

**OFFICE OF RESEARCH AND DEVELOPMENT
VETERANS HEALTH ADMINISTRATION**

**Draft Guidance on the Use of Electronic Mail and Electronic Text Messaging for
Recruiting and Communicating with VA Subjects in VA Research**

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Draft Guidance

This draft guidance document is being distributed for comment purposes only.

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This draft guidance is a new ORD guidance document.

Please submit comments and suggestions regarding this draft document within 120 days of the date of issue. Submit comments and suggestions to the VHA Office of Research and Development at VHACOORDRegulatory@va.gov.

SCOPE: This guidance document provides guidance for VA Investigators and VA research team members on the use of VA electronic mail (email) and text messaging for the purposes of recruitment of VA subjects and communicating with VA subjects in the conduct of VA research. ORD's requirements for the protection of human subjects in VA research and the operation of the Institutional Review Board(s) (IRB) for VA facilities are described in VHA Handbook 1200.05. This ORD guidance is based on the recognition that (a) VA employee emails and VA text messages may be subject to the Freedom of Information Act (FOIA), (b) the privacy and confidentiality of VA subject information sent and received by electronic email or text messaging must always be considered, (c) email and text messaging are not secure and may be seen by others, and (d) the IRB is responsible for ensuring that appropriate safeguards exist to protect the rights and welfare of individuals being recruited for research studies and for research subjects. Email is not inherently confidential and VA researchers should have no expectation of privacy when using government mail systems. The following questions are discussed in this guidance document:

1. Can email messages be sent by VA Investigators to recruit and communicate with VA subjects?
2. Can text messages be used by VA Investigators to recruit and communicate with VA subjects?
3. What are examples of personally identifiable information (PII) that VA Investigators cannot send by emails or by text messaging unless the information is encrypted using a VA-approved encryption method?
4. What are examples of protected health information (PHI) VA Investigators cannot send by emails or by text messaging unless the information is encrypted using a VA-approved encryption method?
5. What should a VA Investigator do if she or he receives PII or PHI from a prospective subject or a VA subject by unencrypted email or text message?

6. What is an example format for a study reminder to a VA subject?
7. What are some considerations for an IRB evaluating a research study proposing to utilize email and/or text messages to recruit or communicate with VA subjects?
8. Can a VA Investigator communicate research study information which includes individually identifiable or personally identifiable information to a study recruiting VA employees using VA email?
9. Are VA Investigators required to keep copies of emails and text messages sent to and from VA subjects?
10. Can VA Investigators utilize My HealthVet's Secure Messaging system to recruit VA subjects in approved VA research studies?
11. Can VA Investigators utilize MyHealthVet's Secure Messaging system to communicate with VA subjects in approved VA research studies?

1. Can email messages be sent by VA Investigators to recruit and communicate with VA subjects?

Yes. VA Investigators can use VA email to recruit prospective VA subjects and to communicate with VA subjects who have consented to participate in a VA research study as described in the IRB-approved research study. VA Investigators may not utilize their personal email accounts (e.g., Google) or university email accounts for research communications with prospective or consented VA subjects. The use of personal email account or the use of a personal email system to conduct official agency business is not allowed. No PII/PHI can be sent by a VA Investigator for VA research purposes to a prospective or consented VA subject by email unless the email is encrypted using a VA-approved encryption method. Your local ISO should review the encryption to ensure it meets all applicable requirements. If the message is not encrypted, ORD recommends that the email message be reviewed as part of IRB review process. The IRB should consult with the VA Facility's Privacy Officer concerning privacy issues outside the scope of the human subject protection regulations.

Note: An external recipient of a VA RMS encrypted email requires enrollment in the VA's external RMS system in order to open the email at the present time.

2. Can text messages be used by VA Investigators to recruit and communicate with VA subjects?

Yes. Text messages can be used by VA investigators to recruit prospective subjects and to communicate with VA subjects who have consented to participate in a VA research study as described in the IRB-approved research study. VA Investigators may not utilize their own personal devices, such as personal cellphones, personal Instant Messages (IMs), or university owned devices to send and receive text messages with prospective or consented VA subjects. No PII/PHI or identifiers can be sent by a VA Investigator for VA research purposes to a prospective or consented VA subject using text messaging unless the text messaging system is encrypted using a VA-approved encryption method. As indicated above, the ISO and Privacy Officer should review these as part of the review of the protocol.

3. What are examples of personally identifiable information (PII) that VA Investigators cannot send by emails or by text messaging unless the information is encrypted using a VA-approved encryption method?

Personally identifiable information (PII) is considered to be the same as VA Sensitive Information/Data. PII is any information about an individual that can reasonably be used to identify that individual that is maintained by VA, including but not limited to, education, financial transactions, medical history, and criminal or employment history and information which can be used to distinguish or trace an individual's identity, such as name, social security number, date and place of birth, mother's maiden name, telephone number, driver's license number, credit card number, photograph, finger prints, biometric records, etc., including any other personal information which is linked or linkable to an individual. (VA Directive 6502)

For purposes of VA research, data which is considered to be PII cannot be sent electronically unless it is encrypted using a VA-approved encryption method. Examples of PII that CANNOT be sent via email unless encrypted include, but are not limited to, the following:

- Names (employee names are acceptable);
- All geographical subdivisions smaller than a State;
- Social Security Number;
- Names of Relatives, including the mother's maiden name;
- Biometric records;
- Fax numbers;
- Electronic mail addresses;
- Any other unique identifying number, characteristic, or code (note this does not mean the unique code assigned by the investigator to code VA research data);
- Any Protected Health Information

In addition to the above list of identifiers described in the HIPAA Privacy Rule, ORD and VHA policy considers a code derived from an individual's Social Security Number to be PII that should not be sent unless it is encrypted.

Additional information regarding sensitive data is described in other VA and VHA Handbooks, including, but not limited to, VA Handbook 6500 and VHA Handbook 1605.01.

NOTE: Even with encryption PII being sent to a non-VA entity requires legal authority to make the disclosure of VHA data.

4. What are examples of protected health information (PHI) VA Investigators cannot send by emails or by text messaging unless the information is encrypted using a VA-approved encryption method?

The HIPAA Privacy Rule defines protected health information (PHI) as Individually-identifiable health information transmitted or maintained in any form or medium by a covered entity, such as VHA. For VA, PHI is considered a subset of PII and includes any health information, not just identifiers or demographics, maintained by VHA that has not been de-identified in accordance with the HIPAA Privacy Rule.

VA Investigators cannot send any PHI to a prospective subject or to a VA subject participating in a VA study unless the email or text message is encrypted using a VA-approved encryption method. The VA National Rules of Behavior require VA employees who access and use VA information or information systems to use VA-approved encryption to encrypt any email, including attachments to the email, which contains VA sensitive information before sending the email. For example, a VA Investigator cannot send the following recruitment email to a prospective subject with the following message unless the email is encrypted because PHI (**in bold**) is conveyed (in addition to ethical issues and IRB regulatory criteria involved in sending this type of recruitment email):

*“Dear Sir,
You are being asked to participate in a research study because you have been recently diagnosed with **Stage IV Lung Cancer**. Please contact the research team at “AAA-BBB-CCCC”.*

In another example, a VA Investigator cannot send the following communication in unencrypted email or text message because the name of the study include information that indicates the VA subject’s medical diagnosis :

*“Dear Ms. X,
This is a reminder that your next study visit for **“Anxiety Reducing Strategies for PTSD Clients”** occurs next Monday at 8:00 a.m. in Room 123. Please contact the research team at “AAA-BBB-CCCC” if you need to reschedule. We look forward to seeing you on Monday. Have a great day.”*

VA Investigators must be aware of the content of emails and text messages sent as part of the study procedures in a VA research study. The content of the unencrypted email cannot contain any sensitive information. VA Investigators should always consider how the content of the email or text message might compromise the subject’s privacy and confidentiality if the message was inadvertently retrieved by someone other than the intended prospective subject or VA subject participating in a VA study. A VA Investigator should not include in the electronic communication information that would allow the reader to conclude that the individual had a specific diagnosis or condition, such as including a signatory line that states, “Research Team for COPD Study”. VA Investigators should also not include links to websites in electronic communications that are publicly accessible and would allow the reader to conclude that the individual has a specific diagnosis or condition if the electronic communication was read by others.

5. What should a VA Investigator do if she or he receives PII or PHI from a prospective subject or a VA subject by unencrypted email or text message?

Sending recruitment messages to a prospective subject or communicating with consented VA subjects using the recipient’s personal, university, or commercial email accounts should always convey that no PII should be sent by email or text messaging to the VA research team. If health information or PII/PHI needs to be conveyed to the VA research team, it cannot be sent using unencrypted email or text messaging. ORD recommends that a statement be included on any research email or text message stating the following: “Email [or texting] is not secure. Please do not reply back to this message with any personal information or personal health information. Please call INSERT #.

Even though it is not anticipated, there may be rare circumstances in which a prospective subject or a VA subject participating in a VA study sends PII or PHI as part of a response using the individual's personal email or text messaging. The VA Investigator should either respond by telephone to the individual or respond using email or text messaging with redaction of any PII or PHI conveyed by the prospective subject or VA subject participating in a VA study. In addition, the VA Investigator should not forward the email to other VA employees without encrypting the email or test message.

For example, a prospective subject sends the following email to the VA research team after receiving a recruitment email brochure approved by the IRB of Record for the specific VA study using the email address on the IRB-approved electronic recruitment flyer:

"I am so excited to receive information about this research study. I would love to be in it. I just happened to see my physician this morning, and he placed me on Norvasc and Captopril and told me that I have worsening COPD, with an oxygen level of 72 and a carbon dioxide level of 56. Please help me understand what this means. I will also send you my labs when I get them."

In the above example, no telephone number was provided by the prospective subject. The VA Investigator cannot respond back using unencrypted email if any PII/PHI is going to be included. Therefore, the VA Investigator could send back an email as follows:

"Our research team received your email indicating interest in the study. You also had questions about your health. Please give me a call at INSERT # at your convenience."

6. What is an example format for a study reminder to a VA subject?

Study reminders sent by a VA research team by email or text messages cannot contain any PII or PHI unless the communication is encrypted using a VA-approved encryption method. Study reminders can be sent by a VA research team without including information that would require encryption. The content should not include any information that would indicate the type of appointment or the specific location, or specific diagnosis or condition; the content must be reviewed by the IRB as part of the IRB approval of the VA research study.

For example, the following is a study reminder that could be sent without encryption because no sensitive data is included in the content:

"Reminder: You have a visit on May 4, 2016 at 8:30 a.m. Please call 111-222-3333 if you need to reschedule or have questions."

This is an example of a study reminder which contains PII/PHI and cannot be sent without encryption:

*"**C70298 Study Reminder:** You have an appointment with the **C70298 Study team on May 11, 2016 at 8:30 a.m.** in Room 115 on the 1st floor of the main hospital building. Please bring all unused study medication and your*

*supplemental Albuterol inhalers to the study visit. Please call the **Pulmonary Clinic** at 111-222-3333 if you need to reschedule or have questions.”*

7. What are some considerations for an IRB evaluating a research study proposing to utilize email and/or text messages to recruit or communicate with VA subjects?

The use of VA email in a VA research study must be evaluated by the IRB. When research studies utilize email or text messaging, the IRB must review the content of standardized communications. Other considerations for the email or text messages include, but are not limited to, the following:

- The VA Investigator must employ measures to avoid disclosing the email addresses of potential research subjects or other consented subjects to others. Common techniques include the use of:
 - (a) Individually targeted messages (only one address in the “TO” line per message)
 - (b) Group targeted messages with all recipient email addresses in the “BCC” line”. NOTE: Sending a group message with all recipient email addresses in the “TO” or “CC” line is inappropriate as all recipients can see the email addresses of the group.
- The VA Investigator should use a standard “SUBJECT” line that does not indicate the name of the study or the name of the recipient or other individually unique identifier. For example, the “SUBJECT” line should contain wording that would be general in nature and not indicate that the individual is being recruited for a study. This will prevent others who may see the list of emails received but cannot open them from knowing that the individual is being recruited. For example, the “SUBJECT” line should not read, “VA Subjects needed for Study on Addiction in Health Care Providers”. SUBJECT lines cannot be encrypted.
- There should be a signature block for the person sending the email, including his or her contact information at the VA but the contact information cannot contain anything that would indicate the specific study. The VA Investigator’s non-VA contact information should not be included for a VA study. There should also be a name and VA contact information for a VA research staff member who would be able to answer questions related to the study (if different than the VA Investigator). No responses related to the study which includes PII/PHI can be sent using unencrypted VA email or text messaging by a VA Investigator or VA research team.

In order to approach human subjects research requiring IRB approval, the IRB is required to determine that all of the IRB approval criteria are met, which includes equitable selection of subjects and if there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data (38 CFR Part 16.111(a)(3) and (a)(7)). The IRB should consider how the contact information, such as email addresses for sending IRB-approved recruitment information, is being obtained by the VA Investigator for the study. Similar to IRB considerations for contacting prospective subjects by telephone for recruitment activities or obtaining follow-up information for VA subjects in a VA study or sending letters by mail, the IRB should also consider how many emails or text messages are sent to prospective subjects for recruitment purposes

or to VA subjects participating in a research study. The IRB should evaluate whether the frequency and/or content is appropriate for the purpose of the research study or evaluate whether or not the frequency and/or content could be considered to be coercive or harassment by prospective subjects or VA subjects participating in a research study.

The IRB cannot approve an informed consent process which uses email or text messaging to document informed consent as described in VHA Handbook 1200.05. ORD permits informed consent for VA research to be obtained electronically, but the informed consent process and documentation must meet all requirements described in VHA Handbook 1200.05 as well as applicable VA requirements. Documentation of informed consent by email or text messages is not an example of consent which is obtained electronically permitted under VHA Handbook 1200.05, Paragraph 16(e)(2)(c). In addition, neither of these types of electronic communication can serve as a signed HIPAA authorization for use and disclosure of PHI for research purposes.

8. Can a VA Investigator communicate research study information which includes personally identifiable information to a study recruiting VA employees using VA email?

VHA conducts numerous studies involving VA employees, and encrypted email using a VA approved encryption method can be used to communicate sensitive information, such as personally identifiable information, between a VA employee and a VA research team if approved by the IRB as part of its approval of the research study. However, it is important to remember that the privacy and confidentiality of VA employees who are asked to participate in VA research must be evaluated by the IRB when using email or text messaging, regardless of whether PII is being sent using encrypted VA email or unencrypted email is being sent by a VA research team member to VA employees.

The content of the message should not include any information that might compromise the employee's privacy, position, or standing as a VA employee if others, such as the employee's supervisor, were to know that he or she was being approached to participate in the project or has consented to be in a VA research study. VA employee email is not confidential and is subject to review by VA. Some VA employees routinely give permission to others (e.g., administrative assistants) to allow them to read the individual's emails. VA also may be required to release VA employee emails under a FOIA request.

The IRB should consider whether or not additional privacy and confidentiality safeguards are needed when VA employees are recruited as VA subjects, regardless of whether or not email or text messaging is involved for the VA research study.

9. Are VA Investigators required to keep copies of emails and text messages sent to and from VA subjects?

Emails and text messages sent and received by a VA Investigator and the VA research team are federal records subject to the VHA Record Control Schedule. Copies of the email communications and text messages sent and received by a VA Investigator and the VA research team must be maintained in accordance with the VHA Record Control Schedule (RCS 10-1) as part of local VA Investigator records.

Text messages may have unique issues for retention because they are not retrievable in the same context as email messages. However, the text messages sent and received in VA research must be printed or captured as part of VA's record retention requirements. If they cannot be retained, then these forms of communication cannot be used.

10. Can VA Investigators utilize My HealthVet's Secure Messaging system to recruit VA subjects in approved VA research studies?

VA Investigators cannot use My HealthVet's Secure Messaging system to recruit VA subjects.

11. Can VA investigators utilize My HealthVet's Secure Messaging system to communicate with VA subjects in approved VA research studies?

At this time, VA investigators cannot send and receive research-related communications as part of a VA-approved research study, however this capability is currently being explored. Additional guidance will be provided

REFERENCES:

VA Handbook 6500 (May 10, 2015): Risk Management Framework for VA Information Systems – Tier 3: VA Information Security Program

VA Directive 6301 (April 24, 1997): Electronic Mail Records

VA Directive 6502 (May 5, 2008) : VA Enterprise Privacy Program

VHA Handbook 1200.05 (November 12, 2014): Requirements for the Protection of Human Subjects in Research

VHA Directive 1605.1 (August 31, 2016): Privacy and Release of Information

VHA Privacy Fact Sheet, Volume 10, No. 5 (May 2014): Use of Individually identifiable Information in Microsoft Office Applications and Vista