



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

**ORD Frequently Asked Question:**

**How Do VA Facilities Change the Clinical Provider/Lead Investigator and Notify the CDC for CDC's Tecovirimat Expanded Access Program (EAP) for Mpox?**

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**Question:** How Do VA Facilities Change the Clinical Provider/Lead Investigator and Notify the CDC for CDC's Tecovirimat Expanded Access Program (EAP) for Mpox?

**Answer:** Anytime the lead clinician (i.e., site investigator) changes (Box 1 of Form FDA 1572), [regaffairs@cdc.gov](mailto:regaffairs@cdc.gov) should be alerted of who the new site investigator is and who they are replacing.

- The new site investigator should register via the [TPOXX IND Online Registry](#), which includes completing and signing Form FDA 1572.

Please remember the following for all lead clinicians participating in the CDC's Tecovirimat EAP for MPOX:

- Lead clinicians (i.e., site investigators) need to register under the CDC TPOXX IND EAP by completing the [TPOXX IND Online Registry](#) prior to or no later than 7 calendar days of first prescribing or administering Tecovirimat, including:
  - Completing and signing Form FDA 1572, which serves as an agreement to abide by the IND regulations for use of Tecovirimat under the CDC-held EA-IND protocol.
  - A licensed clinician who is trained and qualified to manage and care for patients with orthopoxvirus or Mpox virus infection can serve as the lead site investigator on the Form FDA 1572 (Box 1).
  - Other healthcare providers involved in patient care can be listed as sub-investigators in Box 6 of Form FDA 1572.
  - One signed Form FDA 1572, with all other healthcare providers providing care listed in Box 6 as sub-investigators, suffices for all Tecovirimat treatments administered under the EA-IND at the same facility.

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