

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: September 6, 2017.

Open: 8:30 a.m. to 12:00 p.m.

Agenda: To present the Director's Report and other scientific presentations.

Place: National Institutes of Health, Natcher Building Forty-five, Conference Rooms E1/E2, 45 Center Drive, Bethesda, MD 20892.

Closed: 3:45 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building Forty-five, Conference Rooms E1/E2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 7323, MSC 5452, Bethesda, MD 20892, (301) 594-8843, stanfibr@nidk.nih.gov.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Diabetes, Endocrinology and Metabolic Diseases.

Date: September 6, 2017.

Closed: 1:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building Forty-five, Natcher Conference Center, Room E1, 45 Center Drive, Bethesda, MD 20892.

Open: 2:00 p.m. to 3:30 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building Forty-five, Natcher Conference Center, Room E1, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 7323, MSC 5452, Bethesda, MD 20892, (301) 594-8843, stanfibr@nidk.nih.gov.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Kidney, Urologic and Hematologic Diseases.

Date: September 6, 2017.

Open: 1:00 p.m. to 3:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building Forty-five, Natcher Conference Center, Room F2, 45 Center Drive, Bethesda, MD 20892.

Closed: 3:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building Forty-five, Natcher Conference Center, Room F2, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd.

Room 7323, MSC 5452, Bethesda, MD 20892, (301) 594-8843, stanfibr@nidk.nih.gov.

Name of Committee: National Diabetes and Digestive and Kidney Diseases Advisory Council; Digestive Diseases and Nutrition.

Date: September 6, 2017.

Open: 1:00 p.m. to 2:00 p.m.

Agenda: To review the Division's scientific and planning activities.

Place: National Institutes of Health, Natcher Building Forty-five, Natcher Conference Center, Room F1, 45 Center Drive, Bethesda, MD 20892.

Closed: 2:15 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building Forty-five, Natcher Conference Center, Room F1, 45 Center Drive, Bethesda, MD 20892.

Contact Person: Brent B. Stanfield, Ph.D., Director, Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd. Room 7323, MSC 5452, Bethesda, MD 20892, (301) 594-8843, stanfibr@nidk.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 instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors 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: www.nidk.nih.gov/fund/divisions/DEA/Council/coundesc.htm, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: July 27, 2017.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2017-16192 Filed 8-1-17; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Request for Letters of Interest for NCI-MATCH Laboratories

SUMMARY: The National Cancer Institute (NCI) in collaboration with the NCI

Molecular Analysis for Therapy Choice (MATCH) trial leadership (NCT 02465060) 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 MATCH trial. The NCI MATCH trial has implemented a new process for identifying patients for arms with rare variant eligibility criteria. Laboratories will contact any of the approximately 1100 sites that have activated NCI MATCH if a specimen sent from one of these sites has a rare variant that would potentially make the patient eligible for one of the treatment arms open in this initiative.

DATES: LOIs should be submitted to the National Cancer Institute (NCI), National Institutes of Health (NIH) on or before 5:00 p.m. EST on January 31, 2018.

ADDRESSES: Submit LOIs by email to NCIMATCHLabApps@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 NCIMATCHLabApps@nih.gov. James V. Tricoli tricoli@mail.nih.gov can also provide further information.

SUPPLEMENTARY INFORMATION: NCI-MATCH aims to establish whether patients with tumor mutations, amplifications or translocations in one of the genetic pathways of interest are likely to derive clinical benefit (primary objective: Objective response; secondary objective: Progression-free survival of at least 6 months) if treated with agents targeting that specific pathway in a single-arm design (see current arms below).

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. Further information about the NCI-MATCH trial may be found at <http://ecog-acrin.org/trials/nci-match-eay131>.

The selected collaborating laboratories may only act (*i.e.*, refer patients) on any of the rare 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.

CLIA accredited/certified laboratories located in the United States may be

considered for addition to the laboratory network.

Letter of Interest (LOI) and Collaboration Agreement

Candidate laboratories should *submit a letter of interest* to NCIMATCHLabApps@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 per month
- Number of patients whose assay results would make them potentially eligible for the rare

variant arms (below) in the last 6 months

- Willingness to contact sites regarding results with a rare variant potentially eligible for NCI MATCH
- Willingness to sign a collaboration agreement with NCI and to share data and publication rights
- Which arms the laboratory is prepared to address.

The arms that are included in the rare variant protocol amendment are:

Rare variant candidate	MATCH subprotocol (agent)
AKT1 mut	EAY131-Y (AZD5363).
NF2 loss	EAY131-U (Defactinib).
MET amplification	EAY131-C1 (Crizotinib).
BRAF V600	EAY131-H (Dabrafenib + Trametinib).
SMO/PTCH1	EAY131-T (Vismodegib).
BRAF non V600	EAY131-R (Trametinib).
EGFR T790M	EAY131-E (AZD9291).
ALK translocation	EAY131-F (Crizotinib).
cKIT mutation	EAY131-V (Sunitinib).
EGFR mutation	EAY131-A (Afatinib).
ROS1 translocation	EAY131-G (Crizotinib).
GNAQ/GNA11	EAY131-S2 (Trametinib).
MET exon 14 skipping	EAY131-C2 (Crizotinib).
NTRK fusions	EAY131 Z1E (Loxo101).
MTOR mutations	EAY131-L (MLN0128).
TSC1 or TSC2 mutations	EAY131-M (MLN0128).
CCND 1,2,3 amplifications	EAY131-Z1B (Palbociclib).
CDK4 or CDK6 amplification	EAY131-Z1C (Palbociclib).
DDR2 mutation	EAY131-X (Dasatinib).

Following an acceptable eligibility review to the NCI MATCH 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 in which the lab has interest. The lab would then be required to submit an application within 3 months for review by the NCI-MATCH steering 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 must be on tumor tissue only (including lymphoma and myeloma). Assays using circulating nucleic acids will not be accepted at this time.
- Laboratory NGS panels must be analytically and clinically validated, 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 MATCH)
- 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 Rare Variant Arms (see table above). Applicant laboratories must state the MATCH arms in which they would like to participate.

• *Academic* laboratories must be located at a center that participates in NCI MATCH.

• As it is important that the dataset used for analysis in NCI MATCH 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-MATCH central laboratory test to ensure good agreement with that assay. Concordance between the results from each lab and results of the NCI MATCH NGS assay run on an archived specimen will be tracked; if concordance falls below 90% for SNVs and indels, or 80% for CNVs, the laboratory must be willing to address these issues with the NCI MATCH team. If they cannot be addressed to the satisfaction of the NCI MATCH team, the laboratory may be eliminated from participation in NCI MATCH.

• Laboratories shall NOT advertise that they are screening laboratories for MATCH eligibility. Any press release or public disclosure requires clearance by NCI and NCI MATCH.

• Laboratories must agree to use the existing workflow established by the NCI MATCH trial to identify patients for the Rare Variant Arms. This includes use of the MATCH Rare Variant

template to identify aMOIs for submission to MATCHbox.

- 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 MATCH.
- Laboratories must notify NCI MATCH sites that the laboratory results would potentially allow the patient to be eligible for NCI MATCH.
- Laboratories must track how many assays per week detect rare variants that could make a patient eligible for NCI MATCH.
- If the clinician presents the MATCH study and the patient is eligible and desires to enter the study, the laboratory must agree to fill out a spreadsheet that can be used to put the results into the informatics system that assigns treatment in NCI MATCH (MATCHbox).
- Laboratories must have a way to answer questions from NCI MATCH sites about their assay and must have a contact person for optimal communication with the NCI MATCH 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 MATCH 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 MATCH 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 Collaboration Agreement” to NCIMATCHLabApps@nih.gov.
2. LOIs will be accepted until January 31, 2018 at 5:00 p.m. Eastern Time. LOIs will be reviewed on a monthly basis, with those arriving by the 15th day of the month being reviewed and answered by the 15th day of the following month.
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 3 months of notification of acceptance will be deactivated, and a new LOI must then be submitted if the laboratory wishes to participate in NCI MATCH.

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

Review criteria for LOI:

- Laboratory is a CLIA certified or accredited laboratory within the United States.
- Academic laboratories must have NCI MATCH open at their site.
- Laboratory has adequate sensitivity, specificity.
- Laboratory tests tumor tissue for rare variants as described in NCI MATCH.
- Laboratory agrees to provide needed information for evaluation of the analytical validity of the test.
- Laboratory is likely to refer at least 100 patients to NCI MATCH based on detection of rare variants in the past.
- Laboratory agrees to contact sites regarding NCI MATCH eligibility.
- Laboratory agrees to a collaboration with NCI as detailed above.

Review criteria for full application:

- Laboratory NGS assay interrogates inclusionary and all exclusionary variants for arms in which the laboratory will participate.
- Laboratory supplies evidence that the assay meets analytical requirements as detailed above.
- Laboratories are capable of contacting clinical sites, tracking activity, and of referring at least 100 patients to the study based on detection of rare variants in the past.
- 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 MATCH study and to collaborate fully with the MATCH team.

For more information, contact NCIMATCHLabApps@nih.gov.

Dated: July 20, 2017.

James V. Tricoli,

Chief, Diagnostic Biomarkers and Technology Development Branch, Cancer Diagnosis Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute.

[FR Doc. 2017-16203 Filed 8-1-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2); 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 purpose of this meeting is to evaluate requests for preclinical development resources for potential new therapeutics for the treatment of cancer. The outcome of the evaluation will provide information to internal NCI committees that will decide whether NCI should support requests and make available contract resources for development of the potential therapeutic to improve the treatment of various forms of cancer. The research proposals and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the proposed research projects, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Cancer Institute Special Emphasis Panel; Jun2017 Cycle 26 NExT SEP Committee Meeting.

Date: August 31, 2017.

Time: 8:30 a.m. to 4:30 p.m.

Agenda: To evaluate the NCI Experimental Therapeutics Program Portfolio.

Place: National Institutes of Health, 9000 Rockville Pike, Building 31, Wing C, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Persons: Barbara Mroczkowski, Ph.D., Executive Secretary, Discovery Experimental Therapeutics Program, National Cancer Institute, NIH, 31 Center Drive, Room 3A44, Bethesda, MD 20817 (301) 496-4291, mroczkoskib@mail.nih.gov.

Toby Hecht, Ph.D., Executive Secretary, Development Experimental Therapeutics Program, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 3W110, Rockville, MD 20850, (240) 276-5683, toby.hecht2@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)