# IRB Authorization Agreement

This Institutional Review Board (IRB) authorization agreement is intended to document a formal agreement between the Centers for Disease Control and Prevention (CDC) and an institution that relies on the CDC IRB for review of the activities specified below. This agreement is permitted by the Food and Drug Administration (FDA) regulations governing the protection of human subjects, IRBs, and the conduct of clinical investigations at 21 CFR parts 50, 56, and 312.

## 1 Institution Providing IRB Review (CDC IRB)

Centers for Disease Control and Prevention (CDC)
IRB Registration #: 00002724
Federalwide Assurance (FWA) #: FWA00001413

Registration expiration date: 12/17/2024
FWA expiration date: 12/02/2026

## 2 Institution Relying on CDC IRB (Relying Institution)

Name of Relying Institution:

IRB Registration #: _____ IRB Registration Expiration Date: _____

## 3 Authorization

The officials signing below agree that
may rely on the CDC IRB for review under 21 CFR parts 50, 56 and 312 and for continuing oversight, where applicable, of the involvement of human subjects in the Expanded Access Investigational New Drug (IND) described below:

| | **CDC IRB** | **Relying Institution:** |
|---|---|---|
| Title of IND: | Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children | |
| Reference ID: | IND 116039/CDC #6402 | |

Principal/Site Investigator: (name, phone, e-mail)
Brett Petersen, MD, MPH
404.639.5464
ige3@cdc.gov or regaffairs@cdc.gov

IRB Office Contact: (name, phone, e-mail)
CDC Human Research Protection Office
Felecia Peterson
404.639.4961 or huma@cdc.gov

Sponsor: CDC

Award number, if any:

The review and oversight performed by the CDC IRB will meet the human subjects protection and IRB requirements of the FDA regulations cited above, as applicable. The Relying Institution remains responsible for ensuring compliance with the CDC IRB's determinations and with the terms of its own IRB registration as applicable. This agreement must be kept on file at both institutions consistent with recordkeeping requirements set out herein and must be provided to FDA upon request.

**Both parties agree to the following:**

This agreement becomes fully executed upon signatures of the relevant institution's signatory official or designee and remains in effect for as long as the review of the Expanded Access IND by the CDC IRB is required or until terminated under the following circumstances:

- Both parties mutually agree to terminate.
- Either party terminates its participation under this agreement; any such unilateral termination must be communicated by the terminating party to the other party thirty (30) business days prior to the effective date of termination.
- The CDC IRB or Relying Institution's IRB registration is suspended, restricted, terminated, or expires; any such suspension, restriction, termination or expiration must be communicated between parties promptly and no later than 2 business days from occurrence.

## 4 Signatures

**Reviewing Institution: CDC IRB**

**Relying Institution:**

**Date Signed**

**Official Title and Contact Information**

CDC Institutional Official for Human Subjects Protections

1600 Clifton Rd NE MS D-73 Atlanta GA 30333
404-639-7270 huma@cdc.gov (e-mail)

**CDC IRB Responsibilities** (this list is not exhaustive; please see applicable human subjects regulations):

1. *IRB Registration and Membership*. Maintain the CDC IRB registration and IRB membership in compliance with FDA requirements and other applicable federal regulations or policies.

2. *Policies and Procedures*. Make available to the Relying Institution, when applicable and upon request, the relevant policies and procedures of CDC and the CDC IRB.

3. *Review and Oversight*. In accordance with 21 CFR parts 50, 56, and 312 and any other applicable requirements, the CDC IRB will provide:
   a. initial and continuing review of materials related to the Expanded Access IND;
   b. review of amendments to materials related to the Expanded Access IND;
   c. review of local context considerations as provided by the Relying Institution;
   d. review of potential unanticipated problems involving risks to subjects or others as reported to the CDC IRB;
   e. review of serious and/or continuing noncompliance as reported to the CDC IRB; and
   f. oversight of the conduct of the Expanded Access IND to include the informed consent process.

4. *Informed Consent*. The CDC IRB will provide to each Relying Institution an informed consent form(s) for use by the Relying Institution where the CDC IRB has determined that such an informed consent form(s) is required. The CDC IRB will permit a Relying Institution to fill in only limited sections of the informed consent form(s). Generally, these sections pertain to availability of treatment and compensation for Expanded Access IND-related injury, payment or reimbursement of Expanded Access IND-related costs incurred by human subjects, and local contact information. All such modifications must be approved by the CDC IRB, which will then provide a final approved informed consent form(s) to the Relying Institution for its use.

5. *Notifications*. The CDC IRB will promptly notify the Relying Institution of:
   a. findings of serious or continuing noncompliance with applicable human subjects protection regulations or with the requirements or determinations of the CDC IRB pertaining to the Relying Institution as well as any actions the Relying Institution must take to address such noncompliance, including any actions the CDC IRB deems necessary for remediation of the noncompliance at the Relying Institution;
   b. any remediation actions pertaining to findings related to the Relying Institution if the CDC IRB finds that such findings or actions relate to or may affect the conduct of the Expanded Access IND or the safety, rights, or welfare of human subjects participating in the Expanded Access IND at the Relying Institution(s); and
   c. any restriction or suspension of the CDC IRB's authorization to review or any suspension or termination of CDC IRB approval.

6. *Reporting*. The CDC IRB will promptly report to the FDA, appropriate institutional officials, and the CDC Principal Investigator any unanticipated problems involving risks to human subjects or others, any serious and/or continuing noncompliance, and any suspension or termination of CDC IRB approval. The CDC IRB will notify, as appropriate, the Relying Institution in advance of such determinations prior to reporting.

7. *Recordkeeping*. The CDC IRB will maintain records of its membership, its review, determinations, meeting minutes, and other records as required by applicable federal regulations and the policies of the CDC IRB, and will make such records accessible to designated officials at the Relying Institution(s), upon reasonable request and may be required by law.

**Relying Institution's Responsibilities** (this list is not exhaustive; please see applicable human subjects regulations):

1. *Comply with CDC IRB Decisions and Requirements*. The Relying Institution will comply with the decisions and requirements of the CDC IRB. The Relying Institution may not change, or deviate from the approved Expanded Access IND, informed consent, or other approved materials, except where necessary to eliminate apparent immediate hazards to subjects, without first receiving prior approval from the CDC IRB.

2. *Review and Oversight*. The Relying Institution will also oversee the safe and appropriate conduct of the Expanded Access IND at its institution and will ensure compliance with applicable federal, state, local or institutional requirements related to the protection of human subjects. Requirements may include investigating and managing any incidence, experience, or outcome that may rise to the level of an unanticipated problem involving risk to human subjects or others or serious and/or continuing noncompliance. Should any such requirements conflict with the decisions or requirements of the CDC IRB, the Relying Institution must raise those conflicts for consideration by the CDC IRB. The Relying Institution will also provide all information about the conduct of the Expanded Access IND at the Relying Institution that the CDC IRB requires to meet its review and reporting requirements. The Relying Institution will establish a mechanism that allows human subjects and others to report concerns about the conduct of the Expanded Access IND.

3. *Local Context Considerations*. Communicate to the CDC IRB the requirements of all applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews, relevant to the Expanded Access IND that would affect the conduct or approval of the investigation at the Relying Institution. This information should be communicated to the CDC IRB through the CDC Principal Investigator and may be considered by the CDC IRB if the Relying Institution requests a change or deviation from the approved Expanded Access IND.

4. *Informed Consent*. Relying Institution will ensure that the CDC IRB-approved language is used in the informed consent form(s) and will comply with the following:

   a. not make any changes to language in the informed consent form(s), except as may otherwise be approved by the CDC IRB;
   b. submit through the CDC Principal Investigator for CDC IRB approval the informed consent form(s) with any necessary sections filled in for use by the Relying Institution; and
   c. use CDC IRB-approved translations of the informed consent form(s) when available, or provide the CDC IRB with a copy of a version translated for use by the Relying Institution for approval prior to use.

5. *Notification*. The Relying Institution will promptly notify the CDC IRB through the CDC Principal Investigator of any of the following:
   a. unanticipated problems that may involve risks to human subjects or others;
   b. new safety-related information made known to the Relying Institution;
   c. injuries related to the Expanded Access IND reported to the Relying Institution; and
   d. potential serious or continuing noncompliance (e.g., protocol deviations) that occur at the Relying Institution.

6. *Reporting*. The Relying Institution will assist the CDC IRB in preparing for FDA or other relevant agencies, any reports or notifications about any unanticipated problems involving risk to humans subjects, any serious and/or continuing noncompliance, and any suspension or termination of CDC IRB approval.

7. *Recordkeeping*. The Relying Institution will maintain a regulatory and/or administrative file in accordance with FDA requirements and other applicable federal, state, or local laws, and the Relying Institution's recordkeeping policies.