DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22-22HY; Docket No. CDC-2022-0099]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled, Centralized Institutional Review for the CDC Expanded Access Investigational New Drug (EA-IND) for Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections. This proposed project is essential to CDC's Monkeypox emergency response and is designed to assist healthcare providers to provide tecovirimat (TPOXX) treatment to patients with monkeypox under the EA-IND.

DATES: CDC must receive written comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0099 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the

Federal Register concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. 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;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. 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 submissions of responses; and
5. Assess information collection costs.

Proposed Project

Centralized Institutional Review for the CDC Expanded Access Investigational New Drug (EA-IND) for Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections - 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 (also known as 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 tecovirimat (TPOXX) treatment to their patients with monkeypox under the EA-IND.

CDC requests OMB approval for an estimated 13,333 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 hrs.)	Total Burden (in hrs.)
Hospital/IRB Administrators	CDC IRB Authorization	5000	1	1	5,000

	Agreement (for review)				
Hospital/IRB Administrators	CDC IRB Authorization Agreement (for completion and submission to CDC	5000	10	10/60	8,333
Total					13,333

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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