1. The Expanded Access to Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children (IND 116039/CDC #6402) overseen by Dr. Brett Petersen at the Centers for Disease Control and Prevention (CDC) is an expanded access program using a treatment Investigational Drug Application (IND) for Tecovirimat (TPOXX®). It is an expanded access treatment protocol regulated by the Food and Drug Administration (FDA) under its regulations for 21 CFR 50, 21 CFR 56, and 21 CFR 312 because it involves an investigational drug. Because this an FDA-regulated use of an investigational drug or biologic for a non-emergency expanded access use, it requires IRB review and approval under FDA regulations. However, the activity is not research involving human subjects under the Common Rule (38 CFR Part 16).

2. HIPAA defines research similarly to the Common Rule. The HIPAA Privacy Rule defines research as any systematic investigation (including research development, testing, and evaluation) that has as its primary purpose the development of, or contribution to, generalizable knowledge (45 CFR 164.501). The CDC Tecovirimat (TPOXX®) expanded access program does not meet the definition of research under the Common Rule nor the definition of research under HIPAA Privacy Rule, as it is not a systematic investigation designed to develop or contribute to generalizable knowledge. The primary purpose of this expanded access program is access of Tecovirimat (TPOXX®) for treatment of patients with Human Non-Variola Orthopoxvirus Infections, followed by safety monitoring related to the regulatory requirements of the IND under FDA regulation 21 CFR 312.

   a. Waiver of HIPAA Authorization: Expanded access use of Tecovirimat (TPOXX®) for Monkeypox does not meet the definition of research under the HIPAA Privacy Rule. There is no need for an IRB-approved waiver of HIPAA authorization for research for the use of Tecovirimat (TPOXX®) in this use.

   b. Written HIPAA Authorization Language: While expanded access use of Tecovirimat for Monkeypox does not meet the definition of research under the HIPAA Privacy Rule, it is required that the VA Form 10-5345 “Request for and Authorization to
Release Health Information” so that there are no questions of authority for protected health information (PHI) disclosures outside of VHA.

3. Patients participating in the treatment must sign and date the CDC Expanded Access Program Patient Consent (IRB approved) with the VA ICF addendum (once approved by the CDC IRB). When the patient is unable to sign and date, the legally authorized representative (LAR) signs and dates consent to the treatment. Please note that there is also a third method of documenting informed consent when the patient is unable to respond, and no legally authorized representative is present through documentation of both the treating physician and second physician not involved in the treatment protocol. The legal authority under the applicable federal privacy laws and regulations are discussed below.

4. Treatment of the Patient: VHA personnel may disclose patient PII/PHI to the CDC in order for VA to treat the Human Non-Variola Orthopoxvirus patient with Tecovirimat (TPOXX®) under:

   a. The Privacy Act, 5 USC 552a(b)(3) – Routine Use #43 under “Patient Medical Records-VA”, 24VA10P2
   b. HIPAA Privacy Rule:
      1. 45 CFR 164.506(c)(1) - A covered entity may use or disclose protected health information for its own treatment, payment, or health care operations.
      2. 45 CFR 164.514(d) A covered entity may rely, if such reliance is reasonable under the circumstances, on a requested disclosure as the minimum necessary for the stated purpose when: (A) Making disclosures to public officials that are permitted under §164.512, if the public official represents that the information requested is the minimum necessary for the stated purpose(s)
   c. 38 USC 7332(b)(2)(H) – To a non-Department entity for purposes of providing health care to patients or performing other health care-related activities or functions.

5. Adverse Event Reporting: VHA personnel may disclose patient PII/PHI to the CDC to report an adverse event associated with the treatment of the Human Non-Variola Orthopoxvirus patient with Tecovirimat (TPOXX®) under:

   a. The Privacy Act, 5 USC 552a(b)(3) – Routine Use #42 under “Patient Medical Records-VA”, 24VA10P2
   b. HIPAA Privacy Rule - 45 CFR 164.512(b) - A covered entity may use or disclose protected health information for the public health activities and purposes described in this paragraph to (iii) A person subject to the jurisdiction of the Food and Drug Administration (FDA) with respect to an FDA-regulated product or activity for which that person has responsibility, for the purpose of activities related to the quality, safety or effectiveness of such FDA-regulated product or activity. Such purposes include: (A) To collect or report adverse events.
   c. 38 USC 7332(b)(2)(H) – To a non-Department entity for purposes of providing health care to patients or performing other health care-related activities or functions. VHA considers “other health care-related activities or functions” to include health care
operations as defined by the HIPAA Privacy Rule. See VHA Directive 1605.01 Para. 27(a)(1). Routine Reporting – Though the policy is no longer accurate regarding 7332-protected information.

6. Contact Michelle Christiano, ORD Privacy Officer, for any concerns related to the privacy review at michelle.christiano@va.gov.