Centralized Institutional Review for the CDC Expanded Access Investigational New Device (EA-IND) for "Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children" (IND 116039/CDC #6402).

Request for OMB approval of an Emergency Information Collection

July 28, 2021

Supporting Statement B

Contact:
Human Research Protection Office
CDC Office of Scientific Integrity
CDC Office of Science
CDC
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1. Respondent Universe and Sampling Methods

The respondent universe for this requirement is all external entities that request to rely on CDC IRB for Monkeypox rewearch.

2. Procedures for the Collection of Information

The information will be sent to CDC by email to a CDC functional mailbox (huma@cdc.gov). Once the information is received by email, the information collection form will be stored in a restricted SharePoint file. Access to the data collected will be further restricted to users with permission to include the CDC Institutional Official for Human Research Subjects, the Director and Deputy Director of the Office of Scientific Integrity and the Human Research Protection Office, the reliance administrators in the Human Research Protection Office, and an informatics specialist. These data must be made available to the Food and Drug Administration upon request.

3. Methods to maximize Response Rates and Deal with No Response

The Completion of the form is required for external entities that request use of CDC IRB.

4. Tests of Procedures or Methods to be undertaken

CDC will do random compliance checks to help ensure documentation meet the requirement.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

No statistics or analysis of data will be performed