ComboMATCH eligibility without prior review by NCI and ECOG–ACRIN. Any press release or public disclosure requires clearance by NCI and NCI-ComboMATCH regulatory team.

- Laboratories must agree to use the existing workflow established by the NCI-ComboMATCH trial team to identify patients for the variant arms.
  - Laboratory results of NGS assays done for clinical care will be the subject of this initiative. There is no funding for ''screening'' a patient for NCI-ComboMATCH.
  - Laboratories must notify NCI-ComboMATCH sites that the laboratory results would potentially allow the patient to be eligible for NCI-ComboMATCH.
  - Laboratories must track how many assays per month detect variants that could make a patient eligible for NCI-ComboMATCH.
  - If the clinician presents the NCI-ComboMATCH study and the patient is eligible and desires to enter the study, the laboratory must agree to enter the results into the informatics system that assigns treatment in NCI-ComboMATCH (MATCHbox).
  - Laboratories must have a way to answer questions from NCI-ComboMATCH sites about their assay and must have a contact person for optimal communication with the NCI-ComboMATCH team.
- Prior to participation, laboratories must enter into a collaboration agreement with NCI. A sample agreement is available upon request and includes the requirement to participate in trial monitoring by NCI, the trial sponsor. As part of such a collaboration agreement, laboratories must agree to provide the licensing rights described in the CTEP IP Option to the Pharmaceutical Collaborators who provided agents for the NCI-ComboMATCH trial (*https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm*) (*https://www.gpo.gov/fdsys/pkg/FR-2011-03-11/pdf/FR-2011-03-11.pdf*) as well as agree to the data sharing and publication rights consistent with those agreements.
- No reimbursement for these activities (testing or notification of sites of NCI-ComboMATCH eligibility) exists.

Qualified laboratories serving a large component of an underrepresented population are the only ones being considered for this **Federal Register** Notice.

How to apply:

1. Submit letter of interest (LOI) as described above under ''Letter of Interest and Confidentiality Agreement'' to *NCICOMBOMATCHLabApps@nih.gov*.

2. LOIs must be submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH) on or before 5:00 p.m. EST on September 30, 2023. LOIs will be reviewed immediately upon receipt.

3. Notification of acceptance, non-acceptance or questions from Steering Committee will be sent to the designated contact person as soon as the LOI has been reviewed. This notification will include further instructions if a full application is invited.

4. Applications that have not been submitted within 6 weeks of notification of acceptance will be de-activated and not further considered.

5. DO NOT send a full application until you are invited to do so.

Review criteria for LOI:

Laboratory is a CLIA-certified laboratory within the United States.

Laboratory is able to provide evidence that its volume of patients tested is composed >30% underrepresented peoples.

Laboratory NGS assay has adequate sensitivity and specificity.

Laboratory tests tumor tissue for variants required for NCI-ComboMATCH.

Laboratory agrees to provide needed information for evaluation of the analytical validity of the test.

Laboratory agrees to contact sites regarding NCI-ComboMATCH eligibility.

Laboratory agrees to a collaboration with NCI as detailed above.

Review criteria for full application:

Laboratory supplies evidence that the assay meets analytical requirements as detailed above.

Laboratories are capable of contacting providers and tracking activity based on detection of potential variants.

Laboratories agree to execute a collaboration agreement with NCI, as well as to data sharing and sharing publication rights.

Laboratories agree to abide by the procedures in place for the NCI-ComboMATCH study and to collaborate fully with the NCI-ComboMATCH team.

For more information, contact *NCICOMBOMATCHLabApps@nih.gov*.

Dated: August 8, 2023.

Lyndsay N. Harris,

Associate Director, Cancer Diagnosis Program, Division of Cancer Treatment & Diagnosis, National Cancer Institute.

[FR Doc. 2023–17352 Filed 8–11–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the AIDS Research Advisory Committee, NIAID.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/*.

Name of Committee: AIDS Research Advisory Committee, NIAID.

Date: September 11, 2023.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: Report of Division Director and Division Staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, Conference Room: Grand Hall, 5601 Fishers Lane, Rockville, MD 20852 (Hybrid Meeting).

Contact Person: Pamela Gilden, Branch Chief, Science Planning and Operations Branch, Division of AIDS, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 8D49, Rockville, MD 20852–9831, 301–594–9954, *pamela.gilden@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *https://www.niaid.nih.gov/about/committees-aids-research,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: August 9, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–17397 Filed 8–11–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361 or email *Carlos.Graham@samhsa.hhs.gov.*

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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.

Proposed Project: Assessment of Communities Talk To Prevent Alcohol and Other Drug Misuse (Formerly Communities Talk To Prevent Underage Drinking)—(OMB No. 0930–0288)—Revision

The Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention (SAMHSA/CSAP) is requesting a revision from the Office of Management and Budget (OMB) for information collection regarding the Assessment of *Communities Talk to Prevent Alcohol and Other Drug Misuse,* which is implemented by the Substance Use Disorder Prevention Engagement Initiatives (SUDPEI) within CSAP. *Communities Talk* activities are grassroots activities that raise awareness of the public health dangers of substance misuse and engage communities in evidence-based prevention, particularly to individuals aged 12–25 years old. In this survey, substance use disorder (SUD) questions refers to any alcohol or drugs used in the 12 months prior to the survey and the language ''alcohol and other drug misuse'' will be used to ask questions about SUDs throughout the survey. Alcohol misuse includes any underage use of alcohol. Other drug misuse includes use of marijuana, cocaine (including crack), heroin, hallucinogens, inhalants, methamphetamine, and any use of prescription stimulants, tranquilizers or sedatives (*e.g.,* benzodiazepines), and pain relievers.[1] The most recent data collection was reinstated under OMB No. 0930–0288, Assessment of the Town Hall Meetings on Underage Drinking Prevention, which expires on May 31, 2025.

Changes

Under the most recent approval, the Organizer Survey consisted of 14 items. Under this revision, the Organizer Survey includes 12 items about the *Communities Talk* initiative and how communities might be carrying out evidence-based strategies to prevent alcohol and other drug misuse. The following table provides a summary of the changes that were made to the instrument.

Current question/item	Changes made
Burden statement	Updated with language provided by SAMHSA to include ''alcohol and other drug misuse'' verbiage: 'This information is being collected to assist the Substance Abuse and Mental Health Services Administration (SAMHSA) for the purpose of program monitoring of the Communities Talk to Prevent Alcohol and Other Drug Misuse initiative. This voluntary information collected will be used at an aggregate level to assess the *Communities Talk* stipend recipients' experiences with the events and alcohol and other drug misuse prevention activities deployed by their organizations or institutions. Under the Privacy Act of 1974, any personally identifying information obtained will be kept private to the extent of the law. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The OMB control number for this project is 0930–0288. Public reporting burden for this collection of information is estimated to average 15 minutes per encounter, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to SAMHSA Reports Clearance Officer, 5600 Fishers Ln., Room 15 E57B, Rockville, MD 20857.'

[1] Substance Abuse and Mental Health Services Administration. (2022). Highlights for the 2021 National Survey on Drug Use and Health. *https://www.samhsa.gov/data/sites/default/files/2022-12/2021NSDUHFFRHighlights092722.pdf.*