



**VETERANS HEALTH ADMINISTRATION**

## **Guidance for VA Researchers on the Use of My HealthVet Secure Messaging**

**Date:** March 12, 2018

*This is a new Guidance document. Please submit comments and suggestions regarding this document to the VHA Office of Research and Development (ORD) at [VHACOORDRegulatory@va.gov](mailto:VHACOORDRegulatory@va.gov).*

**SCOPE:** This document provides guidance for VA Investigators and VA research team members on the use of My HealthVet Secure Messaging for communicating with VA subjects in the conduct of approved VA research. My HealthVet is an online portal created by the Department of Veterans Affairs to help Veterans, active-duty service members, and their dependents in managing their health care, work with healthcare providers to reach informed decisions, and improve their overall health. My HealthVet offers a suite of tools including access to their health records and a Secure Messaging system to communicate with their healthcare team and other VA staff. This ORD guidance is based on the recognition that (a) the privacy and confidentiality of VA subject information sent and received by VA researchers is a component of the Institutional Review Board (IRB) of Record's evaluation of the human subjects research activity, (b) My HealthVet's Secure Messaging application cannot presently be used to recruit VA subjects or as part of any recruitment activities in research, (c) the clinical functionality of My HealthVet's Secure Messaging must always be considered in relation to the research functionality, and (d) all existing research policies apply. The following questions are discussed in this guidance document:

1. What is My HealthVet?
2. Can My HealthVet Secure Messaging be used by VA researchers?
3. Why can't My HealthVet Secure Messaging be used for research recruitment activities?
4. What is a VA researcher required to submit to an Institutional Review Board if they want to use My HealthVet Secure Messaging to communicate with consented VA subjects?
5. Is a VA researcher required to use a specific format for naming the Secure Messaging Triage Group for a specific study?
6. What do VA researchers need to do to use My HealthVet Secure Messaging once the IRB of Record and R&D Committee have approved a VA study?
7. If I already receive My HealthVet Secure Messages from patients in the context of my clinical service at VA, what do I need to do to establish a separate Secure Messaging triage group for messages from study participants in the context of my research?

8. What do VA researchers need to do if a Veteran has been enrolled into a VA study but does not yet have a Premium My Health<sup>e</sup>Vet account?
  9. What instructions should VA researchers give to Veterans regarding communicating with the study team using My Health<sup>e</sup>Vet Secure Messaging?
  10. If a Veteran sends a complaint about the research study through My Health<sup>e</sup>Vet Secure Messaging, does it require reporting to the IRB of Record or is there a special reporting system?
  11. What happens if a VA research team member receives a Secure Message from a Veteran that is intended for the Veterans' healthcare team?
  12. How should communication with VA research subjects via My Health<sup>e</sup>Vet Secure Messaging be documented? What if a VA research study has a Certificate of Confidentiality?
  13. What are the business rules for timeliness of response to a Veteran Secure Message?
  14. How can I learn more about My Health<sup>e</sup>Vet Secure Messaging?
- 

## **1. What is My Health<sup>e</sup>Vet?**

My Health<sup>e</sup>Vet ([www.myhealth.va.gov](http://www.myhealth.va.gov)) is an online portal created by the Department of Veterans Affairs to help Veterans, active-duty service members, and their dependents work with healthcare providers to reach informed decisions and improve their overall health. My Health<sup>e</sup>Vet offers a suite of tools designed to assist Veterans in managing their health care. VA patients with a Premium My Health<sup>e</sup>Vet account can access their health records, refill VA prescriptions, receive email reminders about appointments, and communicate with members of their healthcare team and other VA staff using Secure Messaging.

## **2. Can My Health<sup>e</sup>Vet Secure Messaging be used by VA researchers?**

Yes, My Health<sup>e</sup>Vet Secure Messaging can be used by VA researchers to communicate securely with VA subjects who have consented to participate in a VA approved research activity as approved by the VA Facility's Institutional Review Board (IRB) of Record as described in VHA Handbook 1200.05: Requirements for the Protections of Human Subjects in Research. VA researchers can use Secure Messaging to send VA sensitive information to VA research subjects. However, Secure Messaging cannot be used to recruit VA subjects or as part of any recruitment activities in research.

## **3. Why can't My Health<sup>e</sup>Vet Secure Messaging be used for research recruitment activities?**

At the present time, there is no option available for individuals with a My Health<sup>e</sup>Vet account to "opt-in" or "opt-out" of receiving research recruitment messages. Individuals with an account should have the ability to decide whether or not they wish to receive research

recruitment messages or flyers through Secure Messaging. Therefore, until functionality is expanded to allow individuals with a My HealthVet account to choose whether or not they wish to receive recruitment information or advertisements for research, use of Secure Messaging to recruit research subjects is not permitted.

**4. What is a VA researcher required to submit to an Institutional Review Board if they want to use My HealthVet Secure Messaging to communicate with consented VA subjects?**

As part of an IRB's evaluation of non-exempt research, the IRB must apply the approval criteria in 38 CFR 16.111 as described in VHA Handbook 1200.05, Paragraph 10. These criteria include evaluation of communications provided to study participants in order to ensure that appropriate safeguards exist to protect the rights and welfare of research subjects and, when appropriate, that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (38 CFR 16.111(a)(7)).

A research activity may use multiple methods to communicate with research subjects, such as face-to-face communication, telephone calls, letters sent by U.S. mail, My HealthVet Secure Messaging, email, or text messaging. The specific types of communication that will be utilized in a particular research study must be specified in the study protocol, IRB application, or supplement to the IRB application as part of the IRB application process. Please note that applicable information security and privacy requirements described in VA 6500: Information Security Handbook and VHA Directive 1605.01: Privacy and Release of Information must be adhered to in addition to IRB approval requirements for non-exempt human subjects research activities. The study team will need to specify in the study protocol, IRB application, or supplement to the IRB application if Veterans can choose Secure Messaging, traditional methods such as telephone calls or letters sent by U.S. Mail, or a combination of communication methods. If a VA researcher is planning to use standardized messages that will be sent to research participants through Secure Messaging, the content of these messages must be reviewed by the IRB of Record for the research activity.

In addition, My HealthVet Secure Messaging allows VA staff to save all or part of a Secure Message or message thread that is deemed clinically relevant as a Text Integration Utilities (TIU) note in the Computerized Patient Record System (CPRS). These TIU notes are then accessible to all VA staff with appropriate access to the individual's VHA Electronic Health Record. Therefore, as part of the informed consent process, prospective subjects must be informed that any research related notes saved in CPRS could be viewed by any VA staff with appropriate access to view the subject's VHA Electronic Health Record.

**5. Is a VA researcher required to use a specific format for naming the My HealthVet Secure Messaging Triage Group for a specific study?**

A study-specific name must be used when My HealthVet Secure Messaging is used for a research study. This study-specific name allows the individual with a My HealthVet account to distinguish between Secure Messages that are related to his or her healthcare versus research related communication. The study-specific name is created using a combination of four items: two standardized phrases and two study-specific phrases. The required format is a combination of three letters indicating the study site, the word "Research", the study name or a short phrase that would allow identification of the message with the study, and "STUDY\_RES". Note that the character limit for the Secure Messaging

Triage Group is 50 characters. The My Health<sup>e</sup>Vet Coordinator at the local VA facility should be consulted when a VA researcher is ready to establish a study-specific name for the study's Secure Messaging Triage Group. For example, if the Baltimore VA was a participating site in a multisite study called, "A comparison of Type II Diabetes and three modalities of activity to evaluate short-term and long-term effects on physical and psychological complications of Diabetes", the study-specific name for the associated Secure Messaging Triage Group would be:

BAL-RESEARCH-DIABETES AND ACTIVITY-STUDY\_RES

The above applies the following in creating a specific study-name for use of Secure Messaging: [3 Character Site]-RESEARCH-[Study Name]-STUDY\_RES

**6. What do VA researchers need to do to use My Health<sup>e</sup>Vet Secure Messaging once the IRB of Record and R&D Committee have approved a VA study?**

To participate in My Health<sup>e</sup>Vet Secure Messaging, VA researchers, including any research team member using Secure Messaging, must receive education and training on the use of Secure Messaging. Each Veterans Integrated Service Network (VISN) and VA Facility has a My Health<sup>e</sup>Vet Coordinator/Secure Messaging Administrator to help facilitate and implement Secure Messaging within their purview. Once the necessary training has been completed, the My Health<sup>e</sup>Vet Coordinator/Secure Messaging Administrator will activate the research team member's account within the Secure Messaging Administrative Portal.

The My Health<sup>e</sup>Vet Coordinator at the local VA facility should be consulted to finalize the study-specific name that will be used for the Secure Messaging Triage Group. Once the study-specific name has been finalized and the research team members' accounts are activated, the VA research study team should identify the triage process that will be used for incoming Secure Messages. Any/all members of the study team Secure Messaging Triage Group can set their individual preferences to be alerted when a message is received from a VA subject. Research subjects can then be manually associated with the study team Secure Messaging Triage Group once they are consented into the study so that an association is created between the research team and the subject. The My Health<sup>e</sup>Vet Coordinator at the local VA facility can assist with setting up a Secure Messaging Triage Group and adding individuals by manual association.

**7. If I already receive My Health<sup>e</sup>Vet Secure Messages from patients in the context of my clinical service at VA, what do I need to do to establish a separate Secure Messaging triage group for messages from study participants in the context of my research?**

If you are a VA researcher who also provides primary or specialty care, you may already be using Secure Messaging. Although VA staff can belong to multiple Secure Messaging Triage Groups, it is important to note that all Secure Messaging users *have one set of preferences for New Message Notification and Inbox View*. For example, if the Secure Message User has his or her Secure Messaging Preferences set to be notified of a Secure Message **only** when it is specifically assigned to him or her, and to **only see** Secure Messages that have been specifically assigned to the them in the Secure Messaging Inbox; he or she would not see a new message that came in for the triage team unless someone else on the team opened it and reassigned it to the them. This "on assignment" preference works for most primary and specialty care teams because an RN, LPN or an MSA that is also on the team is typically the initial reviewer of messages for that team, handling what

they can and reassigning what they cannot resolve. The VA research team can also designate a study team member to review and triage incoming secure messages and respond or assign them to other team members as needed. This may be an effective strategy for VA researchers who are also providers and therefore, may want to keep their Message Notification and Inbox View Preferences to “On Assignment” and “Only Messages Assigned to me” respectively.

**8. What do VA researchers need to do if a Veteran has been enrolled into a VA study but does not yet have a Premium My HealtheVet account?**

There are three different types of My HealtheVet user accounts: Basic, Advanced, and Premium. In order to use My HealtheVet Secure Messaging, the Veteran must be registered for an account (Basic), correlated with the Master Veteran Index or MVI (Advanced), and complete a onetime authentication process (Premium). Authentication is a process by which VA verifies a Veterans' identity before allowing access to all of the features of the My HealtheVet patient portal, including Secure Messaging. The Authentication process can be done in-person or online. Please refer the Veteran to the local VA Facility's My HealtheVet Coordinator if the Veteran wishes to utilize My HealtheVet Secure Messaging but does not yet have a Premium My HealtheVet account. Please note that the Veteran will need to select “VA Patient” when they register for their My HealtheVet account or update their profile.

Please keep in mind that a Veteran's participation in research and use of My HealtheVet Secure Messaging is voluntary. VA researchers are encouraged to develop alternative strategies of communicating sensitive information to VA research subjects if the use of My HealtheVet Secure Messaging is not desired by the Veteran. Alternatively, if a particular study requires access to Secure Messaging as an integral part of the study design, this should be noted in study eligibility criteria and also outlined in the study protocol.

**9. What instructions should VA researchers give to Veterans regarding communicating with the study team using My HealtheVet Secure Messaging?**

VA researchers should consider how and when instructions will be given to VA research subjects when Secure Messaging is used for study related communication. Instructions may need to be given orally and/or in writing. Instructions should be specific enough that the VA research subject is able to identify when the study team is communicating with him or her through the use of the study-specific Secure Messaging Triage Group and how to contact the study team through My HealtheVet Secure Messaging.

Operationally, both Veterans and the research team may have training needs, including training on use of My HealtheVet Secure Messaging. These learning needs should be identified as part of standard operating procedures for the study before the study is submitted to the IRB of Record. Veterans and staff may need to be provided with training on the use of Secure Messaging by the Research Staff and/or the local VA Facility My HealtheVet Coordinator.

**10. If a Veteran sends a complaint about the research study through My HealtheVet Secure Messaging, does it require reporting to the IRB of Record or is there a special reporting system?**

Complaints sent by a Veteran thru My HealthVet Secure Messaging are evaluated in the same way as any complaint received from a VA subject in a VA research study. The Investigator or Research Team member must refer to local Human Research Protection Policy procedures to determine when the complaint is to be reported to the IRB of Record for the specific study.

**11. What happens if a VA research team member receives a Secure Message from a Veteran that is intended for the Veterans' health care team?**

Secure Messages can be reassigned to another Secure Messaging Triage Group or individual using the Internal Healthcare Team Communications Box. Instructions on how to reassign a Secure Message can be found on the [My HealthVet Product Website](#) on the VA Intranet. If a VA research team member receives a Secure Message from a Veteran that was intended for the Veteran's health care team, it must be properly reassigned to the appropriate Secure Messaging Triage Group or individual to ensure delivery to the intended recipient.

**12. How should communication with VA subjects via My HealthVet Secure Messaging be documented? What if a VA research study has a Certificate of Confidentiality?**

Secure Messages to and from VA subjects, as part of a VA approved study, are considered part of the investigator records that must be retained as required by VHA's Record Control Schedule 10-1. VA researchers are strongly encouraged to routinely save a copy of all messages sent and received using My HealthVet Secure Messaging since messages are only available for display for one year.

Some studies, however, have a Certificate of Confidentiality. A Certificate of Confidentiality (CoC) is issued for applicable Department of Veterans Affairs (VA) research by several Department of Health and Human Services (DHHS) agencies to protect research subjects by preventing investigators and institutions from being forced or compelled to release identifiable information on research subjects. It allows the investigator and others who have access to research records to refuse to disclose identifying information on research subjects in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level. The CoC helps to minimize risks by adding an additional level of protection for maintaining the privacy and confidentiality of research subjects in a VA study. Current ORD policy in VHA Handbook 1200.05, Paragraph 21 states that for studies with a Certificate of Confidentiality that do not involve a medical intervention (e.g., observational studies, including interviews and questionnaire studies), no annotation may be made in the health record. Therefore, if the VA study does not involve a medical intervention, My HealthVet Secure Messaging communications cannot be saved as a TIU note in the subject's VHA health record. In this case, the VA research team should document the communication in the investigator's research file.

For studies that do involve a medical intervention, My HealthVet Secure Messaging allows VA staff to save all or part of a Secure Message or set of related messages (message thread) that is deemed clinically relevant as a TIU note in CPRS.

For studies that involve a medical intervention but that also have a CoC, ORD policy states that any details that would affect the subject's clinical care are to be included in progress notes. The VA Principal Investigator (PI) is responsible for determining which My HealthVet Secure Messaging communications will be documented in CPRS. If the Secure

Messaging communication involves a subject safety issue as determined by the VA PI, it must be documented as a TIU note in CPRS and follow all other reporting requirements as dictated by facility, regional (state) and national regulations, including verbal and written communication to patients, facility operations, and local authorities. Subject safety is always the first priority and should never be compromised by withholding information needed by a VA research subject's health care team

### **13. What are the business rules for the timeliness of response to a Veteran Secure Message?**

It is very important that Secure Messages are responded to within a timely manner and marked as complete within the Secure Messaging application. Secure Messages must be marked as complete within three (3) federal business days or they will escalate within the Secure Messaging application. Secure Messages are completed by the user by changing the message status to Complete. Secure messaging response time will be stated clearly to all participants when the participant enrolls in the study.

### **14. How can I learn more about My HealthVet Secure Messaging?**

The My HealthVet Product website on the VA intranet provides a variety of resources to learn more about how to use [My HealthVet Secure Messaging](#).

You can also email [MHVSecureMessagingFieldQuestions@va.gov](mailto:MHVSecureMessagingFieldQuestions@va.gov) with specific questions about accessing and using HealthVet Secure Messaging.

#### **References:**

- VHA Handbook 1200.05: Requirements for the Protections of Human Subjects in Research
- VHA Directive 1605.01: Privacy and Release of Information
- VA Handbook 6500: Information Security Handbook