DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date July 21, 2022

From LaShonda Roberson, DHSc, MPH
CDR, USPHS
Senior IRB Administrator, Human Research Protection Office

Subject CDC Institutional Review Board (IRB) Approval of Continuation #9 of the Expanded Access Investigational New Drug (IND) "Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children" (IND 116039/CDC #6402)

To Brett Petersen, MD, MPH
CDC National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)

The CDC IRB has reviewed and approved the proposed changes to the Expanded Access IND titled "Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children" during the period for which IRB approval has been given in accordance with 21 CFR 56.108(a)(4). The approved changes include:

- streamlining the protocol
- reducing follow-up visits and specifying that all can be telemedicine visits
- reducing the number and length of case report forms
- pharmacokinetic (PK) sampling is optional and no longer required
- not requiring serum samples but serology testing is available at CDC if requested by treating clinicians
- no longer requiring clinical laboratory parameters
- making lesion photos optional
- adding an explanation on infusion rate and syringe pump for administration
- clarifying instructions for pediatric oral and IV dosing
- adding an indication for use of tecovirimat as an alternative or complementary option to post-exposure prophylaxis vaccination

Reminder: CDC IRB approval of this Expanded Access IND will still expire on July 23, 2023.

CDC investigators must report any unanticipated problems involving risks to human subjects or others, or instances of serious or continuing noncompliance with these regulations or the requirements or determinations that occur at participating sites to the CDC IRB in accordance with CDC standard operating procedures. Any proposed changes to this Expanded Access IND, 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 the human subjects.

If you have any questions, please contact the NCEZID Human Subjects Contact or the CDC Human Research Protection Office at (404) 639-7570 or by e-mail at huma@cdc.gov.

cc:
NCEZID Human Studies
Nicole Cohen, MD (CDC IRB Chair)