

The literature search conducted by the WTC Health Program identified nine peer-reviewed, published, epidemiologic studies of PAD in 9/11-exposed populations (including one study by Mani et al. [2013] that was reviewed in the Petition 012 evaluation). None of the nine identified studies, however, demonstrate sufficient validity indicators to be considered high-quality studies.²⁴ Accordingly, the Science Team did not conduct further evaluation of the studies identified in the literature search described above.

Upon review of the evidence available in peer-reviewed, published, epidemiologic studies regarding PAD among 9/11-exposed populations, the Science Team found that there is inadequate evidence to determine a causal association²⁵ between 9/11 exposures and PAD (Category V).

²⁴ Jordan HT, Brackbill RM, Cone JE, Debchoudhury I, Farfel MR, Greene CM, Hadler JL, Kennedy J, Li J, Liff J, Stayner L, Stellman SD [2011a], *Mortality Among Survivors of the Sept 11, 2001, World Trade Center Disaster: Results from the World Trade Center Health Registry Cohort*, Lancet 378(9794):879–887; Mani V, Wong SK, Sawitt ST, Calcagno C, Maceda C, Ramachandran S, Fayad ZA, Moline J, McLaughlin MA [2013], *Relationship Between Particulate Matter Exposure and Atherogenic Profile in “Ground Zero” Workers as Shown by Dynamic Contrast Enhanced MR Imaging*, Int J Cardiovasc Imaging 29:827–833; Stein CR, Wallenstein S, Shapiro M, Hashim D, Moline JM, Udasin I, Crane MA, Luft BJ, Lucchini RG, Holden WL [2016], *Mortality Among World Trade Center Rescue and Recovery Workers, 2002–2011*, Am J Ind Med 59(2):87–95; Jordan HT, Stein CR, Li J, Cone JE, Stayner L, Hadler JL, Brackbill RM, Farfel MR [2018], *Mortality Among Rescue and Recovery Workers and Community Members Exposed to the September 11, 2001 World Trade Center Terrorist Attacks, 2003–2014*, Environ Res 163:270–279; Cohen HW, Zeig-Owens R, Joe C, Hall CB, Webber MP, Weiden MD, Cleven KL, Jaber N, Skerker M, Yip J, Schwartz T, Prezant DJ [2019], *Long-Term Cardiovascular Disease Risk among Firefighters after the World Trade Center Disaster*, JAMA Netw Open 2(9):e199775; Colbeth HL, Zeig-Owens R, Hall CB, Webber MP, Schwartz TM, Prezant DJ [2020], *Mortality Among Fire Department of the City of New York Rescue and Recovery Workers Exposed to the World Trade Center Disaster, 2001–2017*, Int J Environ Res Public Health 17(17):6266; Li J, Hall CB, Yung J, Kehm RD, Zeig-Owens R, Singh A, Cone JE, Brackbill RM, Farfel MR, Qiao B, Schymura MJ, Shapiro MZ, Dasaro CR, Todd AC, Prezant DJ, Boffetta P [2023], *A 15-Year Follow-Up Study of Mortality in a Pooled Cohort of World Trade Center Rescue and Recovery Workers*, Environ Res 219:115116; Singh A, Zeig-Owens R, Cannon M, Webber MP, Goldfarb DG, Daniels RD, Prezant DJ, Boffetta P, Hall CB [2023], *All-Cause and Cause-Specific Mortality in a Cohort of WTC-Exposed and Non-WTC-Exposed Firefighters*, Occup Environ Med 80(6):297–303; Parvin A, Kehm RD, Qiao B, Cone JE, Farfel MR, Zeig-Owens R, Goldfarb DG, Shapiro MZ, Todd AC, Insaf T, Hall CB, Boffetta P, Li J [2026], *Effect of World Trade Center Health Program on Mortality Among 9/11 Responders*, Ann Epidemiol 115:8–14.

²⁵ See *supra* note 5 at Sec. V.E.—Evidence is Inadequate to Determine a Causal Association.

E. Administrator’s Final Decision on Whether To Propose the Addition of Peripheral Artery Disease to the List

Pursuant to the PHS Act, sec. 3312(a)(6)(B)(iv) and 42 CFR 88.16(a)(2)(iv), and in accordance with Sec. VIII.B. of the *Policy and Procedures*, the Administrator has determined that insufficient evidence is available to take further action at this time, including proposing the addition of PAD to the List (pursuant to the PHS Act, sec. 3312(a)(6)(B)(ii) and 42 CFR 88.16(a)(2)(ii)) or publishing a determination not to publish a proposed rule in the **Federal Register** (pursuant to the PHS Act, sec. 3312(a)(6)(B)(iii) and 42 CFR 88.16(a)(2)(iii)). The Administrator has also determined that requesting a recommendation from the STAC (pursuant to the PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the request in Petition 048a to add PAD to the List of WTC-Related Health Conditions is denied.

F. Approval To Submit Document to the Office of the Federal Register

The Secretary, HHS, or his designee, the Director, Centers for Disease Control and Prevention (CDC) and Administrator, Agency for Toxic Substances and Disease Registry (ATSDR), authorized the undersigned, the Administrator of the WTC Health Program, to sign and submit the document to the Office of the Federal Register for publication as an official document of the WTC Health Program. Erica Schwartz, MD, MPH, JD, RADM, USPHS (ret), Director, CDC, and Administrator, ATSDR, approved this document for publication on September 8, 2026.

John J. Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0196]

Proposed Information Collection Activity; Multistate Financial Institution Data Match With Federally Assisted State Transmitted Levy

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), is requesting a 3-year extension of the Multistate Financial Institution Data Match (MSFIDM) with Federally Assisted State Transmitted (FAST) Levy (Office of Management and Budget #: 0970–0196, expiration January 31, 2027). OCSE revised the MSFIDM handbook and the FAST Levy record specifications. Burden estimates were reduced by 32.71 percent to reflect the expected estimated number of respondents and responses per respondent over the next 3 years.

DATES: *Comments due* November 16, 2026.

ADDRESSES: In compliance with the requirements of the Paperwork Reduction Act, ACF is soliciting public comment on the specific aspects of the information collection described above. You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: State child support agencies (CSAs) are statutorily required to enter into data matching agreements with financial institutions doing business in their state to locate obligors’ accounts. OCSE operates the MSFIDM program through the Federal Parent Locator Service (FPLS) and facilitates the required data match between state and multistate financial institutions (MSFIs). State CSAs use the data match outcomes to fulfill a statutory requirement to seize an obligor’s assets to satisfy past-due child support.

OCSE also operates FAST Levy, which is an automated application within the FPLS to exchange electronic lien/levy information securely and efficiently. State CSAs and financial institutions use FAST Levy to exchange

information to freeze and seize financial assets more quickly and efficiently.

On December 19, 2025, ACF published a notice in the **Federal Register** Volume 90, Number 242, Page 59525 to announce that the Office of Child Support Services (OCSS) is now the Office of Child Support Enforcement (OCSE). Any reference to OCSS is changed to OCSE in the collection materials. Further, OCSE revised the MSFIDM handbook to include additional guidance for connectivity, testing, and production. The FAST Levy specifications also underwent other

revisions to remove obsolete text and to clarify file name requirements.

Respondents: MSFIs and State CSAs.

Annual Burden Estimates

The burden estimates were updated to reflect current estimates for the respondents and responses over the next 3 years. The burden reduction is attributable to a reduction in the estimated number of financial institutions electing to join FAST Levy because they use programming on their end and not a transmitter to send their files. Over the last 3 years, only one

financial institution has joined FAST Levy; therefore, we changed the projection from 2 to 1 for each year. Also, the number of financial transmitters using the Child Support Portal decreased from 263 to 160. Many of the transmitters switched to an automated process through Secure File Transfer Protocol while others no longer transmit at all. The prior burden was 5,029.3 hours, the current burden is 3,384.1 hours, and this amounts to a burden reduction of 1,645.2 hours, or 32.71 percent.

Information collection instrument	Total annual number of respondents	Total annual number of responses per respondent	Average annual burden hours per response	Total annual burden hours
Financial Data Match Record Specifications Match File Upload/Download: Portal Users	160	4	0.083	53.12
Election Form	10	1	0.5	5.00
FAST-Levy Response Withhold Record Specifications: Financial Institutions	1	1	1,716	1,716.00
FAST-Levy Request Withhold Record Specifications: State Child Support Agencies	1	1	1,610	1,610.0

Estimated Total Annual Burden Hours: 3,384.12.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 652(l); 42 U.S.C. 666(a)(2) and (c)(1)(G)(ii); 42 U.S.C. 666(a)(17)(A); 42 U.S.C. 652(a)(7); and 45 CFR 303.7(a)(5).

Samantha L. Illangasekare,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2026-N-10165]

Statistical Considerations for the Design of Rare Disease Clinical Investigations; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for information and comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is establishing a public docket to collect feedback on statistical considerations for rare disease clinical investigations. This docket is open in conjunction with a Rare disease Innovation, Science, and Exploration (RISE) Workshop on the same topic. Feedback is welcome both on the attached pre-read documents and on the content covered in the Workshop itself.

DATES: Either electronic or written comments on the notice must be submitted by November 13, 2026.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 13, 2026. Comments received

by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows: