



Ontario Institute
for Cancer Research

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PERSONALIZED MEDICINE RESEARCH FUND

Policy

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ONTARIO INSTITUTE FOR CANCER RESEARCH (OICR)

Personalized Medicine Research Fund (PMRF) Program Policies:

1. Eligibility

1.1 Eligible Host Institutions

OICR's Personalized Medicine Research Funds are awarded to Host Institutions. Eligible Host Institutions are Ontario universities, hospitals, research institutes, colleges, or other Ontario-based non-profit institutions. Such Eligible Host Institutions must be legal entities that will be accountable for both the performance of the approved Project or Activity and the appropriate expenditure of funds, and assume the legal obligations hereunder. OICR will not make an award to an institution that does not have a substantive role in the Project (*see Appendix 4: Definitions*) as proposed in the application and would simply serve as a conduit for another entity.

For multi-institutional applications, one Host Institution must be named as "Lead Institution" and will be responsible for the overall administration and oversight of the Project, and assume the requisite legal obligations.

1.2 Eligible Co-applicant Institutions

Eligible Co-applicant Institutions include universities, hospitals, research institutes, colleges, or other non-profit institutions. For-profit organizations are not eligible to be Host Institutions, but may be included in multi-institutional applications as co-applicant institutions provided that they demonstrate the value of the collaboration through cash/in-kind support. Co-applicant Institutions are not required to be located in Ontario. See limitations on out-of-province spending in section 4.

1.3 Eligible Principal Investigators

Principal Investigators (PIs) applying for Personalized Medicine Research Funds must hold an academic or research appointment at an Eligible Host Institution and meet the minimum qualifications of the Eligible Host Institution to receive external independent research funding. The PI will take overall responsibility for the scientific conduct of the Project, including any portions of the Project conducted at Co-applicant Institutions.

1.4 Eligible Co-applicant Investigators

Co-applicant Investigators (or Co-applicants) must be affiliated with an eligible Host or Co-applicant Institution as defined above. They are not required to be located in Ontario. See limitations on out-of-province spending in section 4.

1.5 Eligibility of OICR-affiliated Investigators

OICR Program and Platform Directors are not eligible as PIs for PMRF applications, but may apply as Co-applicant Investigators provided there is no scientific, budgetary, or effort overlap between the Program/Platform and the PMRF proposal. OICR PIs who are OICR employees are not eligible as PIs for PMRF applications, but may apply as Co-applicant Investigators provided there is no scientific, budgetary, or effort overlap between the Program/Platform and the PMRF proposal.

OICR Program and Platform PIs are eligible as PIs or Co-applicant Investigators for Personalized Medicine Research Funds provided there is no scientific, budgetary, or effort overlap between the Program/Platform and the PMRF proposal.

All OICR Program and Platform Investigators applying for Personalized Medicine Research Funds must include Program/Platform scientific abstracts and budgets as attachments to their PMRF applications in order to demonstrate that there is no scientific or budgetary overlap between their Cancer Research Program activities and their PMRF proposal.

2. Approvals

2.1. Host Institution Approval

Submission of all PMRF applications must be approved by an Institutional Authority of the Eligible Host Institution who is authorized to legally bind the Host Institution. Such approval will confirm that:

- The PI is qualified to conduct the research as proposed and that if the proposal is funded, the Eligible Host Institution will commit the necessary resources and infrastructure required to conduct the research as proposed;
- The Eligible Host Institution agrees to carry out and implement the Project as proposed in its application for Personalized Medicine Research Funds;
- The Eligible Host Institution accepts that the terms and conditions of Personalized Medicine Research Funding include compliance with these policies;
- The information provided in the application for Personalized Medicine Research Funds is complete, accurate and consistent with institutional policies;
- The Eligible Host Institution represents and warrants that it, and all Co-applicant Institutions, has in place policies and procedures with respect to privacy and the confidentiality of information, conflict of interest, financial management of the award contributions, the maintenance of research integrity and the disclosure, ownership and management of intellectual property which shall apply to the Project;

- The Eligible Host Institution shall ensure that the Project is carried out in all its aspects without an unmanaged conflict of interest by any person associated with the Project in whatever capacity. For these purposes, a conflict of interest includes a situation in which a person associated with the Project or any member of his or her family is able to benefit financially from his or her involvement in the Project beyond that identified in the Project and Full Application. The Eligible Host Institution will report in writing to OICR within sixty (60) days of identifying any such conflict and provide an assurance that it has been or will be managed;
- In no event will Ontario or OICR be responsible for any direct, indirect, or consequential damages sustained by the Eligible Host Institution, howsoever caused, to the extent that such damages are not caused by negligence on the part of Ontario or OICR;
- The Eligible Host Institution agrees that OICR and its officers, employees, independent contractors, subcontractors, agents, and assigns shall not be liable to the Eligible Host Institution or its personnel for any losses, expenses, costs, claims, damages and liabilities arising out of or by reason of, or attributable to, the Eligible Host Institution's services or performance of the Eligible Host Institution's obligations under the Project;
- The Eligible Host Institution shall indemnify and save harmless OICR and its officers, employees, independent contractors, subcontractors, agents, and assigns from all costs, losses, damages, judgments, claims, demands, suits, actions, causes of action, contracts or other proceedings of any kind or nature based on, occasioned by, or attributable to anything done or omitted to be done by the Eligible Host Institution or its personnel in connection with the Project. The Eligible Host Institution agrees to maintain in force during the Term of the Project liability insurance in an amount not less than \$3,000,000.00 CDN;
- The Eligible Host Institution agrees that OICR will not make an award if a PI, Co-applicant Investigator or any other individual/collaborator on a proposal is receiving support/funding from the tobacco industry. Host Institutions, Co-applicant Institutions, PIs and Co-applicant Investigators are responsible for ensuring compliance with this requirement. For purposes of this policy, "support" includes, but is not limited to, receipt of a research grant or award, a contract for personal or professional services, a consulting agreement (paid or unpaid) or any other direct or indirect benefit, from the tobacco industry.
- The Eligible Host Institute confirms that the PI of this proposal is not currently barred from applying to any research funding organization (e.g., CIHR, NIH or provincial funding organizations) for reasons of breach of standards of ethics or integrity (i.e. financial or scientific misconduct).
- The Eligible Host Institution represents and warrants that it has established and shall maintain during the Term of Project corporate by-laws, other legal documents, or approved corporate policies and procedures that:
 - Establish and set out decision-making mechanisms;
 - Provide for the prudent and effective management of the Grant;
 - Enable the successful completion of the Project; and
 - Enable the preparation and delivery of all reports required pursuant to section 6.

2.2 OICR Approval

Research grants are awarded based on recommendations made by peer review committees and chairs, and all decisions are final. All research grants are conditional upon, and subject to, availability of funds to OICR from Ontario.

3. Certifications and Assurances

Host Institutions take full responsibility for the ethical conduct and safety of the research being funded by OICR, whether that research is conducted at the Host Institution or at a Co-applicant Institution.

3.1 Research involving Human Subjects

Where the research involves human subjects, the Host Institution has developed policies and procedures that, at minimum, meet the requirements set out in the Tri-Council Policy Statement: Ethical Conduct for Research involving Humans (TCPS) (<http://pre.ethics.gc.ca/eng/policy-politique/tcps-epct/readtcps-lireeptc/>). The Host Institution will not release OICR funds to researchers until the research has been approved by an institutional research ethics board with appropriate jurisdiction, and a copy of this approval has been provided to OICR.

3.2 Research involving Animals

Where the research involves animals, the Host Institution is in compliance with the guidelines and policies of the Canadian Council on Animal Care (CCAC) (http://www.ccac.ca/en/CCAC_Main.htm). The Host Institution will not release OICR funds to researchers until the Project has been approved by an institutional animal care committee with appropriate jurisdiction, and a copy of this approval has been provided to OICR.

3.3 Research Biosafety

Where the research involves biohazards, the Host Institution is in compliance with the Public Health Agency of Canada's Laboratory Biosafety Guidelines (<http://www.phac-aspc.gc.ca/ols-bsl/pub-eng.php>) and all other relevant federal and provincial legislation and regulations, including, but not limited to, the Canadian Food Inspection Containment Standards for Veterinary Facilities and the Transportation of Dangerous Goods Act. The Host Institution will not release OICR funds to researchers until the Project is approved by an institutional biosafety committee or biosafety officer with appropriate jurisdiction, and a copy of this approval has been provided to OICR.

3.4 Radioactive Materials

Where the research involves radioactive materials, the Host Institution is in compliance with the requirements, policies, and guidelines set out by the Canadian Nuclear Safety Commission (<http://www.cnsccsn.gc.ca/eng/lawsregs/index.cfm>).

3.5 Integrity in Research

OICR is dedicated to the maintenance of high standards of integrity in research. Therefore, OICR requires that all Host Institutions that administer OICR funds have in place procedures and policies to ensure the maintenance of research integrity, investigate any charges of scientific misconduct, and impose appropriate sanctions.

In the event that an allegation of scientific misconduct involving any project funded by OICR is found to have merit, the Host Institution shall provide OICR with a report of the allegations made, the results of the investigation,

and the remedial actions taken within sixty (60) days of the finding. The Host Institution is responsible for the maintenance of research integrity and the reporting of scientific misconduct for research conducted at Co-applicant Institutions throughout the Term of the Project.

3.6 Disclosure of Background Intellectual Property, Commercial Interests and Financial Conflict of Interest

At the time that a PMRF application is made, the PI must disclose fully:

3.6.1 any Background IP (Intellectual Property (including Intellectual Property owned or controlled by a third party) that is reasonably expected by the PI or Co-applicant(s) to be required to perform the Project or for the practice of Arising IP); and

3.6.2 any interest that he/she or any Co-applicant Investigator may have in any company, corporation or other commercial venture whose activities are related to the PMRF application, including, but not limited to, ownership of shares of the company, membership on the Board/Committees of the company, having an appointment of the company, acting as a Consultant/Advisor for the company, and receiving remuneration of any kind from the company.

During the Term of the Project, the Host Institution is responsible for informing OICR within sixty (60) days of identifying any unmanaged significant Conflict of Interest related to the Project.

4. Financial Policies

Personalized Medicine Research Funds are paid directly to the Host Institution. The Host Institution shall maintain control of the grant funds, disburse expenditures authorized by the PI, and report to OICR on the grant funds. The Host Institution is responsible and accountable for all Personalized Medicine Research Funds awarded to it, including those disbursed to Co-applicant Institutions.

4.1 Eligible Project Expenditures

The Host Institution will ensure that Personalized Medicine Research Funds are used only for eligible project expenditures, and that all goods and services are acquired in a commercially reasonable manner to achieve the best value for money spent. The Host Institution agrees that any portion of the Grant that has not been used to pay for Eligible Project Expenditures shall be repaid to OICR upon demand, including interest accrued. Eligible Project Expenditures may include:

- Salaries and fringe benefits for research associates, technicians, and other highly qualified personnel working directly on the Project, calculated using the employee's actual base salary amount plus actual fringe benefits amount;
- Stipends for trainees (summer students, graduate students, postdoctoral fellows, medical fellows), calculated at the rate prescribed by the institutional policies of the Eligible Host Institution at which the research will be conducted. If there are no such written policies, the rates currently in effect for similarly qualified personnel under Canadian Institutes of Health Research trainee programs will be used;
- Research equipment and other infrastructure identified in the proposal and agreed upon following grant panel review, up to a limit of ten per cent (10%) of the total direct budget;
- Laboratory materials and supplies;

- Infrastructure costs to link sites (e.g., web-based communications, database sharing);
- Expenses related to the purchase of human tumours and other specimens from the Ontario Tumour Bank (<http://www.ontariotumourbank.ca/>);
- Expenses related to the protection of Intellectual Property; and
- Research Travel and Accommodation (i.e., the actual cost of travel and accommodation incurred by the research staff). Such travel must be necessary for the successful completion of the Project and requested and approved by the review panel, and is limited to a total of five per cent (5%) of the amount of the grant. Appropriate records of travel expenditures and their purpose must be maintained. Travel must always be by the most practical and economical method. When air is the most practical and economical method, only the cost of an economy class flight will be reimbursed by OICR funds.

4.2 Ineligible Project Expenditures

Ineligible Project Expenditures include:

- Salaries and fringe benefits for PIs or Co-applicants;
- Insurance for equipment purchased with OICR funds;
- Fringe benefits (e.g., Canada Pension Plan, Employment Insurance, and Health Taxes) for trainees;
- Any cost which cannot be directly allocated to the Project (see section 4.3 on Indirect Costs);
- Pre-award or retroactive costs;
- Any funding for any PMRF project where there is significant scientific overlap with an existing project (e.g., a specific research objective and/or the research design for accomplishing the objective are the same or closely related in two or more applications or awards); and
- Personalized Medicine Research Funds directed outside of the Province of Ontario without the express written permission of OICR.

4.3 Indirect Costs

Applicants to the OICR PMRF Program should not include a value for indirect costs (i.e., overhead for facilities and administrative costs) to the proposed budget at the time of the Application. OICR will add thirty per cent (30%) of the proposed budget to all successful PMRF grants to cover institutional overhead. The total amount of the grant that can be allocated for overhead will be listed in the Notice of Award issued to the Host Institution. Equipment and services are not eligible to incur overhead/indirect costs.

4.4 Extension period for use of funds beyond grant period (No-Cost Extensions)

The Host Institution agrees to complete the Project during the Term specified in the Notice of Award, and any funds not used by the end of the project period must be returned to OICR along with any interest accrued. In rare cases, OICR may allow a no-cost extension to extend the end date of the project period without supplemental funds. There must be valid programmatic reasons for such an extension – i.e., it will not be permitted simply because there are funds remaining at the end of the project period. Requests for no-cost extensions will only be considered if they are requested and justified in writing six (6) months prior to the end of the project period.

4.5 Carryover of Funds

Up to fifteen per cent (15%) of the total direct costs awarded for one budget year may be carried forward to the following budget year without prior approval from OICR. Carryover of amounts greater than fifteen per cent (15%) requires prior approval from OICR. Host Institutions must request and justify such approvals in writing prior to the end of the budget year.

4.6 Reallocation of Funds

Up to thirty per cent (30%) of the total of any expense category may be reallocated between other expense categories in any budget year without OICR approval, subject to the limitations described in Section 4.1 (Eligible Project Expenditures). Reallocations of over thirty per cent (30%) require the express written permission of OICR.

4.7 Equipment Title

Title to all equipment purchased with OICR funds is with the Host Institution or Co-applicant Institution for whom the purchase of the equipment was proposed in the original application. It is the responsibility of the relevant Host Institution or Co-applicant Institution to ensure that the equipment is appropriately maintained and insured. At the end of the project period, OICR expects the Host Institution or Co-applicant Institution that owns the equipment to make such equipment available to other researchers and/or students at their Institution for research and/or academic purposes.

4.8 Co-mingling and Offset of Funds

Expenses attributed to a PMRF grant may not also be attributed to any other grant or funding source. Funding from other sources (e.g., industry funding for companion clinical trials) may be used to supplement PMRF projects.

4.9 Valuation and Reporting of Items Involving In-Kind Contributions

Valuation and reporting of in-kind contributions will be done in accordance with the guidelines and policies of the Canada Foundation for Innovation (http://www.innovation.ca/docs/guide/2008/2008_cfi_guide_e.pdf).

4.10 Cancellation of Instalment Payments

OICR may cancel the next scheduled instalment if, in its sole discretion, it is judged that the Project's build-up of funds has not been properly justified and that the need for funds has not been demonstrated. This may lead to a permanent reduction in the funding made available under the grant.

4.11 Disbursement of Funds

Funding of successful grants will be advanced quarterly, subject to the Host Institution's and PI's compliance with OICR policies and terms and conditions of funding.

5. Third Party Sponsors

5.1 Establishment of Third Party Agreements

The Host Institution agrees to enter into a funding agreement with any Third Party Sponsor listed in the Full Application.

5.2 Termination of Third Party Agreements

Within thirty (30) days of the termination of, or any amendments to, a Third Party Agreement, the Host Institution agrees to inform OICR of such termination or amendments. Within thirty (30) days of the termination of, or any amendments to, any Third Party Agreement, the Host Institution shall provide assurances to OICR that the Project will proceed successfully, or that a new Third Party Sponsor has been found that will contribute to the Project and that a Third Party Agreement has been entered into, or will be entered into, subject to the consent and approval of OICR. Such assurance will be provided in letter to OICR.

5.3 Reporting of Third Party Agreements

All new agreements, or changes, between the Host Institution and Third Party Sponsors must be included in the annual project progress report.

6. Reporting

OICR's ability to award grants is dependent upon continued support from Ontario. In order to maintain this funding, OICR must account regularly and in detail for the financial and scientific progress of the projects it funds. OICR cannot do this without complete, accurate, and timely reports from its grant Host Institutions and investigators. For this reason, failure of Host Institutions and PIs to submit reports by due dates will result in future funds being encumbered. Consistent submission of late reports will result in the termination of grant funding and/or ineligibility of the Host Institution and the PI for future grant competitions.

6.1 Annual Project Progress Report

Within thirty (30) days of the end of each year of the Project, the Host Institution and PI must submit a completed Annual Project progress Report in a format provided by OICR (*Appendix 1*). The reporting period for this report will be the previous grant year.

6.2 Final Project Progress Report

Within thirty (30) days of the end of the Project, the Host Institution and PI must submit a completed Final Project Progress Report. The reporting period for this report will be the previous grant year with narrative elements covering the entire Project Term.

6.3 Annual Financial Report

Within thirty (30) days of the end of each year of the Project, the Host Institution and PI must submit a completed Annual Financial Report in a format provided by OICR (*Appendix 2*). The reporting period for this report will be the previous grant year.

6.4 OICR Audit

Host Institutions shall maintain appropriate accounting records according to generally accepted accounting principles for costs claimed as incurred in the performance of the Project, and shall keep these records for a minimum of seven (7) years following the completion of the Project. The Host Institution shall also make relevant records and facilities available, upon request, to authorized OICR personnel for audit purposes.

7. Changes to Project

7.1 Change of Institution

Research grants are made for research to be carried out at the Host Institution specified by the PI in the initial grant application. If, however, the PI is transferring to another eligible Ontario Host Institution, arrangements can be made with OICR to have the unspent portion administered by the new institution pending receipt by OICR of a letter of support from the administrative authority of the new Host Institution, creation of a new Notice of Award, and signing of a declaration by the new Host Institution acknowledging acceptance of OICR policies and terms and conditions of funding. If approval is given, new ethics review (see section 3.1), animal care (see section 3.2) and biohazard/biosafety (see section 3.3) certificates are necessary from the new Host Institution.

7.2 Abandonment of a Grant

Should a PI or Co-applicant not be able to continue the research as planned in the initial application for any reason, it is the responsibility of the Host Institution to notify OICR. OICR may, at its sole discretion, allow transfer of a PMRF project to another qualified and willing investigator within the Host Institution. Such a transfer must be requested by the Host Institution and approved by OICR in writing (see sections 7.5 and 7.6 below).

7.3 Interruption of a Grant

If a grant will be interrupted for a period of 90 days or more for any reason other than sabbatical leave (e.g., vacation leave, maternity leave, disability leave of the PI), permission must be obtained from OICR to temporarily interrupt the project and begin again at a later date. Such requests must be made by the Host Institution in writing prior to the start of the investigator's leave.

7.4 Sabbatical Leave

OICR believes that sabbatical leaves can have a positive impact in the direction and outcome of research projects. If a PI wishes to retain a grant award during a period of sabbatical leave, prior permission of OICR is required. The PI must make a written request specifying the dates and location of the leave, a short summary of the research to be conducted and how it will benefit the direction of the project, and a detailed description of the arrangements made for maintaining and supervising the research project in which an award has been granted. Approvals will be given only if it can be guaranteed that the project will be able to proceed as initially outlined in the grant application.

7.5 Changing a PI

A Host Institution may seek to change a PI on an existing grant. To consider this request OICR will require:

- That the new investigator is eligible to serve as a PI on the PMRF grant;
- A letter signed by the current and the new PI describing the circumstances that have initiated the request and the impact the change will have on the research objectives; and
- A letter from the Administrative Authority of the Host Institution in support of the change.

7.6 Adding or Changing a Co-applicant Investigator

A Host Institution may seek to add or change a Co-applicant Investigator to an existing grant. To consider this request OICR will require:

- That the new investigator is eligible to serve as a Co-applicant Investigator on a PMRF grant;
- A letter signed by the current PI and new Co-applicant Investigator describing the circumstances that have initiated the request and the impact the change will have on the research objectives;
- A letter of resignation signed by the departing Co-applicant Investigator (if applicable); and
- A letter from the administrative authority of the Host Institution in support of the change.

7.7 Adding or Changing other personnel

Changes to non-investigator personnel on PMRF grants (e.g., technicians, postdoctoral fellows) may be made at the discretion of the PI and Host Institution without prior OICR approval provided such changes in personnel do not necessitate changes to the project for which prior approval is required.

7.8 Programmatic Changes to Project

Any significant program change in the project (e.g., research plan, specific aims, or scope of work) must be conveyed through a letter to the Director, Grants and Awards at OICR so that the appropriate action can be taken.

7.9 Termination for Breach

OICR may, at its option, terminate the project for any of the following reasons. Upon termination, Host Institutions must immediately repay any and all disbursements from the point of breach including interest (at Prime Rate) accrued:

- The Host Institution or PI fails to observe or perform a PMRF policy or funding term or condition as set out herein, if such failure continues for a period of twenty (20) days after receipt by the Host Institution of written notice by OICR of such failure;
- The Host Institution or the PI abandons the Project in whole or in part, or ceases to actively cause the Project to be completed in an expeditious manner, without the approval or consent of OICR;
- The Host Institution or PI makes or has made a material misrepresentation in their application for the grant to OICR of a material fact relevant to these policies;
- The Host Institution becomes insolvent, bankrupt, or a receiver or manager, court appointed or otherwise, is appointed for its assets;
- An order is made or a resolution is passed or proceedings commenced for the winding up, liquidation, or dissolution of the Host Institution, or the Host Institution is otherwise dissolved or ceases to carry on its operations;
- In the opinion of OICR, acting reasonably, there is a substantial increase in the degree of risk surrounding the implementation and completion of the Project; or
- If any portion of the grant is used for any purpose other than those permitted by OICR policies.

8. Publication and Publicity

8.1 Disclosure to OICR

Prior to submission for publication or disclosure the PI and Co-applicants shall submit to OICR (commercialization@oicr.on.ca) and the appropriate technology transfer office(s) a copy of any proposed Disclosure in order to allow for an assessment and protection, as appropriate, of any Arising Intellectual Property contained therein. OICR will respond within ten (10) business days from the date OICR receives all the relevant information as to OICR's interest in having such Arising Intellectual Property protected and the steps to be taken in accordance with Section 10-Commercialization below. It is understood that publication will not be delayed longer than sixty (60) calendar days to accommodate these steps. In the event the ten (10) business day period elapses without any notification from OICR, the PI and Co-applicants shall be free to make the Disclosure.

8.2 Acknowledgement of Funding

Any OICR-funded research-related advertising, promotion, publication, presentation and/or exhibition produced by the PI or the Host Institution must contain the following acknowledgement: *"This study was conducted with the support of the Ontario Institute for Cancer Research through funding provided by the Province of Ontario."*

The Host Institution agrees to provide OICR with at least fourteen (14) days' prior notice of any media event or announcement related to OICR-funded research to allow OICR to be involved in a format approved by OICR.

9. Open Access Publication and Data Retention

Host Institutions and Investigators accepting Personalized Medicine Research Funds agree to abide by OICR's policies on Open Access Publication and Data Retention (*Appendix 3*).

10. Commercialization

The Host Institution agrees to be bound by the following principles relating to Commercialization of any aspect of any intellectual property arising from an OICR-funded Project (the "Arising Intellectual Property"). **Information received by OICR under this section will be treated as the confidential information of the provider and will be held in strictest confidence.**

10.1 Ownership

Ownership and the assignment of the rights to any Arising Intellectual Property will be in accordance with the policies on intellectual property of the institution(s) of the inventor(s). Except to the extent that employees of the OICR are inventors of Background or Arising IP, OICR will not take or be assigned ownership to any Arising Intellectual Property.

10.2 Reporting

In addition to the obligations described in Section 8.1 above, PIs and Co-applicants shall promptly (and all cases, prior to any form of public disclosure), report and fully disclose in writing to OICR (commercialization@oicr.on.ca) and the appropriate technology transfer office(s) any and all Arising Intellectual Property.

The Host Institution furthermore agrees that reports with respect to the status of commercialization initiatives will be provided to OICR at least annually, through the Project Progress Report. This information will be held in

strictest confidence and only be released to the public in aggregate with information from the Host Institution.

10.3 Best able to commercialize

The appropriate technology transfer officials representing the inventor(s)' institutions will be responsible for the following:

- Receiving disclosures of Arising IP; and
- Assessment of the Arising IP including identification of the inventors and the owners of the Arising IP; and
- Determining the steps to be taken to protect the Arising IP; and
- Establishing an IP Commercialization Committee (IPCC) with responsibility for the development and commercialization of the Arising IP:
 - The IPCC will include representatives from the inventors' institution(s), the OICR, the inventors and others as appropriate.

Taking into account the following factors at a minimum the IPCC will determine the party best able to commercialize the specific IP which party will lead the development and commercialization of the IP (the "Lead"):

- A thorough understanding of the needs of market receptors relative to the IP disclosure(s);
- Financial capacity;
- Opportunities to bundle Intellectual Property, including in-licensing where appropriate, across complementary fields of activity;
- Motivation;
- Demonstrated capability;
- Timeliness;
- Workload; and
- Ownership of the Arising IP and whether the party or parties selected would normally be considered an appropriate commercialization agent.

10.4 Specific benefits to Ontario

In order to promote the commercialization and public availability of Ontario-made inventions by Ontario industry, and to ensure that Ontario businesses obtain sufficient opportunity to commercialize inventions created using financial support from the Province, the Lead must agree to first consider the following options to commercialize the Arising Intellectual Property:

- An existing organization in Ontario with Receptor capacity;
- An expansion of an existing company in Ontario;
- The formation of a new company in Ontario;
- Joint ventures or strategic alliances with a company in Ontario;
- Co-manufacturing involving a company in Ontario;
- Cross-licensing or co-development with a company in Ontario; establishment of a new subsidiary in Ontario (R&D, manufacturing, sales, marketing, distribution); and
- Development and/or production in Ontario by a foreign company.

The Lead will be accountable to the IPCC for the development of a plan for the development and commercialization of Arising IP in accordance with the 'Ontario First' policy.

If unsuccessful efforts have been made to grant licenses to potential licensees that would be likely to manufacture substantially in Ontario, then the Lead will, within thirty (30) days after any decision or legally binding step is made

to pursue commercialization/exploitation by a non-Ontario company, and prior to finalizing the decision or step, report the proposed decision or step in writing to OICR and shall provide the rationale and circumstances that led to the proposed decision or step, including an account of the benefits to Ontario.

Appendix 1: Project Progress Report

Principal Investigator Name:	
By form of a signature, I certify that this report is accurate and correct:	
Date (dd/mm/yy):	
Project Title:	OICR Project #:
Host Institution:	
Grant Year Reported: Beginning of Reporting Period: End of Reporting Period:	

Original signed hardcopy and signed electronic copy (signed & converted to PDF) is to be sent to:

Ontario Institute for Cancer Research
790 Bay St., Suite 401
P.O. Box 14
Toronto ON M5G 1N8
c/o Renu Minhas, Director, Grants and Awards
renu.minhas@oicr.on.ca

Information captured in this Report is used to meet reporting requirements of the contract agreement between the Recipient and OICR. Answers are used for reporting to the OICR Board and the Ministry of Research and Innovation (MRI), to monitor the impact of research grants/awards. Any sensitive information should be highlighted, and OICR will keep it confidential.

NOTE: Appendix 1 is a hard copy printout of a report taken from OICR ReportNet (online year-end reporting module). The exact version may change from that represented in this hard copy template. Moreover, additional details will be captured online. A month prior to year-end, please contact Felix Wan, Grants and Awards Administrator at felix.wan@oicr.on.ca for details on how to complete the report online.

Notes: For OICR Use Only

REPORTING YEAR: SCIENTIFIC SUMMARY OF PROJECT
The aims/objectives of this project are:
Progress:

REPORTING YEAR: LAY SUMMARY OF PROJECT

CHANGES in PROJECT:

FINAL YEAR: Bulleted scientific progress for the FULL course of the project

FINAL YEAR: Lay summary progress for the FULL course of the project

HIGHLY QUALIFIED PERSONNEL				
INDIVIDUALS that have substantially enhanced their knowledge, training or skills through their involvement with the OICR-funded project.				
HQP Role	#	Names	Titles	OICR Funded
Co-op Research Student				
Doctoral Students				

MD Student				
Masters Students				
Postdoctoral Fellows				
Private Sector Employees				
Researchers (including PIs)				
Research Assistant				
Research Associate				
Technicians				
Undergraduate Students or equivalent				
Others (specify)				

PUBLICATIONS
<p>Abstract:</p> <p>Article:</p> <p>Book Chapter:</p> <p>Book/Monograph:</p> <p>Manuscript:</p> <p>Newsletter:</p> <p>Paper:</p> <p>Trade Journal:</p>

CONFERENCES/MEDIA
<p><u>Conference</u></p> <p>Posters:</p> <p>Lectures:</p> <p><u>Media</u></p> <p>Media Interviews:</p> <p>Newspaper Articles:</p>
Presentations at conferences in Canada of work supported by OICR funding
<p>Number:</p> <p>List:</p>
Presentations at conferences outside Canada of work supported by OICR funding
<p>Number:</p> <p>List:</p>

PEOPLE that have left the OICR-funded project
<p>With private sector firms: #</p> <p>In Ontario #</p> <p>Outside Ontario #</p>
<p>With universities or colleges: #</p> <p>In Ontario #</p> <p>Outside Ontario #</p>
<p>With hospitals: #</p> <p>In Ontario #</p> <p>Outside Ontario #</p>
<p>With government or not-for-profit groups: #</p> <p>In Ontario #</p> <p>Outside Ontario #</p>
<p>Others: #</p> <p>In Ontario #</p> <p>Outside Ontario #</p>

HQP ATTRACTED to Ontario to work on the OICR-funded project

MD #

PhD #

MSc #

Researcher #

Postdoctoral Fellow #

Technician #

Research Associate #

HQP RETAINED in Ontario to work on the OICR-funded project

MD #

PhD #

MSc #

Researcher #

Post-doctoral Fellow #

Technician #

Research Associate #

APPLICATIONS

Applications:

Patent Name	Patent #	Application Date	Country

PATENTS

Patents:

Patent Name	Patent #	International Patent Classification	Start Date	End Date	Country

LICENSES

Licenses:

License Name	Status	Date Issued	Start Date	End Date

DISCLOSURES

Disclosures:

Disclosure Name	Date

Spin-off/Start-up Companies

Number of new firms created in the last year:

Estimated number of new employees at new firms:

Total number of active firms spun off from OICR-funded project:

Total estimated number of employees at active firms:

of Spin-off Companies:

Company Name	Number of employees	Status	Date Founded	Reason Founded	Company type

of Start-up Companies:

Company Name	Number of employees	Status	Date Founded	Reason Founded	Company type

# of contract research agreements	Firsts	# of other contractual arrangements (e.g., consulting agreements)	Firsts	# of internships	Firsts	# of collaborations without contractual agreements (e.g., faculty working at a firm)	Firsts	Other	#	Firsts

COMMERCIALIZATION ACTIVITY REPORT on activity surrounding commercialization, reason(s) for such choices, and any benefits to Ontario.

NUMBER/TYPE OF PARTNERS ON OICR-FUNDED PROJECTS		
Type	# in Ontario	# outside Ontario
Private sector		
Universities or Colleges		
Hospitals		
Not-for-profit organizations		
Federal government		
Provincial government		
Foreign government		
Foundation		
Other: ()		

THIRD PARTY SPONSOR ACTIVITY (Cash/In-kind update)

Leveraged Investments						
Cash:						
In-kind contributions:						
Partner Name	Partner Type	Location	Investment Type	Leveraged Investments (\$)	Address	PI who received funding

Educational Outreach				
Type	Title	Date	Total # of participants	Participant evaluation (if available)

Appendix 2: Financial Report -- Accountability and Declaration Form 2

FORM 2

Project Title: _____

Host Institution _____

Principal Investigator _____

OICR PROJECT # : _____

Is this an amendment
of previous report?

Yes / No
Enter Year 2,3 or 4

CLAIM PERIOD (insert the next year):

Year

--

YEARLY GRANT AMOUNT AVAILABLE

	BUDGETED GRANT	GRANT PAYMENT RECEIVED
Year 1		
Year 2		
Year 3		
Contract extension		
TOTAL	0	0

	Yr1	Yr2	Yr3	Yr4 (extension)	Total All Years
less encumbered amt	0	0	0	0	
Salaries and Benefits					0
Supplies/Consumables					0
Minor Equipment					0
Other Infrastructure					0
Services					0
Travel					0
Other Costs (describe)					0
Overhead					0
Total Expenses	0	0	0	0	0
* Encumbered Amt	0	0	0	0	
Total Expensed and Encumbered	0	0	0	0	0
Grant Received	0	0	0	0	0
Underspent (Overspent) Balance per Year	0	0	0	0	0
Cumulative Underspent (Overspent) Balance	0	0	0	0	0

* sufficient verification must accompany the request such as a signed purchase order or other proof of purchase

Appendix 2: Financial Report -- Accountability and Declaration Form 3

ONTARIO INSTITUTE FOR CANCER RESEARCH
 APPENDIX 2: ACCOUNTABILITY & DECLARATION
 FORM 3

FOR THE PREVIOUS YEAR ENDED:

List all capital equipment purchases or contributions to purchases for expenses of \$25,000 or more per item. For items or contributions to items less than this amount, provide a grand total only for all such purchases.

Capital Equipment Item (Description/Model/Manufacturer)	Location & Ownership	Cost attributed to OICR Grant	Total Cost of the Capital Equipment Item
TOTAL			0

Appendix 3: OICR Policies on Open Access Publication and Data Retention

Policy Objective

The objective of this policy is to allow and promote access to research outputs funded by OICR, thus increasing the diffusion and impact of the research process.

This policy applies to recipients of OICR research support awarded on or after July 1, 2008. This policy is binding and applicable if the research activity was supported in whole or in part by OICR. While not required, researchers holding research support that was awarded prior to July 1, 2008 are encouraged to adhere to the requirements of this policy.

Research outputs are conceptual or practical knowledge, data, information, and physical or biological materials developed during the course of a research project that are integral for building on research discoveries. OICR recognizes three categories of research outputs: peer-reviewed journal publications, research materials, and research data.

OICR will limit the open access policy to peer-reviewed journal publications and publication-related biomedical research data, as well as software (source code developed for research purposes), which are typically deposited into public databases as a condition of publication.

Policy

Beginning July 1, 2009, all peer-reviewed journal publications funded by OICR must deposit a copy of the paper in the OICR Institutional Repository (OICR-IR). The OICR-IR will be available from the OICR homepage (<http://www.oicr.on.ca>). All papers will be freely available through the internet within six (6) months of publication.

Submission of papers to the OICR-IR

- Authors of peer-reviewed research papers supported substantially by OICR funding are required to deposit all final peer-reviewed full-text manuscripts in the OICR-IR at the time their publication is accepted (irrespective of the type of journal). OICR-funded scientists are encouraged to deposit all of their publications in the OICR-IR, even if the OICR contribution is minor. Papers where an OICR-funded scientist is the first, last or corresponding author must have the final manuscript deposited in the OICR-IR.

Making publications freely accessible

- All publications should be freely accessible within six (6) months of publication. In all cases, publications will be freely available within twelve (12) months of publication. Publications can be freely accessible through the Publisher's website or through the OICR-IR, which will contain the paper's meta-data (authors' names, title, abstract, journal name, etc.) for search engines; these data will only be made publicly available after the journal is published. The OICR-IR will contain only the manuscript version of the publication, not a PDF copy of the published paper;
- OICR will not violate the Publisher's embargo policy on free access for up to twelve (12) months following publication. Many journals now allow free access, usually through their own website, within six (6) months of the publication date. For these journals, the OICR-IR will provide a link to the journal site. OICR will also make the manuscript version available through the OICR-IR'
- Some Publishers only allow release from an Institutional Repository twelve (12) months following publication. For these journals, the articles will be made available at the OICR-IR through a reprint request service for the interval between six (6) and twelve (12) months following publication. In this case, scientists wishing to obtain a reprint can automatically make this request on the OICR website. An email specifically requesting the article will be automatically sent to the corresponding author. The author can quickly approve the request which will automatically result in the OICR-IR sending an electronic copy of the manuscript version of the paper to the requesting scientist. For journals that provide free access twelve (12) months following publication, the OICR-IR will include a link for scientists to obtain PDF copies from the Publisher's site. For all other journals, the OICR-IR will provide easy access through the reprint mechanism;
- Authors of articles may use the SHERPA/RoMEO database to locate summaries of publisher copyright policies. This database will help scientists determine which journals allow authors to retain copyright and/or archive journal publications in accordance with funding agency policies. The copyright can reside with either the journal/publisher or the author(s), but if the author(s) sign(s) away copyright to the journal, then the journal/publisher needs to agree to the twelve (12) month disclosure rule; and
- OICR encourages scientists to submit their manuscripts to a journal that provides immediate open access to published articles (if a suitable journal exists). OICR considers the cost of publishing in open access journals important and will directly reimburse for articles funded by OICR, up to a maximum of \$3,500.00 CDN per article, if the first, last or corresponding author is funded by OICR. It is assumed that, if scientists belonging to multiple institutions are contributing to a publication, they will share proportionally the cost of publication (Open Access or otherwise).

Publication-related Research Data

Recognizing that access to research data promotes the advancement of science and further high-quality and ethical investigation, OICR requires OICR-supported scientists to deposit bioinformatics, atomic and molecular coordinate data, and source code for software into the appropriate public database, as already required by most journals, immediately upon publication of research results (e.g., deposition of nucleic acid sequences into GenBank, and source code into a publicly accessible FTP or web server).

Policy on Data Retention

OICR requires all OICR-supported scientists to retain original data sets arising from OICR-funded research for a minimum of five (5) years after the end of the research support. This policy applies to all data, whether published or not. The scientist's institution and research ethics board may have additional policies and practices regarding the preservation, retention, and protection of research data that must be respected.

Appendix 4: Definitions

“Arising Intellectual Property” or “Arising IP” means Intellectual Property conceived, developed, or reduced to practice as a result of the Project.

“Background Intellectual Property” or “Background IP” means any Intellectual Property (including Intellectual Property owned or controlled by a third party) that is reasonably expected by the PI or Co-applicant(s) to be required to perform the Project or for the practice of Arising IP.

“Commercialization”: The development of markets and the production and delivering of products or services for sale, including government, public and private sector markets. As used herein Commercialization includes the transfer or licensing of intellectual property rights from not-for-profit institutions to third parties for commercial development.

“Disclosure” means the publication or disclosure or other dissemination (including via a web-site) of any results of the Project in articles, abstracts, posters, theses, scholarly writings, or oral or written presentations at lectures or seminars or in any other forum.

“Equipment”: To be considered equipment an item must meet all three of the following conditions. It must:

1. Be non-expendable tangible property; and
2. Have a useful life of more than one (1) year; and
3. Have a cost of \$4,000.00 CDN or more.

“Institutional Authority”: A person whose signature is legally binding upon an institution for the purposes of OICR research funding.

“Intellectual Property” or “IP” means any intellectual property, including, but not limited to, any invention, new and useful art, product, service, process, methodology, pattern, machine, composition of matter, material, computer software, or any new and useful improvement thereof and any other intellectual property rights.

“Ontario”: Her Majesty the Queen in right of Ontario, as represented by the Ministry of Research and Innovation.

“Project”: The research activity proposed to OICR in a Personalized Medicine Research Fund grant application. Also referred to as Activity.

“Publisher”: The owner of a scientific journal.

“Term”: The period commencing on the Project start date and ending on the Project end date as specified in the Notice of Award.