

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. 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 deactivated 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 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 200 patients at NCTN sites per month for NCI-ComboMATCH.

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 screening at least 200 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: March 5, 2020.

James V. Tricoli,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Member Conflict: Stroke, Traumatic Brain Injury and Sport-Related Concussions, March 25, 2020, 10:00 a.m. to 3:00 p.m., at the National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, which was published in the **Federal Register** on March 04, 2020, 85 FR 12799.

The meeting will be held on March 26, 2020. The meeting time and location remain the same. The meeting is closed to the public.

Dated: March 5, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, RFA-RM-19-008: NIH Director's Early Independence Award Review, March 18, 2020, 08:30 a.m. to March 19, 2020, 12:00 p.m. which was published in the **Federal Register** on February 20, 2020, 85 FR 9787.

The meeting location is being changed to National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, meeting start time is changing to 09:00 a.m. and meeting end time to 03:00 p.m. The meeting is closed to the public.

Dated: March 5, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

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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.

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 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.

NCI-ComboMATCH trial leadership invites applications for Clinical Laboratory Improvements Program (CLIA) certified/accredited laboratories that test tumor specimens from pediatric 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 pediatric patients for the specific variants needed for trial eligibility. Laboratories will be