

Frequently Asked Questions: Institutional Review Board (IRB) and VA Research and Development (R&D) Committee Considerations for Use of Azure Rights Management Services (RMS) in VA Research

1. Question: What is Azure Rights Management Services?

Azure Rights Management System (often abbreviated to Azure RMS) is the protective technology used by Azure Information Protection. It uses encryption, identity, and authorization policies to help secure file attachments and email. Information can be protected both within the VA and outside the VA because the protections remain with the data, even when it leaves the VA. VA OI&T has issued a set of Frequently asked questions (FAQs) about Azure RMS located at

https://vaww.portal2.va.gov/sites/AIP/_layouts/15/WopiFrame.aspx?sourcedoc=/sites/AIP/Shared%20Documents/Azure%20RMS%20Frequently%20Asked%20Questions.docx&action=default

Release Date: 10-25-2019

2. Question: Can Azure RMS be used by VA researchers to send large data files to another researcher?

Azure RMS can transfer files up to 40Mb.

Release Date: 10-25-2019

3. Question: Can Azure RMS be used by VA researchers to communicate personally identifiable information and protected health information (PII/PHI) to VA subjects?

Yes. Azure RMS can be used to communicate PII/PHI to VA subjects as part of the approved VA research protocol. External Recipients can open or view RMS encrypted email from any compatible web browser or through their social email account (Gmail, Yahoo, Outlook).

Release Date: 10-25-2019

4. Question: Can Azure RMS be used by VA researchers to send a secure email to a research collaborator?

Yes. Azure RMS can be used to send a secure email to a research collaborator as part of the approved VA research protocol. Azure RMS provides encryption through email for compliance with Federal Information Protection Standards (FIPS) 140-2 and other VA Sensitive Information (VASI) compliance requirements. Official VA Research communication must be initiated through a VA Outlook account using VA OI&T approved Azure RMS Procedures.

Release Date: 10-25-2019

5. Question: What are some considerations for an IRB or VA R&D Committee evaluating a research study proposing to utilize Azure RMS to recruit or communicate messages containing PII/PHI with VA subjects?

Both exempt and non-exempt human subjects studies may be conducted using Azure RMS to recruit or communicate messages containing PII/PHI with VA subjects. The use of Azure RMS is analogous to any method of communication used in human subjects research; its use must be evaluated by the applicable research oversight committee(s). If standardized communications are used, the applicable research oversight committee must review the content of standardized communications. Other considerations for the use of Azure RMS to recruit or communicate messages containing PII/PHI include, but are not limited to, the following:

- IRBs and/or R&D Committees must review and approve all aspects of recruitment, including the specific methodologies used and the text of recruitment letters or email.
- IRBs and/or R&D Committees should consider prospective subjects' confidentiality issues when Azure RMS is used for recruitment in VA research. Unless the prospective subjects have already given their prior consent, permission, or opted in to receive information by email about possible research opportunities, the prospective subjects are receiving unsolicited emails. Similar to IRB considerations for contacting prospective subjects by physical mail, the IRB and/or R&D Committee should also consider how many emails are sent to prospective subjects for recruitment

purposes. The IRB and/or R&D Committee should also evaluate whether the frequency and/or content could be considered to be coercive or harassment by prospective subjects.

- ORD recommends that reviewing IRBs and/or R&D Committees evaluate information on the source of the email addresses to help ensure the privacy of prospective subjects when Azure RMS is used to send emails for the purpose of recruiting subjects in VA research. Use of Azure RMS is not the same as use of a Personal Identity Verification (PIV) card. Identity verification is not a component of Azure RMS. If Azure RMS is used to recruit VA subjects, it is important to use due diligence to determine the correct email addresses, similar to determining the correct address when mailing physical letters. This is important when using Azure RMS to send recruitment emails to minimize risk of sending sensitive information to unintended email recipients and protecting the privacy of subjects.
- ORD recommends that IRBs and/or R&D Committees evaluate whether the use of Azure RMS is appropriate to communicate about some diagnoses or behaviors. While Azure RMS can be used to communicate PII/PHI, the IRB and/or R&D Committee should consider whether the use of email is appropriate for the type of communication with the VA subject.
- Subjects may not know how to reply to an Azure RMS protected message. Investigators utilizing Azure RMS for recruiting or communicating purposes should consider whether they need to provide a user guide for subjects detailing the proper procedures for replying to an Azure RMS protected message. Any study-specific information materials provided to subjects must be approved by the IRB for research requiring IRB approval. For exempt research,

information material provided to subjects must be approved by the R&D Committee if it is the sole oversight committee of the research activity.

Release Date: 10-25-2019

6. Question: What are some considerations for VA Investigators proposing to utilize Azure RMS to send a secure email to a research collaborator?

The use of Azure RMS is analogous to any method of communication used in human subjects research; its use must be evaluated by the applicable research oversight committee(s).

Although emails encrypted with Azure RMS and their attached content will be encrypted while in transit, there are limitations with ensuring file encryption will remain with certain file types once the email is opened and the content/attachment is saved to the recipient's desktop. ORD recommends that IRBs and/or R&D Committees evaluate whether the use of Azure RMS is appropriate to enforce VA security requirements beyond ensuring the email content is encrypted while in transit.

Research collaborators may not know how to reply to an Azure RMS protected message. VA Investigators may need to provide a user guide for research collaborators detailing the proper procedures for replying to an Azure RMS protected message.

Release Date: 10-25-2019

7. Question: For VA research requiring a written informed consent document, is the IRB required to include specific language about use of Azure RMS?

ORD does not have a policy requiring that Azure RMS must be described in the written informed consent approved by an IRB. However, the IRB has authority to determine the content of informed consent to ensure that it is in accordance with, and to the extent required by 38 CFR 16.116. [The Common Rule](#) (e.g., the Federal Policy for the Protection of Human Subjects codified by VA as 38 CFR Part 16) requires as part of the basic elements of informed consent in 38 CFR Part 16.116(b)(1) that the following be provided to each subject or the subject's legally authorized representative:

“A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental.”

The IRB has the responsibility for determining what must be in the informed consent document as part of the IRB approval criteria for research in 38 CFR 16.111, including the consent needed to ensure that prospective subjects or their legally authorized representatives are given sufficient information to make an informed decision whether to participate in the research. As part of its evaluation, the IRB evaluates what level of detail is needed about the description of procedures to be followed, such as methods used to communicate with subjects.

Release Date: 10-25-2019