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 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 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.

[FR Doc. 2020–04915 Filed 3–10–20; 8:45 am]

BILLING CODE 4140–01–P

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.

[FR Doc. 2020–04928 Filed 3–10–20; 8:45 am]

BILLING CODE 4140–01–P

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.

[FR Doc. 2020–04929 Filed 3–10–20; 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.

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.

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

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.

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 June 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 *tricolij@mail.nih.gov* can also provide further information.

SUPPLEMENTARY INFORMATION: 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 pediatric 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 and lymphomas 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
- Provide a list of other CLIA approved/certified tests that 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 6 weeks 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 variants that could make a pediatric patient eligible for NCI-ComboMATCH.
  - If the clinician presents the NCI-ComboMATCH study and the pediatric 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.

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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 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: March 5, 2020.

James V. Tricoli,

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

[FR Doc. 2020–04916 Filed 3–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Office of the Director, National Institutes of Health, Board of Scientific Counselors, May 15, 2020, 10:00 a.m. to 2:00 p.m., National Institutes of Health, 1 Center Drive, Building 1, Room 151, Bethesda, MD 20892, which was published in the **Federal Register** on February 28, 2020, 85 FR 12797.

The meeting notice is amended to change the email of the Contact Person from *mmburney@od.nih.gov* to *mmcburney@od.nih.gov*. The meeting is partially Closed to the public.

Dated: March 6, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–04930 Filed 3–10–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2020–0013; OMB No. 1660–0061]

Agency Information Collection Activities: Proposed Collection; Comment Request; Federal Assistance to Individuals and Households Program

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the need to collect information from individuals or households, and States, territories, and Tribal governments in order to provide and/or administer disaster assistance through the Individuals and Households Program.

DATES: Comments must be submitted on or before May 11, 2020.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2020–0013. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW, 8NE–1604, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Brian Thompson, Supervisory Program Specialist, FEMA Recovery Directorate, 540–686–3602. You may contact the