

Date: November 7, 2022

From: ORD, Privacy Officer

Subj: Privacy Review "Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children (IND 116039/CDC #6402)" – Amendment (3) Revised Protocol October 24, 2022

To: Director of Regulatory Affairs, ORPP&E (14RD)

1. The CDC IRB approved the above referenced amendment on October 26, 2022 that does not include any new disclosures. The additional information on the implementation of online registry required for new providers and transition to electronic Patient Intake and Clinical Outcome forms do not increase the risks to privacy.

2. The legal authority under the applicable federal privacy laws and regulations continues to be met:

a. The Privacy Act, 5 USC 552a(b)(3) – Routine Uses #43 and #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. 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.

d. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, requirements are met.

3. Contact Michelle Christiano, ORD Privacy Officer, for any concerns related to the privacy review at [michelle.christiano@va.gov](mailto:michelle.christiano@va.gov).