DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date July 20, 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 for Treatment of Human Orthopoxvirus Infections" (IND 116039/CDC #6402)

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

The CDC IRB convened on July 20, 2022, to conduct its continuing review of the Expanded Access IND titled "Use of Tecovirimat for Treatment of Human Orthopoxvirus Infections" in accordance with 21 CFR parts 50, 56, and 312. The CDC IRB determined the existing Expanded Access IND is approved to continue for the maximum allowable period of one year. This approval expires on **July 23, 2023.**

The CDC IRB may serve to meet the requirements for IRB review set forth in 21 CFR parts 50, 56 and 312. Any site that accesses tecovirimat for treatment of non-variola orthopoxvirus (NV-OPXV) infection or post-exposure prophylaxis after NV-OPXV exposure under this Expanded Access IND may elect to rely on the CDC IRB to reduce duplication of effort, delays, and increased expense of site-specific IRB review. For 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 CDC has determined the use of tecovirimat under the Expanded Access IND does not constitute research involving human subjects as defined in 45 CFR 46.102. Since the requirements at 45 CFR part 46 do not apply, sites are not required to have a Federalwide Assurance.

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 approval. CDC investigators are responsible for complying with all requirements to maintain 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 CDC IRB Approval expiration date of 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)