

Requesting Use of DocuSign for VA-approved Research

ORD has purchased a supply of envelopes to be used in research studies requiring documentation of informed consent and or HIPAA Authorization. All requests are considered but studies requiring the creation of <100 envelopes (100 subjects) will need to provide justification due to the support required by the OI&T Identity and Access management Team. Inpatient studies are generally not appropriate for DocuSign and study teams should consider the use of iMedConsent™ for inpatient studies or studies where all study subjects will present to a facility with CPRS access. [Click here for this document.](#)

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. Reimbursement to ORD may be required for studies funded by non-VA sponsors (process under consideration).

Request the number of estimated envelopes needed until **February 13, 2024**. If your study is active longer than that cutoff date (to be noted in the form below), you will be emailed an invitation to resubmit again next year.

If you have multiple sites, envelopes can be used for any/all of the sites, and do not have to be officially "transferred" between them. Determining if each LSI site needs to apply separately for DocuSign will be discussed in the initial meeting with the VA DocuSign team after a request has been submitted. Additionally, not all sites approved must use DocuSign. If a site doesn't want to use DocuSign, don't submit any requests to the VA DocuSign team. It would be up to the local site investigator to determine their need or want to use DocuSign. Even if a site has decided to use DocuSign, they can still use their original preferred method along with DocuSign. The VA DocuSign team can set up templates using your forms (typically ICF and HIPAA) and the study teams can use as needed based on the number of envelopes they have requested.

IRB approval is not required to be obtained prior to submitting an application, allowing approval to be obtained early for planning purposes. However, ORD requests to not put in a service request in for the IAM team until after IRB approval has been obtained for the study and the study is ready to actually use the envelopes.

If more envelopes are needed and/or if you want to add another site, double click on your project ID listed below. (Note: only the person that originally requested the envelopes can view and open a past request.) The original form will open. Click on the blue button at the very top of the page to replicate the record, make updates as needed, then submit.

If there is an amendment to the informed consent document, notify the VA DocuSign team [via email](#). Please include the (1.) service request number assigned to your study, (2.) the project study name, (3.) the template name that needs to be updated (this is provided when you move to PRODUCTION) and (4.) what items are being updated on the form.

Requests for the use of DocuSign and amendments to DocuSign are usually reviewed and decided within 2-3 business days if all appropriate information is provided.

Step 1: To begin, access the [DocuSign request form](#). Clicking on this link will allow you to create a new form or edit a previously submitted form. We need to know how many envelopes you are requesting from today until February 13, 2024.

NOTE: Use the form scroll bar as well as your browser scroll bar to ensure all the required fields have been completed. You will receive an email after your request has been received.

Step 2: You will see the status of your request below. You will also be notified by email when your request has been reviewed.

Step 3: If approved, [click here](#) for Post Approval Instructions, SOPs, and Training Materials.

NOTE: ORD's approval for use of DocuSign is limited to the VA's contract with DocuSign. Only the VA's contract with DocuSign managed by the Identity Access Management (IAM) Program Office has been approved with an Authority to Operate (ATO) to allow electronic signatures for documenting informed consent for VA research studies.

A VA Investigator may not use a non-VA DocuSign account for any VA research activity.

Additionally, DocuSign Cloud is not a place to store study documents indefinitely. Once a document is completed or signed, it must be downloaded to wherever all other study files are stored. If a document that has been signed is older than six months old, it will be deleted. It is the investigator's responsibility to make sure all study documents are stored someplace other than the DocuSign Cloud.

Need Help?

Direct questions regarding ORD approval letters to Brandon.Alexander3@va.gov. (Note: Approvals are sent only to the person that submitted the request.)

*If requesting updates,
Submit a Service Request using our SNOW intake: [eSignature request](#). Please refer to the [Step-by-step](#) guide for how to fill out the request.*

If you have questions about the DocuSign process after ORD approval, notify the VA DocuSign team [via email](#).

Feedback from ORD

[See all](#)