DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date June 20, 2024

From Jerrell Little
IRB Administrator
Human Research Protection Office

Subject CDC IRB Approval of Continuation #11 of Expanded Access Investigational New Drug (EA-IND) Protocol #6402 "Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children" (IND 116039) (Convened)

To Agam Rao, MD
CDC National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

The CDC's IRB has reviewed and approved your request to continue protocol #6402 for the maximum allowable period of one year in accordance with 21 CFR parts 50, 56, and 312. CDC IRB approval will expire on 7/23/2025. The continuation action was reviewed at a meeting of the convened IRB on 6/20/2024.

As a reminder, the CDC IRB must conduct its continuing review at intervals appropriate to the degree of risk, but not less than once per year; there is no grace period beyond the expiration of IRB approval. To avoid a lapse in approval and the possible suspension of access to treatment under the IND, please submit your continuation request at least six weeks before the protocol's expiration date of 7/23/2025.

Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes to the protocol, informed consent, or new materials must be submitted to the CDC IRB as an amendment to the protocol for IRB approval before they are implemented.

Central IRB information:
The CDC IRB may serve as the central IRB to meet the requirements for IRB review and approval set forth in 21 CFR parts 50, 56, and 312. Any site that accesses tecovirimat for treatment under this EA-IND protocol (CDC IRB Protocol #6402) may elect to rely on the CDC IRB to help reduce duplication of effort, delays, and increased expenses of site-specific IRB review consistent with 21 CFR 56.114 and any site/institutional policy, as applicable. For hospitals/sites electing to participate in a centralized IRB review process, CDC's Human Research Protection Office will document this with a written agreement signed by both parties. It is important to note that the CDC IRB determined that the use of tecovirimat under EA-IND does not constitute research involving human subjects as defined in 45 CFR 46.102. Since the requirements of 45 CFR 46 do not apply, sites are not required to have Federalwide Assurance.

If you have any questions, please contact your National Center Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-4721 or by e-mail huma@cdc.gov.