



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

**ORD Frequently Asked Question:**

**What is Required If a VA Facility Wishes to Voluntarily Close the CDC's Tecovirimat Expanded Access Program for Mpox at the VA Facility Under the CDC's IRB Approval?**

**Revised: July 12, 2023**

**Original Issue Date: May 22, 2023**

**Question:** What is Required If a VA Facility Wishes to Voluntarily Close the Centers for Disease Control and Prevention's (CDC) Tecovirimat Expanded Access Program (EAP) for Mpox at the VA Facility Under the CDC's IRB Approval?

**Answer:** If a VA Facility wishes to voluntarily close its participation in the CDC Tecovirimat with the CDC IRB, please email the CDC Regulatory Affairs Office at [regaffairs@cdc.gov](mailto:regaffairs@cdc.gov) and include the answers to these questions:

- How many patients have been treated with Tecovirimat at the VA Facility?
- Does the VA Facility pharmacy have any Tecovirimat at the VA Facility?

Please copy the following on the VA Facility's email to the CDC Regulatory Affairs Office:

- [lrbelianceandsirbexceptions@va.gov](mailto:lrbelianceandsirbexceptions@va.gov)
- [Priscilla.Craig@va.gov](mailto:Priscilla.Craig@va.gov)
- [Elizabeth.Clark3@va.gov](mailto:Elizabeth.Clark3@va.gov)

The clinician listed as the lead provider and the individual(s) submitted by ORD as the CDC IRB liaisons will receive an email which includes a letter as an attachment from CDC Regulatory Affairs acknowledging receipt of the VA Facility's request to close the program and closing the program at the VA Facility by stating that the VA Facility is unregistered with the CDC-sponsored EA-IND for tecovirimat (IND 116,039/CDC IRB #6402). Please upload the letter into the VAIRRS study file for the program. The program can then be closed by the VA Facility's Research and Development Committee. CDC or the Food and Drug Administration (FDA) can request access to your VA Facility's records for your site's participation in the program as part of the agreement when your VA Facility registered to be part of this CDC program.

For questions on the content of this guidance, email the VHA Office of Research and Development at [VHACOORDRegulatory@va.gov](mailto:VHACOORDRegulatory@va.gov).