U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

January 3, 2025 (revised)

Shama Cash-Goldwasser, MD, MPH
Poxvirus and Rabies Branch/ Division of High-Consequence Pathogens and Pathology/National Center for Emerging and Zoonotic Infectious Diseases

RE: CDC IRB Approval of Changes to CDC Protocol 6402, "Expanded Access IND Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children," Version 6.5 dated December 5, 2024 (IND 116039) Amendment #11

Dear Dr. Cash-Goldwasser:

On December 20, 2024, the CDC Institutional Review Board (IRB) reviewed and approved changes to CDC Protocol 6402, "Expanded Access IND Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Orthopoxvirus Infections in Adults and Children" in accordance with 21 C.F.R. §56.110(b) This approval is effective as of December 20, 2024.

The CDC IRB has approved **all proposed changes as follows**:

- The revision is limited to removing the mention of the NIH-sponsored clinical trial STOMP in the protocol and the informed consent since STOMP trial enrollment is now closed. The STOMP Data Safety Monitoring Board recommended stopping enrollment in the STOMP trial based on an interim efficacy analysis that showed no difference in time to lesion healing, or pain scores, among the non-pregnant/non-lactating adult participants with mild to moderate mpox who received tecovirimat compared to those who received placebo in the STOMP trial. The interim findings showed no safety concerns. Subject matter experts at CDC, NIH, FDA, and ASRP concurred with continued access to stockpiled tecovirimat under this EA-IND protocol for treatment options in mpox patients with severe immunocompromise or severe disease, a population that did not participate in the randomized arms of the STOMP trial.

The CDC IRB finds that CDC Protocol 6402 involves greater than minimal risk to patients, consistent with its previous determination.

You are required to adhere to the protocol as approved on December 20, 2024, and implement the changes immediately in accordance with the approved amendment.

CDC investigators must report any unanticipated problems, or instances of serious or continuing noncompliance as described at 21 CFR 56.108 to the CDC IRB in accordance with CDC standard operating procedures. Any proposed changes to this Expanded Access IND protocol, informed consent, other approved materials, or new materials, must be submitted to the CDC

IRB for review and approval prior to implementation except where necessary to eliminate apparent immediate hazards to patients.

We appreciate your commitment to responsible conduct of this expanded access IND protocol and your cooperation with the IRB review process.

If you have any questions or concerns, please do not hesitate to contact your Center Human Subjects Contact or Jerrell Little, IRB Administrator, at 404-639-3536, or via email at jiv4@cdc.gov.

Sincerely,

Robert Chirila, Lead
Human Research Protections Office