non-VA Federal Funding**: The applicant PI and/or MPI (if applicable) must be on a current VA appointment (paid, WOC, or IPA) at the time of submission of the feasibility request form.

# Funding Requirements

### Acceptable funding to support MVP research, including VA and non-VA Federal funding

Projects with MVP aims **must be funded by VA or acceptable federal funding agencies**, as determined by MVP. Unfunded, self-funded, or non-federally funded projects are not considered. Researchers are responsible for meeting all the other requirements of their funding agency.

**VA Funding:**

Applicants can apply to any relevant **VA** funding opportunity, including Career Development Awards, competitive renewals (as indicated by the RFA), and supplemental funding, across

[1] VA funding portfolio includes Notices of Special Interest (NOSIs) for Broad Portfolios (BPs), Actively Managed Portfolios (AMPs) and Other Portfolios and for the Requests for Applications (RFAs)

any ORD Actively Managed Portfolio or Broad Portfolio. Applicants must follow all the rules and requirements of the specific funding opportunity to which they are applying. Budgets, project duration, and eligibility are Portfolio and RFA specific, and are not determined by MVP.

Competitive renewal is defined by the policies of the funding portfolio after the original award period is completed.

Supplemental funding is defined as any relevant supplemental funding opportunity through a VA funding portfolio only if the approved original funding and proposal has an approved and existing MVP component.

Please refer to all VA funding documentation and guidance located on the ORD Electronic Submission page.

**Non-VA Federal Funding:**

1. Research Project Awards, Competitive Renewals & Supplemental Funding

   Non-VA Funding may only be from another federal agency and must be funding for the purpose of conducting research. NIH R01s, NIH R21s and other equivalent grant types for federal entities (e.g., DOE, DoD) are acceptable. **The following non-VA federal funding types will not be accepted: program projects, clinical trials, or any proposal in collaboration with industry in any capacity.**

   Non-VA federal funding must be administered by a VA non-profit corporation (NPC). Affiliated universities will not be considered.*

   This guidance applies to new project submissions, resubmissions, and supplemental funding opportunities by the original funding agency.

   Competitive renewal (as indicated by NIH Type 2) is defined by the policies of the funding agency after the original award period is completed.

   Supplemental funding is defined as any relevant supplemental funding opportunity through the original project funding agency only if the approved original funding and proposal has an approved and existing MVP component.

2. Career Development Awards

   Funding may only be from another non-VA federal agency and for the purpose of career development. NIH K awards and other equivalent grant types for federal entities (e.g., DOE, DoD) are acceptable.

   *Career development awards may be administered by the university affiliate if the VA NPC is unable to do so.

# Available MVP Data and Computing Environment

All data analysis using MVP data must take place behind the VA firewall in approved MVP computing environments, like the Genomic Information System for Integrative Sciences (**Genisis**) research environment or the Veterans Informatics and Computing Infrastructure (**VINCI**). **Genisis** serves as the MVP informatics and computing platform. The MVP data resources include electronic health records extracted from the VA Corporate Data Warehouse (**CDW**) through VINCI, curated self-reported survey data and genomic data, and a High-Performance Computing cluster with analytical tools. Researchers will have access to data, computing resources, and analytical tools within secure study-specific study marts in MVP computing environments. All analysis happens

within approved MVP environments **with no individual level data leaving the system**. The MVP Core team builds and manages the protected data and computing infrastructure for MVP behind the VA firewall.

**The following updated MVP data are currently available for approved projects. Researchers are encouraged to utilize the GenHub Cohort Builder for a description of available data:**

1. **VA Electronic Health Records (EHR) data** on **~1,080,000+ MVP participants,** extracted from the CDW through VINCI.
2. **Data from three surveys completed by the MVP participants**.
    - The first is a "Baseline Survey" on ~75% of the participants who were genotyped, focusing on demographic characteristics, medical and family history, health status, and lifestyle habits.
    - The second is an optional "Lifestyle Survey" designed to gather detailed military and environmental exposure, dietary habits, and other behavior data, available on ~47% of the MVP participants.
    - The third is the COVID-19 Survey data from ~255,000 MVP participants on symptoms, diagnosis, hospitalization, behavioral and psychosocial factors physical and psychological impacts of the COVID pandemic.
3. **MVP Genotype data on ~650,000 MVP participants** generated by a custom designed Axiom genotyping array designed to maximize genomic coverage of common and rare SNPs as well as markers with clinical significance. More information can be found in the MVP publication.
4. **MVP Nutrition data**— Dietary energy and nutrient intake data were derived from food frequency questionnaire (FFQ) data collected on the **MVP Lifestyle Survey**. This included frequency of 61 food items in addition to questions about added sugar, fried food consumption, and 21 dietary supplements. More information can be found at MVP: Nutrient-Level_Data_(MVP_Core_Data).
5. **MVP Whole Genome Sequence (WGS) data**—WGS data from over 100,000 MVP participants. The WGS data has been generated on the short-read Illumina platform with 30X depth of coverage.
6. **MVP Methylation data** – Methylation data on ~45,000 MVP participants. The methylation data is generated on the Illumina EPIC array with ~850,000 probes.

Researchers are encouraged to utilize the Centralized Interactive Phenomics Resource (**CIPHER**), the VA Phenotype library with a catalog of phenotype descriptions and associated metadata. Centralized Interactive Phenomics Resource (CIPHER) - VA Phenomics Library

# MVP Expectations for VA investigators

**Interested applicants should note that MVP is an iterative data resource for VA and the broader research community.**

- Tools and final summary data sets remain inside the MVP Repository for future query and research by other researchers following an initial embargo period.
- No individual level data may leave the MVP computing environments.
- Summary genetic results and statistics from MVP data analyses must be submitted to dbGaP.
- Any new phenotypes created and validated as a result of an MVP project will be submitted by the investigator to the VA Phenotype library: Centralized Interactive Phenomics Resource (CIPHER) - VA Phenomics Library.

# The MVP Feasibility Request Process

The MVP Feasibility Request Process must be completed for:

- **VA Funding:** any relevant RFA, including Career Development Awards, competitive renewals, and supplemental funding.
- **Non-VA Federal Funding:** any non-VA federal funding, including competitive renewals, supplemental funding, and career development awards.

**Step 1: Registration in GenHub and Preparatory to Research Access:**

- Before submitting feasibility requests, LOI (as applicable) and full applications, researchers are encouraged to explore GenHub MVP data explorer. The data explorer allows users to query the MVP participants database and build appropriate study cohorts based on their study subjects' characteristics. The cohort size generated from the data explorer, that meets exclusion/inclusion criteria of your research interest can then be used for performing power calculations and included in your research proposal. Currently, demographics, diagnosis, labs, medications, survey, and nutrition data are available to build your cohort in the data explorer. The option to explore availability of genotype, WGS and methylation data is also available.
- The SNP Look-Up Tool in GenHub helps users in understanding the SNPs that are assayed in the MVP Custom Array 1.0 used for generating the MVP genotype data. Assayed SNPs for specific genes or variants may be queried for their representation on the MVP genotype array.

**Step 2: MVP Feasibility Request**

- The "MVP Feasibility Request" is a feasibility check for VA and non-VA federally funded proposals (original funding renewal & supplemental as defined above) with MVP aims that must be completed prior to submission or resubmission of an LOI/intent to submit (ITS)/Pre-Application (if required) or full grant/award submission or resubmission (if LOI is not required) or supplemental award application.
- Applicants wishing to include MVP aims in their VA or non-VA federal funding proposals

must submit an MVP Feasibility Request form via PowerApps AND receive an MVP Feasibility Approval Memo in advance of the submission deadline for the award/grant. Please note, you must be behind the VA firewall to access.

  - For investigators with pending VA-appointments and no VA SharePoint access please email the MVPLOI@va.gov for assistance.

- MVP will complete a feasibility review based on the information provided by the PI. Concerns regarding requested data or the feasibility of completing the proposed research may be discussed with the PI prior to a final determination. MVP Feasibility Requests are accepted on a rolling basis. Please submit requests at least 4 weeks in advance of any LOI/ITS/Pre-application or application deadline.
  - Earlier submission is advised, as this will give the applicant time to adjust their proposal if needed. Applications not received in a timely fashion may not receive approval on time.
  - Requests for data not explicitly available within MVP need to be vetted and reviewed for MVP regulatory compliance. These requests may take additional time beyond the four-week review process and may be denied.
  - Requests may be denied for reasons such as, but not limited to:
    - Requests inconsistent with current MVP policies
    - Insufficient explanation of aims or planned MVP data use
    - Unavailable data sources
- MVP will provide an **MVP Feasibility Approval Memo** to the applicant that **must** be submitted with the full grant or VA Merit award pre-application AND full application. Questions regarding expectations on data sharing, completion of Data Management and Access Plan (DMAP), or other regulatory considerations that may need to be addressed in the application, can be sent to MVPLOI@va.gov .
- The MVP Feasibility Approval Memo will be valid for the specific cycle and funding type indicated on the submission. Any changes made to the final proposal related to MVP (aims, use of MVP data, etc.) **must** be resubmitted and reviewed by MVP**.**
- Resubmissions must submit a new MVP Feasibility Request Form.
- MVP Feasibility Request requirements are separate and in addition to any RFA/funding announcement instructions.

- **Any application submitted with MVP aims that does not have an MVP Feasibility Approval Memo from the MVP Feasibility Request process may be administratively withdrawn from peer review or funding by ORD's Investigators, Scientific Review and Management (ISRM) unit.**

**Step 3: Notice of award/funding (for VA and non-VA federal funding):**

- VA Investigators are responsible for notifying MVP of Notice of Intent to Fund and JIT deadlines by emailing MVPLOI@va.gov. A representative from MVP will then contact the PI with next steps, including the VA Central IRB application and MVP onboarding.

- **Please do NOT submit the project for IRB review without receiving instructions from MVP.**

## Regulatory Oversight

**Projects can contain both MVP and non-MVP aims.**

- The VA Central IRB (CIRB) is the IRB of record for all funded applications using MVP data. MVP will assist the PI with submission of regulatory approvals to the CIRB.
- MVP aims that are distinct from other non-MVP aims in the proposal are to be submitted, reviewed, and approved as a separate project by CIRB.
- For single site studies, PIs may submit non-MVP aims ONLY to their local IRB.
- For multi-site studies, non-MVP aims are to be submitted as a second project to the VA CIRB.
- It is the responsibility of the PI to ensure the IRB protocol and associated documents accurately reflect the research being conducted and are consistent with the approved Merit.
- Consistent with funding agency expectations, any requests to update the research plan that significantly changes project aims or goals must be submitted to MVPLOI@va.gov and the funding agency, through the appropriate mechanism, such as a Project Modification request. Approval must be granted prior to beginning any work.
- Competitive Renewal and Supplemental funding: MVP will work with researchers to determine regulatory requirements.