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**FOR FURTHER INFORMATION CONTACT:**

Letise Williams, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5441, Silver Spring, MD 20993-0002, [letise.williams@fda.hhs.gov](mailto:letise.williams@fda.hhs.gov), 301-796-8398, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

**SUPPLEMENTARY INFORMATION: Agenda:**

On November 15, 2018, the Committee will discuss and make recommendations on the topic "Connected and Empowered Patients: E-Platforms Potentially Expanding the Definition of Scientific Evidence." The recommendations will address how FDA can leverage patient-driven platforms, such as social media and registries, to better engage patients and consumers as empowered partners in the work of protecting public health and promoting responsible innovation. Social media and other web platform enablers are facilitating the growth of virtual patient communities. Increasingly, patients and health care consumers are using these platforms to share their health experiences and seek information from other patients and consumers, rather than their health care providers alone. Novel approaches and methodologies are being used to tap into some of these platforms as potentially rich sources of patient-generated health data, which could be used as relevant and reliable real-world evidence (<https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm513027.pdf>).

This meeting will help advance FDA's objective to assure the needs, experiences, and perspectives of

patients are included as part of FDA's deliberations involving the regulation of medical devices and their use by patients. For this meeting, FDA is seeking input from the Committee and the public on whether and how FDA can harness the emerging potential of these patient platforms to better engage patients and consumers as empowered partners in the work of protecting public health and promoting responsible innovation. In addition, FDA is seeking recommendations from the Committee on ways to leverage these platforms to disseminate as well as potentially collect and evaluate health information to and from patients and consumers.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee-meeting link.

**Procedure:** Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Oral presentations from the public will be scheduled between approximately 11:15 a.m. to 12:15 p.m. on November 15, 2018. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 15, 2018. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 17, 2018. Individuals who do not wish to speak at the open public hearing session but would like their comments to be heard by the Committee may send written submissions to the contact person on or before October 23, 2018.

FDA welcomes the attendance of the public at its advisory committee

meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact AnnMarie Williams at [Annmarie.Williams@fda.hhs.gov](mailto:Annmarie.Williams@fda.hhs.gov), or 301-796-5966 at least 7 days in advance of the meeting.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm11462.htm> for procedures on public conduct during advisory committee meetings. Please be advised that, for the round table portion of the meeting, FDA will prepare a summary of the discussion in lieu of detailed transcripts.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 18, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: National Health Service Corps Scholar/Students to Service Travel Worksheet, OMB No. 0915-0278—Extension**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR. **DATES:** Comments on this ICR should be received no later than November 23, 2018.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA

Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

*Information Collection Request Title:* National Health Service Corps Scholar/Students to Service Travel Worksheet OMB No. 0915-0278—Extension

*Abstract:* Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program and the Students to Service (S2S) Loan Repayment Program use the online Travel Request Worksheet to receive travel funds from the Federal Government to visit eligible NHSC sites

to which they may be assigned in accordance with the Public Health Service Act (PHSA), section 331(c)(1).

The travel approval process is initiated when a NHSC scholar or S2S participant notifies the NHSC of an impending interview at one or more NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has successfully been matched to an approved practice site in accordance with the PHSA, section 331(c)(3). Upon receipt of the Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the scholar or S2S participant, and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

*Need and Proposed Use of the Information:* This information will facilitate NHSC scholar and S2S clinicians' receipt of federal travel funds that are used to visit high-need NHSC sites. The Travel Request Worksheet is

also used to initiate the relocation process after a NHSC scholar or S2S participant has successfully been matched to an approved practice site.

*Likely Respondents:* Clinicians participating in the NHSC Scholarship Program and S2S Loan Repayment Program.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Travel Request Worksheet .....	250	2	500	.0667	33.35
Total .....	250	.....	500	.....	33.35

HRSA specifically requests comments on (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.

**Amy P. McNulty,**

*Acting Director, Division of the Executive Secretariat.*

[FR Doc. 2018-20708 Filed 9-21-18; 8:45 am]

**BILLING CODE 4165-15-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Meeting of the Secretary's Advisory Committee on Human Research Protections**

**AGENCY:** Office of the Assistant Secretary for Health, Office of the

Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP website at: <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

**DATES:** The meeting will be held on Tuesday, October 16, 2018, from 8:30 a.m. until 5 p.m., and Wednesday, October 17, 2018, from 8:30 a.m. until 4 p.m.

**ADDRESSES:** 6700B Rockledge Drive, Bethesda, MD 20817.

**FOR FURTHER INFORMATION CONTACT:** Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville,

Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; email address: [SACHRP@hhs.gov](mailto:SACHRP@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services (HHS), through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS