

by the petitioner, Stecker *et al.* [2014], does not meet the policy's relevance requirement of being an epidemiologic study of a 9/11-exposed population, because it was an in vitro study conducted in rat tissues;¹⁴ therefore, it was not further considered. The Program also identified a study by Marmor *et al.* [2017]¹⁵ which reported on the prevalence and risk factors for paresthesia, a condition related to and at times a symptom of neuropathy, among community members who attended the WTC Environmental Health Center for treatment of health outcomes resulting from 9/11 exposures. Since the Marmor *et al.* [2017] study concerns paresthesia rather than neuropathy, it is not considered "relevant" and, per Program policy,¹⁶ cannot provide potential support for deciding whether to propose adding neuropathy to the List.¹⁷

The Wilkenfeld *et al.* study was previously reviewed for quality as part of the Program's evaluation of Petition 010, which requested the addition of peripheral neuropathy to the List. As discussed in the **Federal Register** notice regarding Petition 010, the Wilkenfeld *et al.* [2016] study was found to have numerous limitations preventing further evaluation.¹⁸

Upon review, the Stecker *et al.* [2016] study also exhibited significant limitations, including flawed study design and selection bias. Similar to the study by Wilkenfeld *et al.* [2016], the Stecker *et al.* [2016] study was cross-sectional and did not include appropriate population sampling criteria. Although Stecker *et al.* [2016] used an objective measure of neuropathy, the comparison group was inadequate. The small exposure group and multiple statistical tests may have limited the study power. Neither the Wilkenfeld *et al.* [2016] nor the Stecker *et al.* [2016] study addressed potential exposures to toxins outside of 9/11 exposures and other confounders that could explain the findings.

¹⁴ Only epidemiologic studies of the health condition in human 9/11-exposed populations are considered relevant.

¹⁵ Marmor M, Shao Y, Bhatt DH, *et al.* [2017], Paresthesias among Community Members Exposed to the World Trade Center Disaster, JOEM article in press.

¹⁶ See *supra* note 3 and Section A.

¹⁷ Paresthesia refers to abnormal sensations such as prickling, tingling, itching, burning or cold, skin crawling or impaired sensations. Although paresthesia symptoms could arise from nerve damage, including neuropathy, other conditions can also produce paresthesia, such as anxiety, metabolic derangements, and certain infectious diseases such as Lyme disease. Because paresthesia is not exclusively associated with neuropathy, paresthesia is not a proxy for neuropathy.

¹⁸ See 81 FR 19108 (April 4, 2016).

The studies by Wilkenfeld *et al.* [2016] and Stecker *et al.* [2016] exhibited many significant limitations and were found, individually and together, not to provide a basis for deciding whether to propose adding neuropathy to the List.

D. Administrator's Final Decision on Whether To Propose the Addition of Neuropathy to the List

In accordance with the review and determination discussed above, the Administrator has concluded that the available evidence does not have the potential to provide a basis for a decision on whether to add neuropathy to the List. Accordingly, the Administrator has determined that insufficient evidence is available to take further action at this time, including either proposing the addition of neuropathy to the List (pursuant to 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 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 PHS Act, sec. 3312(a)(6)(B)(i) and 42 CFR 88.16(a)(2)(i)) is unwarranted.

For the reasons discussed above, the Petition 015 request to add neuropathy to the List of WTC-Related Health Conditions is denied.

E. 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. Anne Schuchat, M.D., Acting Director, CDC, and Acting Administrator, ATSDR, approved this document for publication on May 2, 2017.

John 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

Proposed Information Collection Activity; Comment Request

Proposed Projects: Reinstate and Extend Collection with Modification—Social Services Block Grant (SSBG) Post-Expenditure Report.

Title: Social Services Block Grant (SSBG) Post-Expenditure Report.

OMB No.: 0970-0234.

Description: The purpose of this is to request approval to: (1) Reinstate and extend the collection of post-expenditure data using the current OMB approved Post-Expenditure Reporting form (OMB No. 0970-0234) with modification past the current expiration date of November 30, 2017; (2) propose 8 minor additions to the current Post-Expenditure Reporting form; and (3) to request that grantees continue to voluntarily submit estimated pre-expenditure data using the Post-Expenditure Reporting form, as part of the required annual Intended Use Plan.

The Social Services Block Grant (SSBG) is authorized under Title XX of the Social Security Act, as amended, and is codified at 42 U.S.C. 1397 through 1397e. SSBG provides funds to States, the District of Columbia, Puerto Rico, American Samoa, Guam, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands (hereinafter referred to as States and Territories or grantees) to assist in delivering critical services to vulnerable older adults, persons with disabilities, at-risk adolescents and young adults, and children and families. SSBG funds are distributed to each State and the District of Columbia based on each State's population relative to all other States. Distributions are made to Puerto Rico, Guam, American Samoa, the Virgin Islands, and the Commonwealth of the Northern Mariana Islands based on the same ratio allotted to them in 1981 as compared to the total 1981 appropriation.

Each State or Territory is responsible for designing and implementing its own use of SSBG funds to meet the specialized needs of their most vulnerable populations. States and Territories may determine what services will be provided, who will be eligible, and how funds will be distributed among the various services. State or local SSBG agencies (*i.e.*, county, city, regional offices) may provide the services or grantees may purchase services from qualified agencies,

organizations, or individuals. States and Territories must administer the SSBG according to their accepted Intended Use Plan, along with amendments, and in conformance with their own implementing rules and policies. The Office of Community Services (OCS), Administration for Children and Families administers the SSBG.

Annually, grantees are required to submit a Pre-Expenditure Report and Intended Use Plan as a prerequisite to receiving SSBG funds. The Pre-Expenditure Report must include information on the types of services to be supported and the characteristics of individuals to be served. This report is to be submitted 30 days prior to the start of the Fiscal Year (June 1 if the State operates on a July–June Fiscal Year, or September 1 if the State operates on a Federal Fiscal Year). No specific format is required for the Intended Use Plan. Grantees are required to submit a revised Intended Use Plan and Pre-Expenditure Report if the planned use of SSBG funds changes during the year (42 U.S.C. 1397c).

In order to provide a more accurate analysis of the extent to which funds are spent “in a manner consistent” with each of the grantees’ plan for their use, as required by 42 U.S.C. 1397e (a), OCS continues to request that States voluntarily use the format of the Post-Expenditure Reporting form to create their Pre-Expenditure Report, which provides estimates of the amount of expenditures and the number of recipients, by service category, and is submitted as part of the grantees’ Intended Use Plan. Most of the States and Territories are currently using the format of the Post-Expenditure Reporting form to report estimated expenditures and recipients (the Pre-Expenditure Report), by service category, as part of their Intended Use Plan.

On an annual basis, States and Territories are also required to submit a Post-Expenditure Report that details their use of SSBG funds in each of 29 service categories. Grantees are required to submit their Post-Expenditure Report within six months of the end of the period covered by the report. The Post-Expenditure Report must address (1) The number of individuals (including number of children and number of adults) who receive services paid for, in whole or in part, with Federal funds under the SSBG; (2) The amount of SSBG funds spent in providing each service; (3) The total amount of Federal, State, and Local funds spent in providing each service, including SSBG funds; (4) The method(s) by which each

service is provided, showing separately the services provided by public and private agencies; and (5) The criteria applied in determining eligibility for each service such as income eligibility guidelines, sliding scale fees, the effect of public assistance benefits, and any requirements for enrollment in school or training programs (45 CFR 96.74a). The Post-Expenditure Report must also; (1) Indicate if recipient totals are actual or if the total reported is based on estimates and/or sampled data; and (2) use its own definition of child and adult in reporting the required data (45 CFR 96.74b).

This request seeks approval to reinstate and continue the use of the current OMB approved Post-Expenditure Reporting form (OMB No. 0970–0234) with modification, for estimating expenditures and recipients as part of States’/Territories’ Pre-Expenditure Reports and for annual Post-Expenditure Reporting. The proposed modifications seek to consolidate information that would be stored or transmitted elsewhere into the singular reporting form to allow OCS to better analyze and provide guidance to improve States efficiency in grant administration. These modifications address the regulations 42 U.S.C. 1397e and 45 CFR 96.74 cited above by providing space on the Post-Expenditure form to indicate the required information.

Beginning in 2013, States completed the current reporting form on the SSBG Portal. The SSBG Portal is a secure web-based data portal. The SSBG Portal allows for more efficient data submission without increasing the overall burden on States. Until recently, Territories reported the data on the Post-Expenditure Reporting form in Microsoft Excel and submitted it to ACF, via email or posted mail. In 2017, Territories can complete the current reporting form on the SSBG Portal. The SSBG Portal provides a user-friendly means for States and Territories to submit and access their Pre-Expenditure and Post-Expenditure and Recipient Data.

Information collected in the Post-Expenditure Reports submitted by States and Territories is analyzed and described in an annual report on SSBG expenditures and recipients produced by the Office of Community Services (OCS), Administration for Children and Families (ACF). The information contained in this report is used for grant planning and management. The data establishes how SSBG funding is used for the provision of services in each State or Territory.

The data is also analyzed to determine the performance of States and Territories in meeting the SSBG performance measures developed to meet the requirements of the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010 [Pub. L. 11–352; 31 U.S.C 1115(b)(10)]. GPRA requires all Federal agencies to develop measurable performance goals.

The SSBG currently has an administrative costs efficiency measure which is intended to decrease the percentage of SSBG funds identified as administrative costs in the Post-Expenditure Reports [U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services. (2007, June). Implementing a new performance measure to enhance efficiency (Information Memorandum Transmittal No. 04–2007). Available from <https://www.acf.hhs.gov/ocs/resource/implementing-a-new-performance-measure-to-enhance-efficiency>]. The SSBG also implements a performance measure designed to ensure that SSBG funds are spent effectively and efficiently while maintaining the intrinsic flexibility of the SSBG as a block grant. The performance measure assesses the degree to which States and Territories spend SSBG funds in a manner consistent with their intended use, as required by Federal law [42 U.S.C. 1397e(a); U.S. Department of Health and Human Services, Administration for Children and Families, Office of Community Services. (2012, February). Implementation of a new performance measure (Information Memorandum Transmittal No. 01–2012). Available from <https://www.acf.hhs.gov/ocs/resource/implementation-of-a-new-performance-measure>]. It will be used to determine how well grantees are doing overall in minimizing variance between projected and actual expenditures of SSBG funds. This program measure began implementation with FY 2013 data and remains ongoing.

Respondents: The Post-Expenditure Reporting form and Pre-Expenditure Report are completed once annually by a representative of the agency that administers the Social Services Block Grant at the State or Territory level. Respondents include the 50 States, the District of Columbia, and Puerto Rico, as well as the territories of American Samoa, Guam, the Virgin Islands, and the Commonwealth of Northern Mariana Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Post-Expenditure Reporting Form	56	1	110	6,160
Use of Post-Expenditure Reporting Form as Part of the Intended Use Plan	56	1	2	112

Estimated Total Annual Burden Hours: 6,272.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chap 35), the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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.

Robert Sargis,
Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Nominations to the Advisory Council on Alzheimer’s Research, Care, and Services

AGENCY: Office of the Assistant Secretary for Planning and Evaluation, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Secretary of HHS established the Advisory Council to provide advice and consultation to the Secretary on how to prevent or reduce the burden of Alzheimer’s disease and related dementias on people with the disease and their caregivers. The Secretary signed the charter establishing the Advisory Council on May 23, 2011. *HHS is soliciting nominations for seven (7) new non-Federal members of the Advisory Council to replace the seven members whose terms will end September 30th, 2017.* Nominations should include the nominee’s contact information (current mailing address, email address, and telephone number) and current curriculum vitae or resume.

DATES: Submit nominations by email or USPS mail before COB on June 16, 2017.

ADDRESSES: Nominations should be sent by email to Rohini Khillan at rohini.khillan@hhs.gov; or sent by USPS mail to: Rohini Khillan, Office of the Assistant Secretary for Planning and Evaluation, Room 424E, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

FOR FURTHER INFORMATION CONTACT: Rohini Khillan (202) 690–5932, rohini.khillan@hhs.gov.

SUPPLEMENTARY INFORMATION: The Advisory Council on Alzheimer’s Research, Care, and Services meets quarterly to discuss programs that impact people with Alzheimer’s disease and related dementias and their caregivers. The Advisory Council makes recommendations to Congress and the Secretary of Health and Human Services about ways to reduce the financial impact of Alzheimer’s disease and related dementias and to improve the health outcomes of people with these conditions. The Advisory Council also provides feedback on a National Plan for Alzheimer’s disease. On an annual basis, the Advisory Council evaluates the implementation of the recommendations through an updated National Plan. The National Alzheimer’s Project Act, Public Law 111–375 (42 U.S.C. 11225), requires that the Secretary of Health and Human Services (HHS) establish the Advisory Council on Alzheimer’s Research, Care, and Services. The Advisory Council is

governed by provisions of Public Law 92–463 (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

The Advisory Council consists of 22 members. Ten members will be designees from Federal agencies including the Centers for Disease Control and Prevention, Administration for Community Living, Centers for Medicare and Medicaid Services, Indian Health Service, National Institutes of Health, National Science Foundation, Department of Veterans Affairs, Food and Drug Administration, Agency for Healthcare Research and Quality, and the Health Resources and Services Administration.

The Advisory Council also consists of 12 non-federal members selected by the Secretary who fall into 6 categories: Dementia caregivers (2), health care providers (2), representatives of State health departments (2), researchers with dementia-related expertise in basic, translational, clinical, or drug development science (2), voluntary health association representatives (2), and dementia patient advocates, including an advocate who is currently living with the disease (2). The member living with the disease serves a 2-year term.

At this time, the Secretary shall appoint one member for each category, to replace the seven members whose terms will end on September 30th, 2017, for a total of seven (7) new members to the Council. After receiving nominations, the Secretary, with input from his staff, will make the final decision, and the new members will be announced soon after. Members shall be invited to serve 4-year terms, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of such term. The member living with the disease will serve a 2-year term. A member may serve after the expiration of the member’s term until a successor has taken office. Members will serve as Special Government Employees.