

**ORD Guidance: Instructions for Use of VA DocuSign for
VA Facilities Conducting the CDC Expanded Access Program:
“Protocol #6402 "Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola
Orthopoxvirus Infections in Adults and Children” (IND 116039)**

Date of Revision: July 23, 2024

Date of Original Issue: September 6, 2022

*Questions regarding this guidance should be sent to
vhacoordfindproquestions@va.gov.*

Purpose: The purpose of this Office of Research & Development (ORD) guidance document is to provide guidance on procedures designed to streamline the use of VA DocuSign with the Centers for Disease Control and Prevention (CDC) Institutional Review Board (IRB)-approved informed consent form and the VA Form 5345 - Request for and Authorization to Release Health Information for VA Facilities conducting the Expanded Access Program (EAP): “Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children” (IND 116039/CDC #6402). ORD in coordination with VA DocuSign team within the Office of Information and Technology (OIT), Development, Security, and Operations (DevSecOps) have developed streamlined procedures for using VA DocuSign for this expanded access program with modified submission and review procedures.

The July 23, 2024 revision addresses procedures for VA Facilities under oversight of the CDC IRB already approved to use DocuSign for this program to revise their existing IRB-approved informed consent documents to CDC IRB-approved Version 6.4, June 5, 2024.

Background: ORD submitted an amendment to the CDC IRB requesting approval for amending the approved CDC informed consent to allow participating VA facilities to use VA DocuSign to obtain electronic signatures of the patient or patient’s legally authorized representative (LAR) using the CDC IRB-approved informed consent. The CDC IRB approved the ORD amendment on 08/25/2022.

Procedures: The procedures listed below are to be used for VA Facilities when requesting envelopes to use VA DocuSign to send patients or their LAR the CDC IRB-approved informed consent form and VA Form 10-5345. This procedure bypasses usual procedures as the templates for both the English CDC IRB-approved informed consent form and VA Form 10-5345 have already been made into DocuSign templates.

***Note:** The DocuSign procedures described below are specific to the CDC Tecovirimat EAP and are not to be used for any other DocuSign request.*

A. Initial VA Facility Request/ORD and IAM Approval

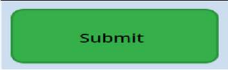
1. **Step 1: Preparation - Estimate the expected number of requested envelopes for your VA Facility** needed from the date of the DocuSign request to February 13, 2025, prior to submitting the DocuSign request to ORD.
 - a. Decide who will be entering the request for your VA Facility.
 Multiple requests should not be submitted from a single VA Facility.
2. **Step 2: Enter your VA Facility’s request using the DocuSign Request Form.**

This form is located on the [ORD DocuSign SharePoint](#) site. The individual entering the DocuSign application will access the ORD DocuSign [Request Form](#) to create a new form/item specific to your VA Facility for DocuSign envelopes for the CDC Tecovirimat EAP.

The following table is supplied to help with your VA Facility’s completion of the different fields on the VA DocuSign Request form.

Name of Field	Information to be Entered into Field or Selected From the Options for the Specific Field
Name of Study	Use of Tecovirimat for Treatment of Human Orthopoxvirus Infections
VAMC	Select the name of your VA Facility from the drop-down arrow on the right side of the field.
PI Name	Enter the lead treating clinician’s name under PI name (First Name, Last Name). Please note that multiple treating clinicians may be prescribers and must be listed on the FDA Form 1572 for this program. A separate DocuSign request is not required nor should be entered for each separate treating clinician.
PI Email	Enter the lead treating clinician’s VA email address.
PI Phone Number	Enter the lead treating clinician’s VA phone number.
Study Point of Contact Email (e.g., Study Coordinator)	<p>Enter the point of contact for your VA Facility for the use of DocuSign for this program using a va.gov email address in the Study Point of Contact (e.g., Study coordinator) field.</p> <p>The person who is listed as the PI for purpose of this application may be the same person who is the point of contact.</p>
Is this study funded by ORD?	Select the “no” option.
ORD Funded Award Number	Leave blank.
Is this study COVID-19 Related?	Select the “no” option.

Name of Field	Information to be Entered into Field or Selected From the Options for the Specific Field
Is this an FDA-regulated study? (Does it involve a drug, supplement, or medical device?)	Select the “yes” option.
Is this a multi-site study involving more than one VA?	Select the “yes” option.
List anticipated VA sites by City, State (if known). Example: Little Rock, AR; San Diego, CA	Leave blank.
Is there more than one approved Informed Consent Form (ICF)? Example: more than one language, more than one subject group (caregivers, providers, Veterans)	Select the “no” option.
If Yes, indicate number of versions of the ICF	Leave blank.
Is there a HIPAA Authorization form?	Select the “yes” option.
If Yes, is the ICF/HIPAA combined?	Select the “no” option.
Indicate the total number of subjects to be enrolled at your facility.	Enter the estimated number of patients who will participate in this program. If more envelopes are needed later, additional envelopes can be requested. Please do not overestimate.
If multisite, indicate the total number of subjects to be enrolled across all VA facilities	Enter the number “500”.
Number of Envelopes Being Requested	Enter the number of DocuSign envelopes requested for your VA Facility.
Is this a multi-year study?	Select the “yes” option.
Estimated completion of study	Enter the date “12/31/2023”.
Comments for Reviewer:	Enter the following information: “TPOXX Treatment Study”
Add supporting documents if needed.	Attach the English version of the Version 6.4 (June 5, 2024) Informed Consent Document and VA Form 10-5345 template for this EAP.



Submit the request by pressing the green submit button on the DocuSign Request Form.

3. **Step 3: ORD processing of the submitted request.**

- a. ORD will process the submitted DocuSign request with an initial acknowledgment of receipt. The individuals listed as the study point of contact and PI will receive an email confirming receipt of the submitted DocuSign application.

The email subject line will have the ORD DocuSign ID number (e.g., ID-111). Please note the ID number; it will be needed for a subsequent step in the streamlined process for obtaining DocuSign envelopes for the CDC Tecovirimat expanded access program.

- b. Upon approval of the application, ORD will send an approval letter by email to the individuals listed as the study point of contact and PI. The email will have the same ID number as referenced in the acknowledgement of receipt. The DocuSign Approval Letter will be an attachment with this email.

Example of Confirmed DocuSign request with ID number in title

From: Example: <Name of ORD@va.gov>
Sent: Wednesday, August 31, 2022 8:41 AM
To: john.doe@va.gov



Subject: ID= 111 - DocuSign Request for VA Study Name - Name of Principal Investigator

4. **Step 4: Forward the ORD DocuSign approval email to Identity and Access Management (IAM) to Request Use of the DocuSign envelopes**

Forward the ORD DocuSign approval email including the attached DocuSign approval letter for your VA Facility and the following required additional information directly to the IAM team at IAMDocuSignPOCs@va.gov.



The following information must be included in the email subject line and body along with attachment of the copy of the ORD DocuSign approval letter:

- a. Subject line: The subject line must be the following:

SR 2839 Monkey Pox study (VA Name and Location)

Example Subject Line:

SR 2839 Monkeypox study (Central Arkansas Veterans Healthcare System, Little Rock, Arkansas)

- b. VA Facility information in a table format (Example provided):
 - i. Site PIs (Treating Clinicians) Name and emails
 - ii. ORD DocuSign Line ID #
 - iii. The number of approved envelopes
 - iv. Usernames: Please list the first and last names of the treating clinicians and treatment team members who will send the DocuSign envelopes (such as the treating clinician’s nurse or coordinator) containing the informed consent form and the VA Form 10-5345 to obtain the signatures with the patient or LAR and who will be obtaining consent.

Example Table
 (This Table is available as a Word Document on the [ORPP&E Webpage for this Program](#) under Additional Supporting Document and Tools)

Name of VA Facility: Central Arkansas Veterans Healthcare System	
ORD ID Number	123
Number of Envelopes Approved by ORD	15
Treating Clinicians and Usernames	Treating Clinicians and User Emails
S. Doe	s.doe@va.gov
A. Study Coordinator	a.studycoordinator@va.gov
A. Nurse	a.nurse@va.gov
J. Doe	j.doe@va.gov

5. **Step 5: IAM Notification to VA Facility.**

IAM will notify the individuals listed as the study point of contact and PI of IAM approval via email. The DocuSign templates for the CDC IRB-approved informed consent form (Version 6.4, dated June 5, 2024) and the VA Form 10-5345 have already been set up. Training on how to use DocuSign for this specific project will be provided by IAM. Questions regarding the training should be submitted to IAMDocuSignPOCs@va.gov.

B. Revising Your VA Facility’s IRB-Approved Informed Consent Form when the IRB Approves a Revised Informed Consent Form

ORD is notified by the CDC IRB when the CDC IRB approves a revision in the CDC IRB-approved informed consent form; ORD works with IAM to set up the revised informed consent form template, followed by notification of the participating VA Facility sites. When the CDC IRB approves a revision in the informed consent document for the CDC TPOXX IND EAP program, please do the following:

OFFICE OF RESEARCH & DEVELOPMENT

VA DocuSign Instructions for CDC Tecovirimat Expanded Access Protocol – IND 116039/CDC #6402

1. Send the following information to the DocuSign SaaS email (IAMDocuSignPOCs@va.gov):

Subject line: SR 2839 Monkey Pox study (VA Name and Location)
Submit a revised table (Word version located on ORD's [ORPP&E Webpage for this Program](#)):

Example:

Name of VA Facility: Central Arkansas Veterans Healthcare System	
ORD ID Number	123
Number of Envelopes Approved by ORD	15
Treating Clinicians and Usernames	Treating Clinicians and User Emails
S. Doe	s.doe@va.gov
A. Study Coordinator	a.studycoordinator@va.gov
A. Nurse	a.nurse@va.gov
J. Doe	j.doe@va.gov

2. The DocuSign team has already updated the master CDC TPOXX IND EAP informed consent document for Version 6.4 (June 5, 2024).
3. IAM will notify the individuals listed as the study point of contact and PI of IAM approval via email.