



Pan-Canadian Project Applications

Summary of Clarifications and Frequently asked questions

APPLICATION CONTENT

- The budget request through the Pan-Canadian application should be used to generate **gold cohort standard cases**, which means as a minimum the generation of WGTS, H&E, and Clinical Data. Please refer to the Gold Cohort Policy and Clinical Data Model for more definitions: <https://www.marathonofhopecancercentres.ca/researcher-hub/policies-and-guidelines>
- The application should include the 3 years until the end of the Health Canada (HC) funded project, **FY2023-24 to FY2025-26**. Awarded applications will sign one single RPGA for the 3 years (1 RPGA directly with each Institution).

The Application includes the Application file in word format plus a work plan template in excel. Please submit your application as one combined PDF if possible.

- The application should include the total number of cases for the project's full term, by year, so we can reasonably rely on them for our 15,000-case count gold cohort projections to Health Canada. It is important to show evidence and rationale that the cases can be completed in the time proposed. The review committees will seriously consider the probability of full case delivery as part of their assessment.
- Are **figures and tables** included in the page limits of the application?

Figures and tables can be added as an Appendix with a 5-page limit.

- Although we encourage prospective cases, justified retrospective cases will be considered. Cohorts would be able to use retrospective expenses as match funds up to 1 year prior to the start of the funding, which is projected for April 1, 2023. This means that expenses incurred in the preparation of the proposed cases **from April 1, 2022, would be allowed to be included as match expenditures**. In exceptional cases only, we will consider requests to go further back in time (with a maximum of April 1, 2019) with a detailed justification that should include the scientific rationale and an estimation of the gold standard cases that would be additionally delivered if an earlier start of the period of performance is allowed.
- If we have banked tissue from patients, is this considered always retrospective? Or by prospective do you mean "new cases" to MOHCCN, so banked tissue of newly enrolled patients would be considered prospective? Our study on metastatic breast cancer is prospective for liquid biopsy and clinical data acquisition but has banked archival tissue to be used for sequencing.

Banked archival tissue to be used for sequencing will be considered retrospective. Please see the below definitions.

Prospective specimen procurement is the set of procedures to collect and store new (since the time of study approval) patient specimens for WGTS. Solid tumour tissues can be collected via surgical resection or CT-guided needle-core biopsies at baseline.

Retrospective specimen procurement is the set of procedures to identify the most optimal available/archival (previously collected) patient specimen for WGTS. This procedure may also involve identifying and obtaining available partial germline WGS and or tumour WGTS data. As the specimens may originate from multiple biobanks and storage facilities, this is a labour-intensive and nuanced process. It has been the experience that, cohorts relying on retrospective specimen procurement encounter many unique challenges prohibiting successful WGTS data generation.

- The rare cancer that I am proposing to sequence has two distinct populations of cancer cells in distinct areas of the tumors. For a few cases, we have the primary tumor and a metastatic sample. In these examples, it would be important that both areas or tumor sites be sequenced separately, which means that it will cost twice as much to sequence them. Can I consider them as two cases for budget purposes in the application?

Health Canada funds are based on the sequencing per patient, for the addition of companion samples (longitudinal/spatial samples) from a patient, we cannot provide additional funds. These samples can be added to the work plan as a different activity line for a given cohort where match funds or any other additional funding should be indicated.

- Some tumors are only available as FFPE samples, are they acceptable for the project?

Yes, they are acceptable. We would suggest connecting with already MOHCCN-enrolled cohorts for lessons learned on how to handle FFPE samples and help you assess with confidence the projection of cases to be contributed with your application.

- Are international cases acceptable for the project?

Only Canadian cases as the collection of clinical data and follow-up of international patients may not be possible to achieve. In addition, it is important to note that MOHCCN data cannot be shared outside Canada.

APPLICATION PROCESS

- A prerequisite to receiving TFRI MOHCCN funds through Research Project Grant Agreement (RPGA), is that each applicant and collaborating institution in the project must first be a MOHCCN Member by agreeing to the terms of the MOHCCN Network Master Agreement through the signing of a Joinder Letter Agreement.

- The **Master Network Agreement - Phase I** was made effective September 1, 2021, by TFRI and the four Founding Consortia. The Consortium leads are the Founding Partners, University Health Network (UHN), BC Cancer (BCC), Le Centre Hospitalier de L'Université de Montréal (CHUM), and McGill University (McGill). No additional signatories will be added to this agreement, rather, a new Institution will become a member of the Network through the Joinder Letter Agreement.
- Institutions that were not part of the initial Master Network Agreement will be able to join the MOHCCN upon agreeing to be bound to the same terms and conditions of the Master Network Agreement by execution of a **Joinder Letter Agreement**. This Joinder Letter Agreement is between the Institution and TFRI on behalf of all existing Network Members. All organizations who will receive Health Canada funding from the MOHCCN, either directly or indirectly, must be members of the Network via signing a Joinder Letter Agreement.
- **Research Project Grants Agreement (RPGA)** describes the specific approved workplan/project/studies to be performed, deliverables and reporting to be provided by the Institution, and the approved budget. RPGAs also reflect the notion that the investigators of the associated Institutions are bona fide members of MOHCCN, with the ensuing prerogatives and expectations.
- The MOHCCN Network Master Agreement and Joinder Letter Agreement will be made available to any applying institution if they are not already a Network Member. Requests for these documents should be made to iserrano@tfri.ca. A membership process is a one-time event and once a member, project funds can be provided by TFRI to the institutions through one or more RPGA agreements over time.
- Can we submit an application that includes an Institution that is not a Network member yet?

Yes, at the time of application an Institution is not required to be a Network member. Once/if the application is successful, The Joinder Letter Agreement to become a MOHCCN Member organization, must be signed prior to the RPGA execution and any receipt of funds. We are happy to share any agreement templates in advance to expedite legal review.

Feel free to request any of the following documents for review:

- Introduction to MOHCCN
- MOHCCN Agreements Guideline
- Network Master Agreement - signed by the Founding Centres (Terms and Conditions on Network Membership) This does not need to be signed by applicant institutions, but the terms are incorporated into the Joinder Letter Agreement.
- **Joinder Agreement** - any institutions must sign to join as new members of the Network (one-time requirement)
- **Research Project Grant Agreement (RPGA)** - Project model template for workplan and budget.

MATCH FUNDS AND MATCH EXPENDITURES

- Cash Match Commitment Letters may cover the full project term but must cover the amount of the 2023-24 fiscal year cash match requirement as a minimum. Subsequently, new or updated Cash Match Commitment Letters must be provided annually (February) for the following fiscal year's cash match. Failure to provide updated or appropriate commitment letters may result in the termination of the RPGA. Note that expenditures made from both TFRI-provided and cash-match funds must be reported regularly to TFRI, and it is the expenditures of the match funds (not the collection of match funds themselves) that constitutes the official match reported to Health Canada). Accordingly, prompt reporting of expenditures of match funds is critical.

In the work plan, there is a column to indicate the status of the letter of commitment, allowing it to specify that it has been 'requested'. This means **it is not mandatory to submit the letter(s) of match commitment at the time of application**. These letters are mandatory only for the awarded applications before we can proceed to sign any agreements.

- I am told that the matching funds can include the cost already used to pay to collect the samples. Is that the case?

Yes, as mentioned above. We will consider eligible cash match expenditures from one year prior to the start of funding (April 1st, 2022).

- Prospective trial projects that have started recruiting and biobanking before April 1st, 2022. Can those expenses be included, with justification as well? The longer the follow-up, the greater the value of the specimens.

We will consider a request for an earlier than April 1st, 2022, for cohorts that will clearly benefit from this, for instance, rare cancers cohorts. Please include this as an additional request with a scientific justification on how far back in time and the exact number of cases that it would signify.

- I understood that only cash funds are eligible for match, but I am hearing that research personal time (salary) or similar in-kind contributions are acceptable, is that the case?

While in-kind support can be very helpful to a project, in-kind contributions are not an allowable expense under the Health Canada agreement and TFRI RPGAs. Similarly, indirect cost allocations such as those based on standard percentages are not eligible because the percentage is an indirect estimate and not directly traceable to the actual amount of the expense used by the project activities. For this reason, overhead and other indirect cost allocations based on general percentages are not considered eligible expenses.

However, if the research salary or any other expense is used directly in the MOHCCN project it will be eligible if it has a clear source of matched cash, the amount of the expense is clearly calculable to the MOHCCN project (such as with a timesheet), justified

as needed for the delivery of the project, and auditable in the financial records of your institution.

- It is not easy to find the matching funds and I am afraid that it may prevent me from applying. Do we absolutely need to have confirmed the matching funds at the time of the application?

Yes, as a minimum, for the first year of the project we request to have secured letters of financial commitment for the match. This is a condition under the Health Canada agreement for TFRI to provide their funds. We will need these letters as a condition for funding (prior April 1st 2023) or the signing of any RPGA funding agreements.

At the time of application, the status of the letters of cash match commitment can be "attached" (if included with the application) or "requested" (if they are in progress). There is a place in the work plan to indicate this status.

- Does the Terry Fox Foundation have alternative ways to help secure matching funds for researchers who can't find them locally?

To help with the new cash contributions, the Terry Fox Foundation is leading a campaign to raise a \$150 M match to Health Canada funds, by partnering with major local/regional Foundations at the different provinces across Canada. Sites are encouraged to reach out to their local Foundations to ensure they are participating in this major cash-raising campaign. They should reach out to the Terry Fox Foundation for more information.

- In the \$6k per patient for sequencing, can we build in other expenses, e.g. specimen processing, bioinformatics, etc.

Yes, any expenses used directly in the MOHCCN project are allowed. Match funds will bring the budget to at least \$12k per patient, allowing for additional expenses. Those must be clearly calculable (such as with a timesheet if a salary), justified as needed for the project, and auditable in the financial records of your institution.

DEADLINES

- There will be an extension to **January 9th** to complete the **Collaborating Institution's Signatory** (Appendix A) **ONLY**. All other Lead signatures on the cover page and the Collaborating Applicant PI on each Appendix A must be included in the application by the RFA deadline on December 9th.

Full applications are to be submitted by December 9, the extension to January 9 is only to collect any **Collaborating Institution's Signatory**, which is part of each Appendix A. The Principal Investigator's signature should be included in each Appendix A at the time of application.