*Agenda:* Discussion of Patient Safety and Clinical Quality, Activities Regarding Novel Coronavirus, and Facility Planning.

*Place:* National Institutes of Health, Building 1, One Center Drive, 9000 Rockville Pike, Bethesda, MD 20892 (Virtual Meeting).

*Virtual Access:* The meeting will be videocast and can be accessed from the NIH Videocast *https://videocast.nih.gov/* and the CCRHB website *https://ccrhb.od.nih.gov/meetings.html.*

*Contact Person:* Gretchen Wood, Staff Assistant, National Institutes of Health, Office of the Director, One Center Drive, Building 1, Room 126, Bethesda, MD 20892, 301–496–4272, *woodgs@od.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: June 24, 2020.

**Ronald J. Livingston, Jr.,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2020–14023 Filed 6–29–20; 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 Pediatric Focused NCI-MATCH Laboratories

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice; extension.

**SUMMARY:** The National Cancer Institute (NCI) through its National Clinical Trials Network (NCTN) is developing a successor precision medicine trial to 'NCI-Molecular Analysis for Therapy Choice (NCI-MATCH)' entitled 'NCI-ComboMATCH'. The principal of this intiative 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. Due to the coronavirus pandemic the NCI is providing an extension of the previously published notice in the **Federal Register** on March 11, 2020, to allow candidate more time to submit LOIs.

**DATES:** The due date for Letters Of Interest (LOIs) has been extended and should now be submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH) on or before 5:00 p.m. EST on September 30, 2020.

**ADDRESSES:** Submit LOIs by email to *NCICOMBOMATCHLabApps@nih.gov.* 9609 Medical Center Drive, 3 West, Room 526, MSC 9728, Rockville, MD 20892.

**FOR FURTHER INFORMATION CONTACT:** Questions about this request for LOIs should be directed to *NCICOMBOMATCHLabApps@nih.gov.* James V. Tricoli, at 240–276–5725 or *tricolij@mail.nih.gov,* can also provide further information.

**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. In order to support this trial, the designated laboratories participating in NCI-ComboMATCH will identify patients for the specific variants needed for trial eligibility. Laboratories will be required to contact any of the NCTN sites that have activated NCI-ComboMATCH if a specimen sent from one of these sites has a variant(s) that would potentially make the patient eligible for one of the treatment arms.

This notice was previously published in the **Federal Register** on March 11, 2020, page 14208–14210 (85 FR 14208). The purpose of this notice is to allow an additional 90 days for submission of the LOI. The due date for LOI submission has been extended from the previous date of June 30, 2020 to September 30, 2020 to allow more labs to submit. This is necessary due to the impact of the coronavirus pandemic. In accordance with 42 U.S.C. 285, of the Public Health Service Act, as amended. Similar to 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 pediatric focused labs that can specifically screen 250 pediatric patients seen at NCTN sites per month.

Patients with histologically documented solid tumors, lymphomas and multiple myeloma 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.

The selected collaborating outside laboratories may only act (*i.e.,* 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
- 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 pediatric patients per month
- Number assays on patients seen at NCTN study sites per month
- What other CLIA approved/certified tests have been validated in your laboratory?
- Willingness to contact sites regarding results with a potentially eligible for NCI-ComboMATCH
- Willingness to sign a collaboration agreement with NCI (*https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm*) 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 the 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 within 2 months 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 can be on tumor tissue (including lymphoma) or circulating tumor DNA (ctDNA).
- Laboratory NGS panels must be analytically and clinically validated on DNA from human tumor tissues, 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 SNV, indels, CNV must be stated.

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 also 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. Applicant laboratories must state which NCI-ComboMATCH arms they would like to participate in.
- Academic laboratories must be located at a center that participates in NCI-ComboMATCH.
- The designated lab should be willing to provide residual nucleic acid from the sample they tested if the patient enrolls on NCI-ComboMATCH.
- 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 the NCI-ComboMATCH team.
- Laboratories must agree to use the existing workflow established by the NCI 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 Combo MATCH.
  - Laboratories must track how many assays per month detect rare variants that could make a pediatric 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 results into the informatics system that assigns treatment in Combo MATCH (MATCHbox).
  - Laboratories must have a way to answer questions from Combo MATCH 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. 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*) 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 underserved populations are encouraged to participate.

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 will be accepted for 3 months from the date of this notice. 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 of the LOI 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.

Academic laboratories must have NCI-ComboMATCH open at their site.

Laboratory NGS assay has adequate sensitivity and specificity.

Laboratory tests tumor tissue for rare variants as described in NCI-ComboMATCH.

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

Laboratory is likely to screen at least 250 pediatric patients at NCTN sites for NCI-ComboMATCH per month.

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 clinical sites, tracking activity, and of screening at least 250 pediatric patients at NCTN sites per month to the study 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: June 24, 2020.

**James V. Tricoli,**

*Chief, Diagnostic Biomarkers and Technology Branch, Cancer Diagnosis Program, National Cancer Institute.*

[FR Doc. 2020–14043 Filed 6–29–20; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Submission for OMB Review; 30 Day Comment Request Application Process for Clinical Research Training and Medical Education at the Clinical Center and Its Impact on Course and Training Program Enrollment and Effectiveness (Clinical Center)

**AGENCY:** National Institutes of Health, HHS.