**Title of Project:** Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children

<table>
<thead>
<tr>
<th>Type of Submission:</th>
<th>Amendment 06</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of Review:</td>
<td>☒ Final Review □ Preliminary Review</td>
</tr>
</tbody>
</table>

**VAIRRS ID:** N/A

**Local Board Reference Number:** IND 116039/CDC #6402
Table of Contents

1. Introduction .................................................................................................................................................. 2
2. Web Portal and Application Security ........................................................................................................... 2
3. ROTC-D Reviewer ......................................................................................................................................... 2
4. Research Project Approval ........................................................................................................................... 2
1. **Introduction.**

The amendment added information on the implementation of the Tecovirimat (TPOXX) IND Registry for Providers/Facilities web portal.

2. **Web Portal and Application Security.**

ROTC-D reviewed the web portal and it’s approved for use in the EAP.

<table>
<thead>
<tr>
<th>Application</th>
<th>Security</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tecovirimat (TPOXX) IND Registry for Providers/Facilities (cdc.gov)</td>
<td>Encrypts data in transmission with FIP 140-2 (or Successor) validated encryption.</td>
</tr>
</tbody>
</table>

3. **ROTC-D Reviewer.**

- Kenneth C. Blagg

4. **Research Project Approval.**

☐ **Preliminary ISSO Review:** I have reviewed the protocol and IRB submission. Additional information is requested from the PI/Project team to address the questions in paragraph 15.

☒ **Final ISSO Review:** The research Project meets VA security requirements in accordance with VA Directive 6500, VA Cyber Security Program and meets the requirements of VHA Directive 1200.01, Research and Development Committee.

---

**TERRY PETERS**

Digitally signed by TERRY PETERS  
Date: 2022.11.09 12:26:33 -05'00'

---

**ROTC-D Approving Official**