DEPARTMENT OF HEALTH & HUMAN SERVICES

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

Memorandum

Date May 5, 2023

From Felecia Peterson
IRB Analyst, Human Research Protection Office

Subject CDC Institutional Review Board (IRB) Approval of Amendment #7 of the Expanded Access Investigational New Drug (IND) protocol "Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children", Version 6.3 (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 your request to amend protocol #6402. The amendment was reviewed in accordance with the expedited review process outlined in 21 CFR 56.110 (b)(i)(2), minor changes in previously approved research during the period (of 1 year or less) for which approval is authorized. The approved changes include:

- Added/updated relevant information from the 2022 mpox response.
- Included relevant updates from the CDC's published interim clinical guidance for treatment of mpox, treatment considerations based on severity of mpox disease, revised text regarding clinical trial (STOMP) for tecovirimat treatment.
- Added clarifying text regarding duration therapy and available information regarding tecovirimat resistance.
- Updated the instruction for enhanced clarity regarding completion of Patient Intake, Clinical Outcomes, MedWatch forms for submitting to CDC with text clarification on evolving outbreak or public health emergency situations that may change reporting requirements.
- Added clarifying text on no patient-specific results being reported back to providers and patients on tecovirimat resistance and PK testing.
- Revised summary on the clinical use of tecovirimat for treatment of NV-OPXV-infected patients (2007-2021) and added a summary of tecovirimat clinical uses during the 2022 mpox response.
- Informed Consent Form (Attachment #1) updated to add that patient-specific tecovirimat resistance result cannot be reported due to CLIA regulations and the purpose of optional specimen and blood sample testing; revised the text under What about privacy? For enhanced clarity.

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

CDC investigators must report any unanticipated problems, or instances of serious or continuing noncompliance as described 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 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