ACCESS National Molecular Pathology Board (MPB) Clinician Submission Guide

Guide Overview

About ACCESS and the MPB

ACCESS is a national initiative with the mission that every child with cancer in Canada will have access to the latest scientific advances, diagnostic tools, therapies, and supportive care leading to better outcomes and improved quality of life. Within ACCESS, the **Cancer Biology Theme** focuses on advancing key biological questions and establishing pathways to develop and equitably access novel tools and therapies. One such pathway is the **National Molecular Pathology Board (MPB).**

The **aim of the MPB** is to improve patient access to emerging molecular pathology tests on a case-by-case basis. The MPB reviews pediatric, adolescent, and young adult (AYA) patient cases in which there is significant potential benefit from specialized molecular pathology expertise or access to assays not currently available at the treating centre. Where cost is a barrier to access, the MPB may recommend and support coverage for some or all of the associated testing.

The MPB is intended to complement—not replace—the work of clinical care teams and existing tumour boards. Whenever possible, it works in close collaboration with these teams to support patient care.

MPB Study and Eligibility Criteria

The work of the Molecular Pathology Board (MPB) is conducted as part of the **MPB study (H25-02517)**, titled *"Assessing the Need, Accessibility, and Utility of Advanced Molecular Tests for Pediatric Oncology Patients."* This study has received approval from the UBC C&W Research Ethics Board (REB).

The study aims to assess the accessibility and clinical utility of advanced molecular tests for pediatric and adolescent and young adult (AYA) patients with cancer across Canada. Through the development of a de-identified clinical data registry, the study seeks to identify molecular tests that may benefit individual patients and to characterize existing gaps in access. Findings from this work will help inform strategies to improve equitable access to advanced molecular testing nationwide.

Clinician Eligibility Criteria to Participate in the MPB Study

Eligible health care professionals must:

- Be a medical professional involved in the care of cancer patients at a Canadian health institution
- Agree to present the patient case to the MPB, participate in case discussion, and provide updates as required by the study
- Complete the MPB electronic consent (e-consent) form. For more information and to sign the form, please initiate the case submission process in REDCap.

Patient Case Eligibility Criteria

Eligible patient cases must meet the following criteria:

- Child, adolescent, or young adult (AYA) aged 39 years or younger
- Confirmed or suspected current or prior cancer diagnosis
- Patient is being treated or followed at a Canadian health institution

Biospecimens for Testing

- Relevant biospecimens are available or will be collected prospectively and can be accessed for testing
- No minimum sample requirements have been established, as the list of MPB-approved assays and associated sample requirements is evolving
- Please refer to the MPB-approved list of assays on the MPB webpage for the most up-to-date information

Requirements

To Submit a Patient Case to the MPB

The following information is required:

☐ **Completed clinician e-consent form** to participate in the MPB study (this can be completed during the case submission process)
☐ **Clinical information** that will need to be entered on the MPB Data Collection – Intake Form, including de-identified patient information, history of present illness, prior and current treatments, and relevant test results
☐ **Availability of biospecimens** for molecular testing that will need to be entered on the MPB Data Collection – Intake Form

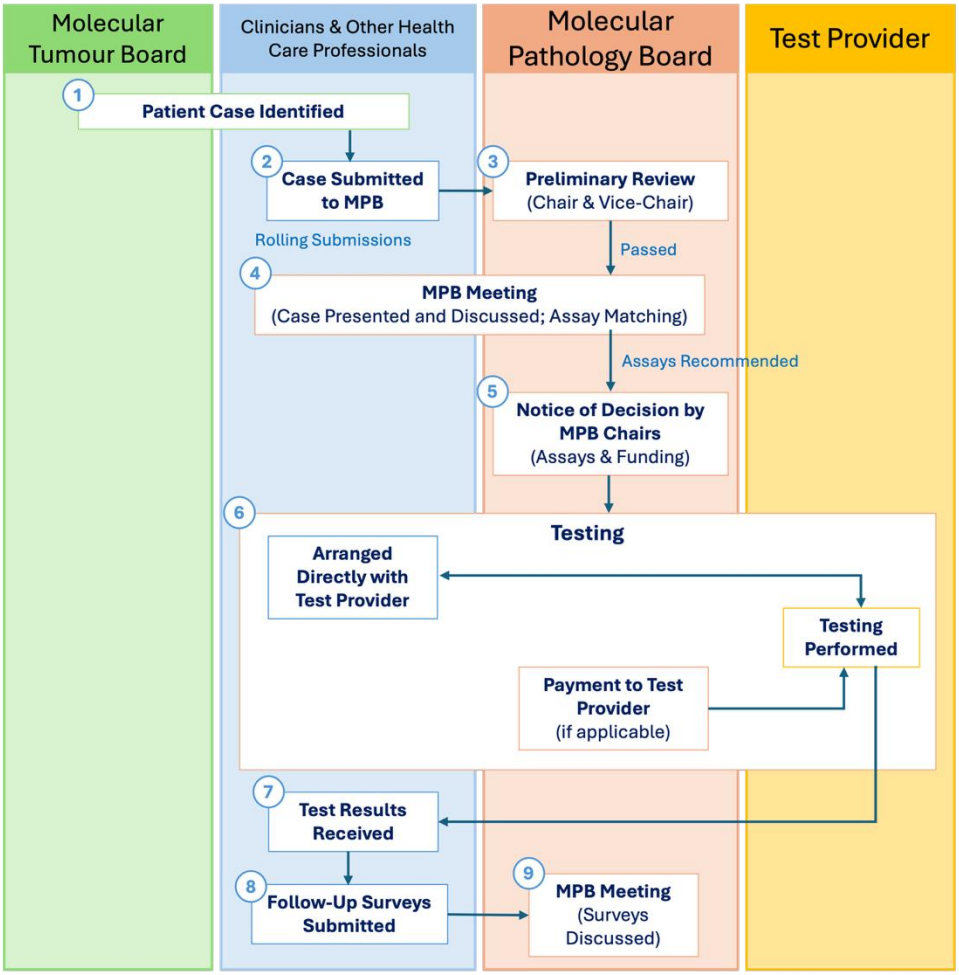
To Attend the MPB Meeting

☐ **An electronically signed MPB attestation form** for anyone presenting at or attending an MPB meeting. By signing, participants agree not to share patient-specific or discussion-related information outside the Board. Because incidental information from other cases may be discussed, all attendees are asked to sign the form. Once completed, the attestation applies to all future MPB meetings.

Workflow

The MPB workflow is subject to change. Any updates or modifications will be implemented with MPB approval and may occur without prior notice.

Workflow Diagram



1. **Patient Case Identified**
   Identified by a clinician (or another member of the healthcare team), or by a molecular tumour board (MTB) or a committee.
2. **Patient Case Submitted to the MPB**
   *Submitted by the clinician via completion of the *MPB Data Collection – Intake Form* (REDCap).*
3. **Preliminary Review by the MPB Chair and Vice-Chair**
   Review conducted to confirm alignment with the MPB mandate and eligibility criteria.
4. **MPB Meeting**
   The responsible clinician presents the patient case.
   The case is discussed, assay matching occurs, and recommendations are made to the MPB Chairs.
5. **Notice of Decision by MPB Chairs**
   A letter outlining recommended assay(s) and the funding decision is shared with the clinician.
6. **Testing**
   Testing is arranged between the clinician and the test provider.
   Payment is made by the MPB to the test provider (if applicable).
7. **Report of Test Results**
   Test reports are sent by the test provider directly to the clinician.
   The MPB does not receive test results or reports from the lab.
8. **Follow-Up Surveys**
   *The clinician reports on impact and patient outcomes by completing the *MPB Data Collection – Follow-Up Surveys* at 6-month intervals.*
9. **Additional Communications and Discussions**
   Follow-up survey findings are discussed with the MPB for study purposes.
   Additional meetings or follow-up communications may be arranged at the request of the MPB or the clinician.

Submission Process

Clinicians can submit patient cases to the MPB on a rolling basis and may request specific assays for priority matching. If no specific assay is requested, all relevant assays will be considered equally. Submissions begin by completing the **MPB Data Collection – Intake Form** on REDCap. An automatic acknowledgement will be sent upon submission. The study coordinator will contact the clinician to arrange a meeting with the full Board, provided the form passes preliminary review (see **Case Review Process**).

Some cases may also be identified through molecular tumour boards (MTBs) or other boards and committees linked to programs such as **Precision Oncology For Young peopLE (PROFYLE)**, **Kids Cancer Sequencing (KiCS)**, **SIGNATURE**, and **Pediatric Personalized OncoGenomics (PedsPOG)** sequencing programs. In such instances, the physician responsible for the patient may be asked by the board to consider submitting the case to the MPB.

Case Review Process

Following submission, patient cases undergo **preliminary review** by the MPB Chairs to confirm alignment with the MPB's mandate and eligibility criteria. If approved, the responsible physician is invited to present the case to the MPB. Additional subject-matter experts may be invited by the Chairs as needed.

During the **full Board review**, the responsible physician presents the patient case. The Board evaluates the clinical context, disease characteristics, prior testing, treatment history, and the potential clinical or scientific value of additional molecular testing. Focus is placed on advanced molecular assays that may provide meaningful insights into diagnosis, prognosis, treatment selection, or disease monitoring, while also considering feasibility and relevance. Discussions may also address assay accessibility and disparities for the purposes of the MPB study.

The MPB serves as an expert advisory body, providing multidisciplinary input and recommendations to support clinical decision-making. It does not replace the treating clinician's judgment but offers guidance on potential molecular testing strategies and assay prioritization.

Key decision points include determining whether additional molecular testing is warranted, assessing whether recommended assays are already accessible through institutional, provincial, federal, or other funding mechanisms, and identifying assays that may require MPB support. Final funding decisions for MPB-recommended assays are made by the MPB Chair and Vice-Chair.

Assay Matching

When appropriate, the MPB matches patient cases to potential molecular assays based on disease type, clinical question, prior results, and emerging scientific evidence. The Board may recommend assays that are already clinically available or investigational/preclinical tests where there is a strong rationale for potential benefit.

In the REDCap **MPB Data Collection – Intake Form**, clinicians may request specific assays for priority consideration by the MPB. If no specific assays are selected, all relevant assays from the MPB-approved list on the ACCESS MPB webpage will be considered.

If a clinician is aware of an assay that meets minimum criteria but is not yet on the MPB-approved list, there is a section in the intake form to describe and request that assay.

Assay Criteria:

- Highly developed research or clinical molecular assay
- Potential to benefit the patient (e.g., clarify diagnosis, guide treatment, monitor relapse, recurrence, or metastasis)
- Available at a Canadian institution(s)
- Applicable to pediatric, adolescent, and/or young adult cancer patients
- Substantial gaps in assay accessibility exist among healthcare professionals

Please note that even assays meeting the above criteria may not be added to the MPB-approved list for various reasons. To notify the MPB of an assay without submitting a patient intake form, complete the **"Notify the MPB of an Advanced Molecular Assay"** form on the MPB webpage.

Testing and Reporting

For any assays recommended by the MPB, testing is arranged directly between the health care professional and the test provider. Assay results are reported directly to the health care professional by the test provider. Under the current MPB model, the MPB does not receive patient case information directly from test providers.

It is important to note that MPB approval does not guarantee testing. All conditions set by the test provider must also be met. For example, testing may not proceed if the patient declines consent for assays conducted under a study requiring it, or if there is insufficient biospecimen available. For more information on assay-specific requirements, please refer to the **MPB-approved list of assays**, which includes contact details and links to test provider websites and relevant publications.

Follow-Up

The MPB requests follow-up information from clinicians to understand the impact of the assay and assay accessibility. Automatic email reminders will be sent out at regular intervals set at every 6 months for 2 years and will be completed on the REDCap platform.

Timelines

- **Acknowledgement of receipt of the intake form:** Automatic via REDCap and by email.
- **Decision from preliminary review:** Typically within 2–3 business days, communicated via email from the study coordinator. If approved for full MPB review, scheduling will begin at this time.
- **Scheduling the MPB meeting – Case discussion and recommendations:** Meetings are generally scheduled within 2–3 weeks of passing preliminary review, depending on case complexity and volume.
- **Written recommendations with final decision of the Chairs:** Typically within 2–3 business days of the MPB meeting.
- **Testing and results:** The MPB will connect clinicians with the test provider as soon as possible. Receipt of results is highly variable and depends on the assay and whether the test provider's conditions are met (see the MPB-approved list of assays for links and additional information).
- **Follow-up surveys:** Every 6 months for 2 years, beginning with an initial follow-up survey.

Timelines are approximate and may vary. The MPB may continue to review and support patient cases for as long as expertise, services, and funding are available.

Funding and Access Considerations

For any assay recommended by the full Board to the Chair and Vice-Chair, the Chairs may choose to recommend it with or without funding support. If MPB funds are approved, payments—including shipping—are arranged directly between the MPB and the test provider.

Please note that the MPB may also recommend tests that are already accessible and covered by institutional, provincial, federal, or other funding. MPB funds will **not** be applied to these assays or tests.

Data Handling and Privacy

Patient data is collected and managed on the REDCap platform of the BC Children's Hospital Research Institute. Any information is de-identified at the source and summarized on the patient intake form. MPB members and any individuals attending meetings where patient cases are discussed are required to have signed the MPB Attestation Form, confirming their commitment to confidentiality and ensuring that data are not transferred or disclosed. Any permission to access data by external research groups will be governed by the MPB, and any data sharing will be conducted in accordance with ethical guidelines and institutional privacy regulations.

Contact Information

For help before or during submission, please contact the study coordinator listed at the bottom of the MPB webpage.

Forms and Resources

- ACCESS National Molecular Pathology Board Webpage (everyone)
    - Up-to-date MPB-Approved List of Assays (everyone)
    - Submit a Patient Case (health care professionals)
    - Notify the MPB of an Advanced Molecular Assay for Consideration
- MPB Attestation Form (members of the MPB; researchers & health care professionals attending meetings)
- Clinician's E-Consent Form – MPB Study (health care professionals)