U.S. FOOD & DRUG ADMINISTRATION

January 16, 2025

Baxter Healthcare Corporation
Attention: Ximena Semensato
Senior Manager, Global Regulatory Affairs
Acute Therapies
1 Baxter Parkway
DF64E-087
Deerfield, IL 60015

**Re: Revocation of EUA 068**

Dear Ms. Semensato:

This letter is in response to the request from Baxter Healthcare Corporation (Baxter) that the U.S. Food and Drug Administration (FDA) revoke the EUA for REGIOCIT. This EUA was issued initially on August 13, 2020. Baxter has informed the FDA that it does not intend to offer REGIOCIT under the EUA in the United States anymore. FDA understands that Baxter will issue a communication to notify healthcare facilities and providers that have received REGIOCIT under the EUA of this revocation and to stop using REGIOCIT with instructions for product return for any product that remains in distribution.

The authorization of a drug for emergency use under section 564 of the Act (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). While there is no new safety concern with REGIOCIT, the Agency recognizes that FDA-approved replacement solutions are in sufficient supply to meet the public health need. Accordingly, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization.

FDA hereby revokes EUA 068 for REGIOCIT pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, REGIOCIT is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Dated: May 7, 2025.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

[FR Doc. 2025–09065 Filed 5–20–25; 8:45 am]

**BILLING CODE 4164–01–C**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–0279]**

## Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before July 21, 2025.

**ADDRESSES:** Submit your comments to Natalie Klein, *Natalie.Klein@hhs.gov* and *PRA@hhs.gov* or by calling (240) 453–6900.

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier ''0990–0279–60D'' and project title, ''Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form'' for reference, to Natalie Klein, email: *Natalie.Klein@hhs.gov, PRA@hhs.gov* or by calling (240) 453–6900.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* Department of Health and Human Services (HHS) Registration of an Institutional Review Board Form.

*Type of Collection:* Revision.

*OMB No.:* 0990–0279.

*Abstract:* The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a revision of the currently approved collection for the Office of Management and Budget (OMB) No. 0990–0279, Department of Health and Human Services (HHS) Institutional Review Board (IRB) Registration Form. The revision request involves implementing a burden reducing change. Specifically, OHRP is seeking to

remove the IRB roster membership information from the IRB registration form. This change will align the IRB registration form with the 2018 Requirements at 45 CFR 46.103. The change, when implemented, is anticipated to result in a shorter, simplified IRB registration process for respondents. Updates to the software applications OHRP uses to manage IRB registration will be deployed to enable such changes.

The current form is approved through June 30, 2025. The purpose of the form is to provide a simplified procedure for: (1) IRBs to satisfy the requirements for IRB registration at 45 CFR part 46, subpart E; and (2) IRBs in the United States (US) to satisfy the FDA requirements for IRB registration at 21 CFR 56.106.

Institutions engaged in nonexempt human subjects research conducted or supported by HHS, or another Common Rule department or agency, are required by the terms of the Federalwide Assurance (FWA) to rely upon only IRBs registered with OHRP for review of research to which the FWA applies, and must designate a registered IRB on the institution's FWA submission to OHRP. In this way, OHRP's FWA submission process, established pursuant to the requirements for assurances at 45 CFR 46.103, is linked to the regulatory requirements for IRB registration.

The respondents for this information collection are institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS; or, in the case of FDA's requirements, each IRB in the United States that reviews clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and each IRB in the United States that reviews clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products. Many of the IRBs also review research conducted or supported by other Common Rule departments and agencies.

ANNUALIZED BURDEN HOUR TABLE

| Form name | Number of respondents | Number of responses per respondent | Average burden per response (in hours) | Total burden hours |
|---|---|---|---|---|
| IRB Registration 0990–0279 Update and Renew | 5,350 | 1 | 0.33 | 1,766 |
| IRB-Registration 0990–0279 Initial and Update | 350 | 2 | 0.5/0.33 | 291 |
| Total | | | | 2,057 |

**Susan R. Little,**

*Department Information Collection Clearance Officer, Paperwork Reduction Act Program, Department of Health and Human Services.*

[FR Doc. 2025–09001 Filed 5–20–25; 8:45 am]

**BILLING CODE 4150–36–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

**[Document Identifier: OS–0990–new]**

## Agency Information Collection Request; 60-Day Public Comment Request

**AGENCY:** Office of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT, Office of the Secretary, HHS.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

**DATES:** Comments on the ICR must be received on or before July 21, 2025.

**ADDRESSES:** Submit your comments to *ASTP_Data@hhs.gov.*

**FOR FURTHER INFORMATION CONTACT:** When submitting comments or requesting information, please include the document identifier 0990–New–60D and project title for reference to *ASTP_Data@hhs.gov* and Meghan Gabriel at *Meghan.Gabriel@hhs.gov, PRA@hhs.gov* or call 202–465–0597.

**SUPPLEMENTARY INFORMATION:** Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

*Title of the Collection:* National Survey of Digital Health Companies.

*Type of Collection:* New Data Collection.

OMB No.

*Abstract:*

The 21st Century Cures Act (Cures Act) aimed to advance the exchange of electronic health information by promoting patient access through standardized application programming interfaces (APIs). Digital health companies develop apps and health IT tools that enable human interaction with APIs to exchange electronic health information. Prior studies indicate widespread adoption of standardized APIs for interoperability with electronic health records (EHRs). Ongoing assessment of these technologies is crucial to examining the impacts of the Cures Act's health IT provisions and is critical to informing the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health IT's (ASTP/ONC's) policy efforts. With ASTP/ONC's support, the University of California, San Francisco (UCSF) conducted a 2022 survey of digital health companies assessing implementation of and experiences with healthcare APIs; findings from this survey work are published in the Journal of the American Medical Informatics Association. ASTP/ONC finds it essential to continue efforts to survey digital health companies to assess ASTP/ONC's implementation of statutorily mandated information blocking (42 U.S.C. 300jj–52) and APIs ''without special effort'' policies (42 U.S.C. 300jj–11) under the Cures Act. Information gathered from this effort will help inform ongoing ASTP/ONC efforts to help nurture an ecosystem of innovation and transparency in health care.