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.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, contact: Robert M. Lembo, MD, Office of Clinical Research Training and Medical Education, NIH Clinical Center, National Institutes of Health, 10 Center Drive, Room 1N252C, Bethesda, MD 20892–1158, or call non-toll-free number (301) 496–2636, or Email your request, including your address to: *robert.lembo@nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on April 16, 2020, page 21255–21256 (85 FR 21255–21256) and allowed 60 days for public comment. One comment was received. The purpose of this notice is to allow an additional 30 days for public comment.

The Clinical Center, National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

Proposed Collection Title: Application Process for Clinical Research Training and Medical Education at the NIH Clinical Center, OMB #0925–0698, Expiration date July 31, 2020, REVISION, National Institutes of Health Clinical Center (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The primary objective of the application process is to allow the Office of Clinical Research Training and Medical Education (OCRTME) at the NIH Clinical Center to evaluate applicants' qualifications to determine applicants' eligibility for courses and training programs managed by the Office. Applicants must provide the required information requested in the respective applications to be considered a candidate for participation. Information submitted by candidates for training programs is reviewed initially by OCRTME administrative staff to establish eligibility for participation. Eligible candidates are then referred to the designated training program director/administrator or training program selection committee for review and decisions regarding acceptance for participation. A secondary objective of the application process is to track enrollment in courses and training programs over time.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours is 333.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
Clinical Electives Program	Pre Doctoral Students	300	1	20/60	100
Graduate Medical Education	Physicians	100	1	20/60	33
Medical Research Scholars Program	Pre Doctoral Students	200	1	20/60	67
Resident Electives Program	Physicians	100	1	20/60	33
Bioethics Fellowship Program	Pre Doctoral, Post-Doctoral	300	1	20/60	100
Total			1000		333

Dated: June 25, 2020.

Laura M. Lee,

Project Clearance Liaison, NIH Clinical Center, National Institutes of Health.

[FR Doc. 2020–14057 Filed 6–29–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) 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: National Institute on Aging Special Emphasis Panel; Long-Term Services for Dementia Care.

Date: July 17, 2020.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Video Meeting).

Contact Person: Kimberly Firth, Ph.D.,Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2W200, Bethesda, MD 20892, (301) 402–7702, *firthkm@mail.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. 93.866, Aging Research, National Institutes of Health, HHS)