Concurrence with the Office of Research and Development (ORD) Agreement with Centers for Disease Control and Prevention (CDC) Institutional Review Board (IRB) For CDC IRB Oversight For

Participation in the Expanded Access Program: "Expanded Access IND Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Orthopoxvirus Infections"

BACKGROUND

1. The FDA is working in conjunction with the CDC to implement an expanded access protocol to treat patients with Orthopoxvirus (Monkeypox) infections. To meet VA requirements and enable VHA facility participation the VHA Office of Research and Development (ORD) has executed a national level agreement between ORD and the CDC IRB for IRB review of the Expanded Access Program (EAP) of IND Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Orthopoxvirus Infections" for treatment of VA Patients with Monkeypox.

2. The national IRB Reliance Agreement between CDC IRB and ORD clearly defines the responsibilities of the IRB and each VA medical facility.

3. The VHA Medical Center Director's signature on this document serves as written Concurrence with the national IRB reliance agreement which allows your VA Facility to rely upon the CDC IRB for the above-named expanded access program.

SIGNATURES:

By signing this MOU, the VHA Facility named in this MOU agrees to:

a. Rely upon the CDC IRB for the Expanded Access Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Orthopoxvirus Infections, to follow the requirements specified in the ORD agreement with the CDC IRB.

b. Disseminate CDC IRB SOPs relevant to this expanded access program. Maintain written IRB Reliance SOPs for communication with, and reporting to, the IRB.

SIGNATURES ON NEXT PAGE

Signature Blocks:

Name and Title of Signatory Official for the VHA Medical Facility:

Name of Signatory Official:

Date:

Electronic Signature:

Attachment: IRB Authorization Agreement between the CDC IRB and the VHA Office of Research and Development