Products.'' This guidance provides recommendations to industry and FDA staff on the purpose and content of a URRA and how a URRA, along with other information, can be used to determine HF data needs during product development and to support a marketing application. This guidance applies to drug- and biologic-led combination products that are the subject of an investigational new drug application (IND), a new drug application (NDA), or a biologics license application (BLA) and supplements to these applications. This guidance also applies to human prescription drug products, including biological products, that are the subject of an IND, NDA, or BLA and supplements to these applications, and to human nonprescription drug products that are the subject of an IND or NDA and supplements to these applications. This guidance does not describe the methods used to design, conduct, or analyze human factors studies (for example, human factors validation studies or comparative use human factors studies).

The URRA is a risk management tool that supports the entire human factors engineering process and should be considered as part of an overall risk management framework. The URRA can be used in all phases of the medical product lifecycle. As part of evaluating the products as described above, FDA will evaluate human factors data submitted by sponsors to support the product user interface when submission of such data is warranted. The URRA can be used as one data element to help determine whether submission of human factors data is warranted.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products and Combination Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 pertaining to the submission of INDs have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to the submission of NDAs and supplements to NDAs have been approved under 0910–0001. The collections of information in 21 CFR part 601 pertaining to the submissions of BLAs and supplements to BLAs have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: July 2, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15003 Filed 7–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–6395]

Request for Applications for New Members of the Clinical Trials Transformation Initiative/Food and Drug Administration Patient Engagement Collaborative

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for applications.

SUMMARY: The Food and Drug Administration (FDA or Agency), in collaboration with the Clinical Trials Transformation Initiative (CTTI), is requesting applications from patient advocates interested in participating on the Patient Engagement Collaborative (PEC). The PEC is an ongoing, collaborative forum coordinated through the FDA's Patient Affairs Staff, Office of Clinical Policy and Programs (OCPP), Office of the Commissioner at FDA, and is hosted by CTTI. Through the PEC, the patient community and FDA staff are able to discuss an array of topics related to increasing meaningful patient engagement with diverse populations in medical product development and regulatory discussions at FDA. The activities of the PEC may include, but are not limited to, providing diverse perspectives on topics such as systematic patient engagement, transparency, and communication; providing considerations for implementing new strategies to enhance patient engagement at FDA; and proposing new models of collaboration in which patient, caregiver, and patient advocate perspectives can inform medical product development and regulatory discussions.

DATES: Applications can be submitted starting at 11:59 p.m. Eastern Time on July 9, 2024. This announcement is open to receive a maximum of 75 applications. Applications will be accepted until 11:59 p.m. Eastern Time on August 8, 2024 or until 75 applications are received, whichever happens first.

ADDRESSES: All applications should be submitted to FDA's Patient Affairs Staff in OCPP. The preferred application method is via the online submission system provided by CTTI, available at *https://duke.qualtrics.com/jfe/form/SV_3DllHjcaGryUIlg.* For those applicants unable to submit an application electronically, please call FDA's Patient Affairs Staff at 301–796–8460 to arrange for mail or delivery service submission. Only complete applications, as described under section IV of this document, will be considered.

FOR FURTHER INFORMATION CONTACT: Wendy Slavit, Office of the Commissioner, Office of Clinical Policy and Programs, Patient Affairs Staff, Food and Drug Administration, 301–796–8460, *PatientEngagementCollaborative@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background and Purpose

The CTTI is a public-private partnership cofounded by FDA and Duke University whose mission is to develop and drive adoption of practices that will increase the quality and efficiency of clinical trials. FDA and CTTI have long involved patients and considered patient perspectives in their work. Furthering the engagement of diverse patients as valued partners across the medical product research and development continuum requires an open forum for patients and regulators to discuss and exchange ideas.

The PEC is an ongoing, collaborative forum in which the patient community and FDA Staff discuss an array of topics related to increasing patient engagement

in medical product development and regulatory discussions at FDA. The PEC is a joint endeavor between FDA and CTTI. The activities of the PEC may inform relevant FDA and CTTI activities. The PEC is not intended to advise or otherwise direct the activities of either organization, and membership will not constitute employment by either organization.

The Food and Drug Administration Safety and Innovation Act (Pub. L. 112–14), section 1137, entitled ''Patient Participation in Medical Product Discussions,'' added section 569C to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c). This provision directs the Secretary of Health and Human Services to ''develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions.'' On November 4, 2014, FDA issued a **Federal Register** notice establishing a docket (FDA–2014–N–1698) for public commenters to submit information related to FDA's implementation of this provision. Upon review of the comments received, one common theme, among others, included establishing an external group to provide input on patient engagement strategies across FDA's Centers. After considering the comments, FDA formed the PEC in 2018 to discuss a variety of patient engagement topics. This group is consistent with additional legislation subsequently enacted in section 3001 of the 21st Century Cures Act (Pub. L. 114–255) and section 605 of the FDA Reauthorization Act of 2017 (Pub. L. 115–52), further supporting tools for fostering patient participation in the regulatory process.

The PEC currently has 16 members. To help ensure continuity in its activities and organizational knowledge, the PEC maintains staggered membership terms. During the fall of 2024, eight members will complete a term and up to eight new members will be selected. The purpose of this notice is to announce that the application process for up to eight new members of the PEC is now open, and to invite and encourage applications by the submission deadline for appropriately qualified individuals.

II. Criteria for Membership

The PEC includes up to 16 diverse representatives of the patient community. Eight members from the previous application process will remain on the PEC. The current application process is to select up to eight new PEC members. Selected members will include the following: (1) patients who have personal experience with a disease or medical condition; (2) caregivers who help support a patient—parent, child, partner, other family member, or friend—as they manage their disease or medical condition; and/or (3) representatives of patient groups who, through their role in the patient group, have direct or indirect disease experience. Please note that for purposes of this activity, the term ''caregiver'' is not intended to include individuals who are engaged in caregiving as healthcare professionals; and the term ''patient group'' is used herein to encompass patient advocacy organizations, disease advocacy organizations, voluntary health agencies, nonprofit research foundations, and public health organizations. The ultimate goal of the application and selection process is to identify individuals who can represent patient voices for their patient community.

Selection criteria include the applicant's potential to meaningfully contribute to the activities of the PEC, ability to represent and express patient voices for their constituency, ability to work in a constructive manner with interested parties/groups (such as patients, caregivers, advocates, academic institutions, government agencies, medical product development companies), and understanding of the clinical research enterprise. Consideration will also be given to ensuring the PEC includes diverse perspectives and experiences, including but not limited to sociodemographic factors (such as age, gender, ethnicity, and education level) and disease experience. PEC members are required to be residents of the United States and must be 18 years of age or older.

Financial and other conflicts of interest will not necessarily make applicants ineligible for membership in the PEC. However, applicants cannot be direct employees of the medical product development industry or a currently registered lobbyist for an FDA-regulated industry.

III. Responsibilities and Expectations

Participation as a PEC member is voluntary. Meetings will be held up to four times per year and will be conducted virtually with the potential for in-person events (in the Washington, DC area).

Reasonable accommodations will be made for members with special needs for participation in a meeting or for any necessary travel. Applications for PEC membership are encouraged from individuals of all ages, sexes, genders, sexual orientations, racial and ethnic groups, education levels, income levels, geographic locations, and those with and without disabilities. Travel support will be provided, as applicable.

To help ensure continuity in its activities and organizational knowledge, the PEC will maintain staggered membership terms for patient community representatives. Membership terms for new members will be 2-year appointments, beginning January 1, 2025.

Additional responsibilities and expectations are set forth in the PEC Framework, which should be reviewed prior to submitting an application, and is available at *https://ctti-clinicaltrials.org/wp-content/uploads/2023/05/PEC-Framework_Revised-Apr-10-2023_FINAL.pdf.*

IV. Application Process

Any interested person may apply for membership on the PEC. To apply, go to *https://duke.qualtrics.com/jfe/form/SV_3DllHjcaGryUIlg.* The application is completed online and includes questions to help determine eligibility for the PEC, demographic and other background questions, and four brief essay questions. The brief essay questions, to be answered in 500 characters or fewer (including spaces), are as follows:

- Please explain why and how you would be able to represent and express the patient voice for the disease area(s) you selected above.
- Please give a few examples of experiences that demonstrate how you use active listening and two-way communication to work across interested parties/groups (such as patients, caregivers, advocates, academic institutions, government agencies, medical product development companies).
- Please provide a few examples of any experience you have with medical product development or understanding regulatory processes.
- Please tell us why you are interested in becoming a member of the PEC and how you would enrich our group discussions.

Completing the application also involves submitting: (1) a current one-page résumé or bio that summarizes your patient advocacy experience and related activities (PDF format required) and (2) a one-page letter of endorsement from a patient group (or other similar group) with which the applicant has worked closely on activities that are relevant to the PEC (PDF format required). Please note, only the application and the two documents specified above will be reviewed. Your completed application form, résumé or

bio, and letter of endorsement should all be submitted at the same time.

The résumé or bio must provide examples and descriptions of relevant activities and experiences related to the applicant's qualifications for PEC membership. The letter of endorsement should emphasize information relevant to the criteria for membership described above. This letter must be from and written by someone other than yourself. The letter may address topics such as the applicant's involvement in patient advocacy activities, experiences that stimulated an interest in participating in discussions about patient engagement in medical product development and regulatory decision processes, and other information that may be helpful in evaluating the applicant's qualifications as a potential member of the PEC.

Applications will be accepted until 11:59 p.m. Eastern Time on August 8, 2024 or until 75 applications are received, whichever happens first. Only complete applications will be considered.

The application review period will take a minimum of 2 months after 11:59 p.m. Eastern Time on August 8, 2024.

Additional information may be needed from some applicants during the review period, including information relevant to understanding potential sources of conflict of interest, in which case applicants will be contacted directly. All applicants (both those selected for PEC membership and those who are not selected) will be notified by email of the final application decision no later than December 31, 2024.

Dated: July 3, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15008 Filed 7–8–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Funding Opportunity for Ending the HIV/HCV/Syphilis Epidemics in Indian Country II (ETHIC II): A Syndemic Elimination Program for American Indian/Alaska Native Tribes and Urban Indian Communities

Announcement Type: New.

Funding Announcement Number: HHS–2024–IHS–ETHIC–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.933.

Key Dates

Application Deadline Date: July 31, 2024.

Earliest Anticipated Start Date: September 1, 2024.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for the second round of cooperative agreement for the Ending the Human Immunodeficiency Virus (HIV), Hepatitis C Virus (HCV), and Syphilis Epidemics (known as ''the Syndemic'') in Indian Country (ETHIC II) program. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and the Indian Health Care Improvement Act, 25 U.S.C. 1621q, 1660e. The Assistance Listings section of SAM.gov (*https://sam.gov/content/home*) describes this program under 93.933.

Purpose

The purpose of this program is to support communities to directly increase the diagnoses, treatment, and prevention of HIV, HCV, and syphilis.

The full Notice of Funding Opportunity and all application materials can be found on *Grants.gov* at *https://grants.gov/search-results-detail/355020.*

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for fiscal year (FY) 2024 is approximately $14 million. Individual award amounts are anticipated to be between $150,000 and $2,000,000.

Anticipated Number of Awards

The IHS anticipates issuing approximately 26 awards under this program announcement.

Period of Performance

The period of performance is for 5 years.

III. Eligibility Information

1. Eligibility

To be eligible for this funding opportunity an applicant must be one of the following, as defined by 25 U.S.C. 1603:

- A federally recognized Indian Tribe as defined by 25 U.S.C. 1603(14).
- A Tribal organization as defined by 25 U.S.C. 1603(26).
- An Urban Indian organization, as defined by 25 U.S.C. 1603(29).

IV. Agency Contacts

1. Questions on the program matters may be directed to:

Rick Haverkate, HIV/HCV/STI Branch, 5600 Fishers Lane, 08N07, MAIL STOP: 08N34–A, Rockville, MD 20857, Phone: 240–678–2873, Fax: 301–594–6213, Email: *Richard.Haverkate@ihs.gov.*

2. Questions on awards management and fiscal matters may be directed to:

Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Email: *DGM@ihs.gov.*

3. For technical assistance with *Grants.gov*, please contact the *Grants.gov* help desk at (800) 518–4726, or by email at *support@grants.gov.*

4. For technical assistance with GrantSolutions, please contact the GrantSolutions help desk at (866) 577–0771, or by email at *help@grantsolutions.gov.*

V. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

Roselyn Tso,

Director, Indian Health Service.

[FR Doc. 2024–14963 Filed 7–8–24; 8:45 am]

BILLING CODE 4166–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should