DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-23-22HY]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled, "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)," to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on August 22, 2022, to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW,

Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

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) – New – Office of Science (OS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Monkeypox is a zoonosis, caused by the Orthopoxvirus (OPXV) Monkeypox virus (MPXV), and is endemic to forested areas of West and Central Africa. In humans, infection with MPXV can lead to a smallpox-like illness with fatal outcomes in up to 11% of patients without prior smallpox vaccination.

Since May 2022, clusters of monkeypox cases, have been reported in 19 countries that do not normally have monkeypox, and the number of confirmed cases in the U.S. is rapidly increasing.

Tecovirimat (TPOXX) is FDA-approved for the treatment of human smallpox disease caused by Variola virus in adults and children. However, its use for other orthopoxvirus infections, including monkeypox, is not approved by the FDA. CDC currently holds a non-research expanded access Investigational New Drug

(EA-IND) protocol that allows for the use of tecovirimat for primary or early empiric treatment of non-variola orthopoxvirus infections, including monkeypox, in adults and children of all ages.

FDA regulations require that an Institutional Review Board (IRB) review, approve and maintain oversight of the activities under the EA-IND as set forth in 21 CFR parts 50, 56, and 312. The CDC IRB is positioned to serve as the central IRB for review and approval of the EA-IND consistent 21 CFR 56.114.
This arrangement allows facilities to use or rely on the CDC IRB for centralized review and approval for this protocol in place of review by the site-specific IRB to help reduce duplication of effort, delays, and increased expenses. Any facility that receives tecovirimat for treatment of orthopoxvirus infection under the EA-IND may elect to rely on the CDC IRB to meet FDA's regulatory requirements.

The IRB review is required by FDA under the CDC's approved EA-IND. Therefore, CDC must maintain records of which facilities have elected to rely on the CDC IRB for centralized review and which facilities elect to obtain IRB review on their own. CDC will use collected data to track and document the institutions relying on the CDC IRB so they can provide TPOXX treatment to their patients with monkeypox under the EA-IND.

This collection was initially approved as an Emergency ICR in August 2022 (OMB Control No. 0920-1366), and is being submitted here to create a standard version of the collection.

CDC requests OMB approval for an estimated 1,333 annual burden hours. There is no cost to respondents other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Avg. Burden per response (in hours)
Hospital/IRB Administrators	CDC IRB Authorization Agreement (for review)	500	1	1
Hospital/IRB Administrators	CDC IRB Authorization Agreement (for completion and submission to CDC	500	10	10/60

Jeffrey M. Zirger,
Lead,
Information Collection Review Office,
Office of Scientific Integrity,
Office of Science,
Centers for Disease Control and Prevention.

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