Agenda: To review and evaluate grant applications

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

Contact Person: Kelly Y. Poe, Ph.D., Acting Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 4F50, Bethesda, MD 20892–9834, 301–496–7291, *poeky@mail.nih.gov.*

Name of Committee: National Advisory Allergy and Infectious Diseases Council Acquired Immunodeficiency Syndrome Subcommittee.

Date: September 11, 2023.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

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

Open: 1:00 p.m. to 4:00 p.m.

Agenda: Report of the 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: Kelly Y. Poe, Ph.D., Acting Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 4F50, Bethesda, MD 20892–9834, 301–496–7291, *poeky@mail.nih.gov.*

Name of Committee: National Advisory Allergy and Infectious Diseases Council Microbiology and Infectious Diseases Subcommittee.

Date: September 11, 2023.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, Conference Room: Garden 2, 5601 Fishers Lane, Rockville, MD 20852 (Hybrid Meeting).

Open: 1:00 p.m. to 4:00 p.m.

Agenda: Report of the Division Director and Division Staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, Conference Room: Garden 2, 5601 Fishers Lane, Rockville, MD 20852 (Hybrid Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Acting Director, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 4F50, Bethesda, MD, 20892–9834, 301–496–7291, *poeky@mail.nih.gov.*

Name of Committee: National Advisory Allergy and Infectious Diseases Council Immunology and Transplantation Subcommittee.

Date: September 11, 2023.

Closed: 8:30 a.m. to 10:15 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, Conference Room: Garden 1, 5601 Fishers Lane, Rockville, MD 20852.

Open: 1:00 p.m. to 4:00 p.m.

Agenda: Report of the Division Director and Division Staff.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, Conference Room: Garden 1, 5601 Fishers Lane, Rockville, MD 20852 (Hybrid Meeting).

Contact Person: Kelly Y. Poe, Ph.D., Acting Director Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 4F50, Bethesda, MD 20892–9834 301–496–7291, *poeky@mail.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/advisory-council,* 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. 2023–17398 Filed 8–11–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Imaging Technology Development Study Section.

Date: August 25, 2023.

Time: 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Guo Feng Xu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5122, MSC 7854, Bethesda, MD 20892, 301–237–9870, *xuguofen@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: August 8, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–17316 Filed 8–11–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Letters of Interest (LOI) for NCI-ComboMATCH Laboratories

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) through its National Clinical Trials Network (NCTN) has developed a successor precision medicine trial to 'NCI-Molecular Analysis for Therapy Choice (NCI–MATCH)' entitled 'NCI-ComboMATCH'. The principle of this initiative is to overcome drug resistance to single-agent therapy by developing genomically-directed targeted agent combinations. All combinations must be supported by robust, preclinical *in vivo* evidence.

DATES: Letters of Interest (LOIs) should 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.

ADDRESSES: Submit LOIs by email to *NCICOMBOMATCHLabApps@nih.gov*. 9609 Medical Center Drive, 3 West, Room 360, Rockville, MD 20892.

FOR FURTHER INFORMATION CONTACT: Questions about this request for LOIs should be directed to *NCICOMBOMATCHLabApps@nih.gov* or Benjamin Kim at *benjamin.kim@nih.gov* or by phone at (240) 276–5961.

SUPPLEMENTARY INFORMATION:

NCI-ComboMATCH trial leadership invites applications for Clinical Laboratory Improvements Program (CLIA) certified/accredited laboratories that test tumor specimens from patients utilizing Next-Generation Sequencing (NGS) assays to participate in the NCI-ComboMATCH trial. These laboratories are required to have a catchment area that serves underrepresented populations and should be able to provide documentation of the proportion of subjects seen by the lab by race/ethnic origin. Laboratories serving a large percentage (≤30%) of African Americans, Native Americans, Hispanics, Asians and Pacific Islanders will be considered. In order to support this trial, the designated laboratories participating in NCI-ComboMATCH will identify patients for the specific molecular variants needed for trial eligibility. Laboratories will be asked to indicate on their report if a patient is eligible for one of the NCI-ComboMATCH subprotocols. If this is not feasible the lab is asked to contact the patients provider via letter, email or fax that the individual may be eligible for a NCI-ComboMATCH subprotocol if a specimen sent from the lab has a variant(s) that would potentially make the patient eligible for one of the treatment arms. Physicians will also be able to refer the patient directly to the NCI-ComboMATCH registration trial. In any of these cases, the laboratory will be required to provide the variant data to the NCI-ComboMATCH 'MATCHbox' which is a computer program that serves to gather information used to determine the eligibility of the particular patient to a treatment arm.

In accordance with 42 U.S.C. 285, of the Public Health Service Act, as amended. Like NCI–MATCH, NCI-ComboMATCH is conceived as a signal-seeking study. The NCI-ComboMATCH team will determine whether patients with tumor mutations, amplifications or translocations in the genetic pathway(s) of interest are likely to derive clinical benefit if treated with a combination of precision medicine agents targeting those specific pathway(s). This recruitment is for laboratories in areas serving underrepresented populations that can screen at least 100 patients per month.

Patients with histologically documented solid tumors whose disease has progressed following at least one line of standard systemic therapy or for whom no standard therapy exists are eligible if they meet the eligibility criteria for the trial. Further information about the NCI-ComboMATCH trial may be found at *https://ecog-acrin.org/clinical-trials/eay191-combomatch/.*

The selected collaborating outside laboratories may only refer patients on any of the variant arms for which their assay reports actionable mutations of interest (aMOIs). The assay must also report all exclusionary variants for the arm unless these occur at a frequency of <1% in cancer patients.

Only CLIA accredited/certified laboratories located in the United States may be considered for addition to the laboratory network.

Letter of Interest (LOI) and Confidentiality Agreement

Candidate laboratories should submit a letter of interest to *NCICOMBOMATCHLabApps@nih.gov* stating:

- Statement of interest in the proposed activity
- Laboratory name
- Proportion of underrepresented groups or populations tested by the lab
- Lead contact name, address, email address, and telephone number
- CLIA certification number
- Assay name
- Brief description of assay
  - Sensitivity and specificity for SNVs, indels, CNV, fusions
  - Method of analysis
  - Platform and variant calling
- Number of assays on patients per month
- Willingness to report to or contact providers of patients who are potentially eligible for one of the subprotocols on NCI-ComboMATCH
- Willingness to sign a collaboration agreement with NCI and to share data and publication rights.

Following an acceptable eligibility review to the NCI-ComboMATCH screening committee, the laboratory would execute a confidentiality agreement with NCI and will be provided with a detailed list of eligibility and exclusion variants for arms (approved at that time). The lab would then be required to submit an application by September 30th, 2023 for review by the NCI-ComboMATCH review committee. Candidate laboratories will be required to meet the following general requirements:

- Testing must be performed in a CLIA-certified or -accredited laboratory located in the United States.
- Assays may be on tumor tissue or circulating nucleic acids.
- Laboratory NGS panels must be analytically and clinically validated on DNA from human tumor tissue, with performance characteristics as follows:
  - Specificity at least 99% for single nucleotide variants, indels;
  - Sensitivity at least 95% for single nucleotide variants, indels;
  - Sensitivity of 90% for copy number variants (state fold of copy number variants that can be detected with 90% sensitivity);
  - 99% reproducibility between sequencers (if more than one sequencer is used) and between operators;
  - Lower limit of detection for SNVs, indels, and CNVs must be stated;
  - Laboratories should also provide these parameters if they have a validated circulating tumor DNA (ctDNA) assay;

  Laboratories must supply the following information in their application:
  - Lower limit of % tumor accepted, and whether (and which) enrichment procedures are employed;
  - Whether the lab archives images of slides from the tumor;
  - Whether the lab runs germline as well as tumor with the assay (a simultaneous germline sequencing is not required by NCI-ComboMATCH);
  - A detailed description of assay procedures, including starting material, extraction of nucleic acids, quality assurance, quality metrics, data analysis and filters must be supplied.
- Laboratory NGS test panels must interrogate actionable mutations of interest (aMOIs) required for enrollment into the available variant arms.
- The designated lab should be willing to provide residual nucleic acid from the sample they tested if the patient enrolls on NCI-ComboMATCH.
- As it is important that the dataset used for analysis in NCI-ComboMATCH be as robust as possible, the laboratory NGS test will require qualification, during which the performance of the laboratory will be compared with the NCI-ComboMATCH Central Laboratory test to ensure good agreement with that assay.
- Laboratories shall NOT advertise that they are screening laboratories for

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)