

Remote Consent, Data Collection & Video Communications Guidance for Research

This guidance addresses the use of electronic methods to send informed consent documents to potential VA subjects and obtain informed consent using electronic signatures from VA subjects or their Legally Authorized Representative (LAR).

This applies to Institutional Review Board (IRB)-approved research studies requiring a written informed consent form or written HIPAA authorization.

Prior to implementation, use of electronic methods for obtaining and documenting written informed consent must be approved by the IRB (except for emergency use of a test article as per VHA Directive 1200.05 and FDA regulations). If applicable, the IRB must approve obtaining consent from LARs.

VA DocuSign

As of March 22, 2021, VA ORD allows e-signature on VA research consent documents (informed consent and HIPAA Authorization Form) via VA DocuSign. **E-Consent by DocuSign must be requested and approved through the VA Central Office of Research and Development (ORD),** not the San Francisco VA facility research office.

You must first request the use of DocuSign by submitting the form at the [ORD SharePoint site](#). Requests for the use of DocuSign are usually reviewed and decided within 2-3 business days if all appropriate information is provided.

All requests are considered but studies enrolling less than 100 subjects must provide justification for use due to the support required by the OI&T Identity and Access management Team. For studies funded by sponsors outside of VA, please make sure that your sponsor will not require the use of their electronic signature platform prior to requesting DocuSign use. See additional [VA DocuSign guidance](#) provided by ORD.

Once ORD approved use of DocuSign:

1. Forward the approval notification to V21SFCHRPP@va.gov.
2. Submit a request to use DocuSign to the IRB and include the following in your submission:
 - a. Complete the Recruitment and Consent section of the IRB Study Application describing how/when you'll use DocuSign. You may borrow language from the [DocuSign SOP](#): see "The procedures for using DocuSign for Research e-consenting"
 - b. In the CONSENT METHODS item, check "Sign an electronic consent form using DocuSign (signed consent)"
 - c. Attach 1) email script and 2) consent phone script—see Appendix A and B for script templates.
 - d. Attach a copy of your ORD approval correspondence.

Note: *Other external web-based platforms such as Qualtrics, REDCap, etc. are not permitted for obtaining electronic signatures on VA informed consent and HIPAA authorization forms.*

Hand-signed consent

If signed consent is required for your study and in-person or VA DocuSign consent is not possible, you may obtain hand-signed documents remotely using the following methods:

Send VA consent and HIPAA forms via encrypted VA email using Azure Rights Management Services, or send consent documents via MyHealthVet secure messaging. The subject (or LAR) must be able to print the forms and sign by hand. See Azure RMS [FAQs](#) and [User's Guide](#) and [Guidance for VA Researchers on the Use of My HealthVet Secure Messaging](#).

Option 1 (this is the preferred method): the subject scans/photographs each page of the signed documents and emails legible images back to the research team using encrypted VA email or the MyHealthVet secure messaging system.

Option 2 (this method should only be used if option 1 is not possible and if the study team is using government furnished equipment): using secure two-way video conference, ask the subject to display the signed documents, then the study team takes screen shots of each *signed* page. Ensure the IRB stamp with the consent form approval and expiration dates is clearly visible in the screen shot. More guidance on video communication technologies is included below.

For either option, the digitized, signed versions must be legible and downloaded to the VA network. There is no requirement to print hard copies; VHA accepts a legible digital image of a signed authorization the same as the original. Remember that the VA Research Compliance Officer is required to audit all signed VA consent documents.

Additional guidance on sending encrypted VA email using RMS:

There are a few extra steps that external users need to take to open encrypted VA emails using RMS. Therefore, before the first encrypted email is sent, we recommend that you send a generic message with written instructions about using unencrypted email. It is recommended that you send a test encrypted VA email to your personal/non-UCSF email and then follow the steps for encryption. Do not test with a UCSF email because there are no additional steps to open VA to UCSF emails using RMS encryption.

Sample initial email language:

Hello SFVA patient/research participant/potential research participant,

We are conducting a research project that you may be interested in/have expressed interest in/etc. We will provide further information about the project via a separate encrypted email. Please review the attached instructions/instructions below (if embedded within the text) on how to open and respond to the encrypted email, or feel free to call us at _____ to talk you through it over the phone.

Thank you,

Name

SFVAHCS

Electronic data collection and use of two-way video communication

Prior to implementation, any changes to data collection methods and/or use of video communication technologies must be approved by the IRB.

Data collection:

VA research data can be collected electronically using external (i.e., outside of the VA network) systems. However, only *copies* of VA data can exist on external networks. Per VA requirements, the original long-term data must reside within the VA-protected environment, unless you have a signed waiver.

External data collection systems:

Always first pursue internal VA systems or VA-approved external systems for remote data collection (e.g., VA REDCap). If those solutions are not feasible, we recommend the following secure, HIPAA-compliant systems accessible via UCSF MyAccess:

- UCSF REDCap: <https://myresearch.ucsf.edu/redcap>
- UCSF Qualtrics: <https://it.ucsf.edu/services/qualtrics-web-surveys>

Before choosing an external system, do your due diligence to research the information security standards (e.g., FIPS 140-2 encryption compliance, data backup and storage location, access controls, etc.). Document this information in the study's [Enterprise Research Data Security Plan](#) (ERDSP) and in the IRB Study Application. The external entity to whom individually identifiable health information is disclosed must be named in the Disclosure section of the HIPAA form.

You may contact the ISSO at v21sfclSOStaff@va.gov and Privacy Officer at v21sfcPOStaff@va.gov for more information.

Data storage:

If you use an external system for remote data collection, you must download and store a full set of the original data on the VA network. The full VA research dataset stored on the VA network will be considered the original data. The VA research data stored on external systems will be considered a copy. You can also store copies of de-identified data on external systems (i.e., UCSF Box). If you wish to store copies of individually identifiable health information on external systems, the legal entity hosting the system must be named on the VA HIPAA authorization.

Use of video communication technologies:

Please refer to the [VA memorandum](#) regarding use of video communication technologies. To summarize, we have been granted temporary flexibility to use external technologies. This flexibility is only in effect for the duration of the COVID-19 national emergency and could be reversed sooner.

In addition, this memorandum authorizes VHA personnel to use personally owned equipment (POE) in the absence of government furnished equipment (GFE). However, you may not use a personal phone to send text messages or emails regarding study visits.

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[VA Video Connect](#) (VVC) is a VA-approved video communication technology and remains the preferential method to conduct video encounters, so explore this option first. Chrome is the preferred browser to use for VVC.

If VVC is not feasible, permitted non-public facing remote audio or video communication technology includes (but is not limited to): Apple FaceTime, Facebook Messenger video chat, Google Hangouts video, Skype (non-VA), and WhatsApp.

PHI and PII shall not be recorded or stored on temporarily permitted non-public facing remote audio or video communication technology used during COVID-19 pandemic. Be sure that all possible security protections are used/enabled such as entry passwords, especially if using Zoom. See UCSF's guidance on using Zoom: <https://it.ucsf.edu/news/recommended-security-settings-zoom>

Other helpful links:

[VA DocuSign Request Form](#)

[VA ORD Policy and Guidance page for human research,](#)

[VHA Directive 1200.05](#)

[Research Guidance for the Use of Electronic Methods to Securely Obtain Informed Consent](#)

[FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic](#)

[ORD COVID-19 SharePoint site](#) which includes:

- FAQs regarding COVID-19 and VA research
- ORD Notices and Guidance

Appendix A—DocuSign Email Script

Hi [Participant Name],

This is [Person Obtaining Consent's Name] from the San Francisco Veteran Affairs Health Care System. Thank you for your interest in our study. Please find the link to the study consent documents below:

[LINK—generated by DocuSign]

These documents must be signed before we proceed with study procedures. Please do not sign these documents until we review the forms over the phone.

Our call is scheduled for [Date, time]. Let me know if you are unable to make it at this time and we will reschedule accordingly.

Best, [Person Obtaining Consent's Name]

Appendix B—DocuSign Phone Script

Study Title:

Principal Investigator:

Hello, my name is _____. I am a [staff member role] from the San Francisco VA Health Care System. I want to thank you again for your interest in participating in our research study entitled, [study title].

You should have received an email with our consent documents and I would like to go over them with you. Is now a good time?

The overall research study is designed to _____. You have been asked to take part in this study because _____. The Principal Investigator for this study is _____ from the San Francisco Veterans Affairs Health Care System (SFVAHCS). The purpose of this phone call is to review the consent forms, provide instructions to complete these forms with DocuSign, and to address any questions you may have about the study.

Participation in our study is completely voluntary; you don't have to complete the consent documents unless you want to continue with the study. Do you have any questions before I go on?

To begin, open the email I sent you containing the link to the consent forms. If you cannot find it, let me know and I will resend it [resend as needed]. Please follow along as I provide information about each section of the consent form.

At the beginning of the consent form, you will find an outline of what will occur during the study.

[Describe study procedures, time commitment, study payments, study team contact information, etc.]

Add confidentiality information as needed, for example: By signing this consent form, you will allow us to collect specific information from you and we may need to access your VA medical record to obtain information about _____. We will do everything we can to protect your privacy and keep your information confidential. The information that identifies you includes only your name, address, phone number, and your SSN. This information will be securely stored in a locked file that is separate from all other information we collect. In other words, your responses to our telephone interview questions will not be linked to your name or social security number or any other direct way to identify you.

Add additional consent information as needed, such as: Please take your time to read over the consent form and sign accordingly. On the last page of the consent form, initial to authorize the use of digital audio recordings of the interview for review by research team members (required for study participation), opt in or opt out of the optional [study procedures], opt in or opt out of video recording, sign to agree to take part in our research, and lastly opt in or opt out of being contacted about future research studies.

Let me know if any questions come up as you read through the forms. Please let me know when you have signed the forms so I can look over them and sign in the appropriate places. You will be given a copy of this consent form to keep.

[Check that form has been completed]

Thank you for completing the forms and taking the time to meet with me today. I will be in contact soon about next steps. If you any questions after this call, please contact me at [phone] number or via email at [email].

End call.