The format of the public meeting will consist of a series of presentations, panel discussions, and open discussion.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free. Persons interested in attending this public meeting must register. Registrants will receive confirmation once they have been accepted. Registered participants will be sent technical system requirements in advance of the event. We recommend that you review these technical system requirements prior to joining the virtual public meeting. The meeting will be recorded, and the recording will be available after the meeting.

There will be live closed captioning for the event. If you need other special accommodations due to a disability, by January 25, 2021, please contact Jasmine Smith, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, at *ONDPublicMTGSupport@fda.hhs.gov* or 301–796–0621; or Catherine Sewell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 5360, Silver Spring, MD 20993–0002, Fax: 301–796–9897.

FDA has verified the website addresses in this document as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that transcripts of the public meeting will be available by February 8, 2021, at the event page *https://healthpolicy.duke.edu/events/scientific-and-ethical-considerations-inclusion-pregnant-women-clinical-trials.*

Dated: December 14, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–28069 Filed 12–18–20; 8:45 am]

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: Scientific Registry of Transplant Recipients; Information Collection Effort for Potential Donors for Living Organ Donation OMB No. 0906–0034—Extension

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than January 20, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

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

Information Collection Request Title: Scientific Registry of Transplant Recipients Information Collection Effort for Potential Donors for Living Organ Donation, OMB No. 0906–0034—Extension.

Abstract: The Scientific Registry of Transplant Recipients (SRTR) is administered under contract with HRSA, a sub agency of HHS. HHS is authorized to establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations (42 U.S.C. 273a) and is required to submit to Congress an annual report on the long-term health effects of living donation (42 U.S.C. 273b). In 2018, the SRTR contractor implemented a pilot living donor registry in which transplant programs registered all potential living organ donors who provide informed consent to participate in the pilot registry. The SRTR's authority to collect information concerning potential living organ donors is set forth in the HHS organ procurement and transplantation network regulation, 42 CFR part 121, requiring organ procurement organizations and transplant hospitals to submit to the SRTR, as appropriate, information regarding ''donors of organs'' and ''other information that the Secretary deems appropriate'' (42 CFR 121.11(b)(2)).

In 2018, an updated version of the data collection instrument was approved. The data collection modifications improve the quality of the data and reduce the administrative burden for respondents.

A 60-day notice published in the **Federal Register** on September 8, 2020, vol. 85, No. 174; pp. 55464–65. There were no public comments.

Need and Proposed Use of the Information: The transplant programs submit health information collected at the time of donation evaluation through a secure web-based data collection tool developed by the contractor. The SRTR contractor maintains contact with registry participants and collects data on long-term health outcomes through surveys. The data collection includes outcomes of evaluation, including reasons for non-donation. The living donor registry is an ongoing effort, and the goal is to continue to collect data on living organ donor transplant programs in the United States over time. Monitoring and reporting of long-term health outcomes of living organ donors post-donation will continue to provide useful information to transplant programs in their future donor selection process and aid potential living organ donors in their decision to pursue living donation.

There were minor revisions to the burden per response as it has decreased from the current amount due to improvements to the efficiency of the processes used by programs for data submission, as well as the tools provided for program use by SRTR.

Likely Respondents: Potential living donors, transplant programs, medical

and scientific organizations, and public organizations.

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 and 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	Average number of responses per respondent	Total number of responses	Average burden per response (in minutes)	Total burden hours
Potential Living Donor Registration form	[a] 16	112	1,792	.27	484
Potential Living Donor Follow-up form	[b] 754	1	754	.50	377
Reasons Did not Donate form (liver or kidney)	[a] 16	106	1,696	.23	390
Total	786		4,242		1,251

[a] Number of respondents is based on the current number of transplant programs and is likely to increase as additional programs decide to participate.

[b] Number of living organ donor candidates submitting follow-up forms in 2019.

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.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–28017 Filed 12–18–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the National Vaccine Advisory Committee (NVAC) will hold a virtual meeting. The meeting will be open to the public and public comment will be heard during the meeting.

DATES: The meeting will be held February 4–5, 2021. The confirmed meeting times and agenda will be posted on the NVAC website at *http://www.hhs.gov/nvpo/nvac/meetings/index.html* as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted online at: *http://www.hhs.gov/nvpo/nvac/meetings/index.html* at least one week prior to the meeting. Pre-registration is required for those who wish to attend the meeting or participate in public comment. Please register at *http://www.hhs.gov/nvpo/nvac/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Ann Aikin, Acting Designated Federal Officer, at the Office of Infectious Disease and HIV/AIDS Policy, U.S. Department of Health and Human Services, Mary E. Switzer Building, Room L618, 330 C Street SW, Washington, DC 20024. Email: *nvac@hhs.gov.* Phone: 202–695–9742.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa–1), the Secretary of HHS was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program.

During this NVAC meeting, NVAC will hear presentations on vaccine safety, communication activities for COVID–19 vaccines, and immunization equity. Please note that agenda items are subject to change, as priorities dictate. Information on the final meeting agenda will be posted prior to the meeting on the NVAC website: *http://www.hhs.gov/nvpo/nvac/index.html.*

Members of the public will have the opportunity to provide comment at the NVAC meeting during the public comment period designated on the agenda. Public comments made during the meeting will be limited to three minutes per person to ensure time is allotted for all those wishing to speak. Individuals are also welcome to submit written comments in advance. Written comments should not exceed three pages in length. Individuals submitting comments should email their written comments or their request to provide a comment during the meeting to *nvac@hhs.gov* at least five business days prior to the meeting.

Dated: October 27, 2020.

Ann Aikin,

Acting Designated Federal Official, Office of the Assistant Secretary for Health.

[FR Doc. 2020–28046 Filed 12–18–20; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director Notice of Proposed Reorganization

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.