

Cancer Therapeutics Innovation Pipeline Request for Applications #RFA-CTIP-1718-01

May 2017



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1 INTRODUCTION

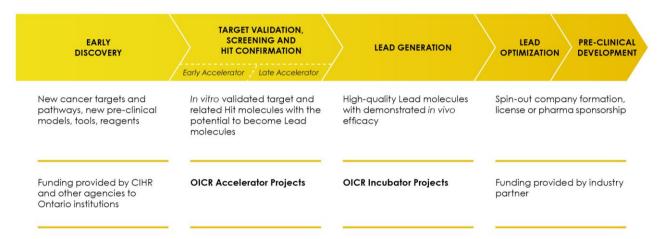
1.1 CANCER THERAPEUTICS INNOVATION PIPELINE: BACKGROUND

The Ontario Institute for Cancer Research (OICR) has established the Cancer Therapeutics Innovation Pipeline (CTIP) strategic initiative to capitalize on Ontario's expertise in cancer biology and drug discovery. CTIP aims to support the translation of Ontario discoveries into therapeutic assets with the potential for improving the lives of cancer patients. The goal of the CTIP initiative is to create a pipeline of validated cancer targets and novel, selective lead molecules (small molecules or biologics) that would attract partnerships and/or investment for further preclinical and clinical development.

To generate a sustainable pipeline, CTIP will support projects that aim to provide increasing evidence of target validation using functional assays and drug screening in relevant *in vitro* and *in vivo* models of the disease of interest. Thus, CTIP funding will be available to support projects in two stages of preclinical drug discovery (Figure 1):

- 1. **Accelerator Projects**, whose goal is to deliver an *in vitro* validated target and related Hit¹ molecules. A confirmed Hit molecule should possess features that support its potential to become a Lead² molecule. To achieve this goal, the project must describe an integrated flow scheme of experiments focused on *in vitro* target validation coupled with medium-to-high-throughput screening for Hits.
- 2. **Incubator Projects**, whose goal is to deliver high-quality Lead molecules (small and/or large), with demonstrated *in vivo* efficacy, ideally accompanied by a pharmacodynamic biomarker that correlates with target modulation. Lead molecule profiles should be sufficiently mature to attract partnership/investment for further development and ultimately commercialization. To achieve this goal, the project must describe an integrated flow scheme of experiments coupling efficacy with target modulation. There must be an emphasis on establishing a connection between *in vitro* and *in vivo* assays and biomarker modulation (or other surrogate measure of efficacy).

Figure 1. OICR's Cancer Therapeutics Innovation Pipeline



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¹A minimal definition of a Hit is a molecule series with an understood Structure–Activity Relationship (SAR) and selectivity profile in relevant *in vitro* models.

²A minimal definition of a Lead is a molecule series with an understood SAR and selectivity profile in pharmacologically relevant *in vivo* models.



1.2 REQUEST FOR APPLICATIONS: OVERVIEW

The purpose of this Request for Applications (RFA) is to stimulate collaborative research with the Ontario cancer research community in the area of cancer therapeutic discovery. OICR invites applications from investigators at Ontario academic institutions, small biotechs or start-up companies seeking support for early stage drug discovery.

The timeline for this RFA is as follows:

Registration deadline (mandatory):

 Registration feedback:
 Full application deadline:
 Notification of award:

 June 16, 2017

 August 15, 2017

 October 16, 2017

Registrations will be reviewed for eligibility and suitability for CTIP funding and only those deemed appropriate will be invited to submit a full application. Funding is anticipated to begin in December 2017, pending execution of research agreements. CTIP funding is only tenable in Ontario.

1.3 CTIP PROJECTS

1.3.1 Accelerator Project: Target validation, medium-to-high-throughput screening and Hit confirmation

An Accelerator Project is an early stage project with the ultimate goal of delivering an *in vitro* validated target and related Hit molecules. A confirmed Hit molecule should possess features that support its potential to become a Lead molecule.

CTIP will fund two types of Accelerator Projects:

- 1. Early Accelerator Projects will be funded to a maximum of \$100,000 per year for a maximum of one year. Most projects are expected to complete within 6-9 months. Early Accelerator Projects will focus on target identification/validation experiments and the generation of a validated, primary assay to enable initial screening.
- 2. Late Accelerator Projects will be funded to a maximum of \$250,000 per year for a maximum of two years. Most are expected to complete in 15-18 months. Late Accelerator Projects will focus on screening, using validated primary and secondary assays, with the goal of generating confirmed Hit molecules.

An Accelerator Project can include the following activities so long as they represent components of an integrated flow scheme that leads to a validated primary assay to enable screening (for an Early Accelerator Project) or a confirmed Hit molecule (for a Late Accelerator Project):

- Functional genomic screens (e.g., knockdown experiments using RNA interference or CRISPR);
- Medium-to-high-throughput screens for large and/or small molecules;
- Development and validation of biochemical and cell-based target modulation assays for screening and orthogonal target validation;
- Structure-activity relationship (SAR) assessments to define minimum pharmacophores that demonstrate potential for further optimization;
- X-ray structure generation;
- Cross-target and cross-species selectivity assessments;
- Characterization of in vitro pharmacokinetic properties (absorption, distribution,

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metabolism, excretion, ADME) and toxicology;

- Computational approaches (i.e., virtual screening);
- In vivo pharmacokinetics for representative molecules;
- Assessment of the viability of candidate Hit molecules to support a lead generation effort.

Disbursement of funds for approved projects will be gated against agreed-upon deliverables and associated milestones. Failure to meet key deliverables or milestones (e.g., inability to establish a critical path assay, experimental results do not achieve threshold values, etc.) could lead to a decision to terminate and defund the project. Thus, it will be essential to clearly delineate go/no-go decision points as milestones.

1.3.2 Incubator Project: Lead generation

An Incubator Project is a later stage project that will be funded to a maximum of \$2,000,000 over two years. The goal of an Incubator Project is to deliver high-quality Lead molecules by the end of the funding period. Leads must demonstrate *in vivo* efficacy and ideally be accompanied by a pharmacodynamic biomarker that correlates with target modulation. Lead molecule profiles should be sufficiently mature to attract partnership/investment for further development.

An Incubator Project application must describe an integrated flow scheme for advancing a confirmed Hit into a quality Lead. The project should focus on experiments that couple target modulation with efficacy, and the flow scheme should be geared towards establishing a connection between *in vitro* and *in vivo* assays and biomarker modulation or other surrogate measure of efficacy. It is critical that the proposed Incubator Project possesses a well-articulated hypothesis for modulation of the target as a treatment for the cancer type in the intended patient population.

Projects entering into the Incubator stage of the CTIP portfolio will possess Hit molecules characterized by a range of supporting evidence as described in the Accelerator Project stage (section 1.3.1). Incubator Projects can include the following activities:

- SAR studies exhibiting a sufficiently broad dynamic range that would allow for optimization in potency, selectivity and safety, within chemical space where there is legal freedom to operate and the opportunity to generate intellectual property (IP);
- Experiments demonstrating differentiation in the context of the expected therapy in the target patient population (e.g., mechanism of action studies);
- Protein engineering studies (for large molecule therapeutics);
- Cell line generation and biophysical characterization for large molecule therapeutics;
- Bioavailability studies using the intended route(s) of administration;
- Pharmacodynamic (PD) or efficacy animal model development;
- Dose ranging PD, PK and efficacy;
- *In vivo* proof of concept or efficacy in a relevant biological system (model species) that will be used for margin of safety calculations;
- Assessment of the viability of candidate Lead molecules to support a lead optimization effort.

It is recognized that Incubator Projects may require funding in excess of what OICR can provide to achieve the Lead molecule deliverable. In such situations, applicants will need to identify leveraged funding or describe a plan to secure additional support from a commercial partner(s) during the funding period. Co-funding may be particularly important during the later stages of an Incubator Project when costs exceed OICR support, prompting the need

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to secure funds from commercial partners, including the Fight Against Cancer Innovation Trust (FACIT, OICR's commercialization partner), based on commercial interest in the Lead molecule.

Disbursement of funds for approved projects will be gated against agreed-upon deliverables and associated milestones. Failure to meet key deliverables or milestones (e.g., inability to establish a critical path assay, experimental results do not achieve threshold values, etc.) could lead to a decision to terminate and defund the project. Thus, it will be essential to clearly delineate go/no-go decision points as milestones.

2 REGISTRATION

Use **Form I** for application registration. Registrations are mandatory, and will be reviewed for eligibility and suitability for CTIP funding. All sections are mandatory and must be completed using 11-point Verdana font and single spacing. Margins cannot be modified in the form provided. The completed form must not exceed **five pages**.

An electronic copy of Form I must be submitted to OICR's Scientific Secretariat department (<u>scientificsecretariat@oicr.on.ca</u>) by **June 16**, **2017**. All applicants will be advised of results and those deemed appropriate will be invited to submit a full application. Applicants may choose to withdraw after the registration stage.

3 FULL APPLICATION

The full application package consists of **Form II** (Research plan and administrative information), **Form III** (Biographical sketches) and **Form IV** (Budget and justification).

All sections are mandatory and must be completed using 11-point Verdana font and single spacing. Margins cannot be modified in the forms provided. Page limits of the Research Plan of an Accelerator and an Incubator Project proposal are defined in section 3.1.2. Page limits must be strictly followed and are inclusive of tables, figures and references.

Electronic copies of Forms II, III and IV must be submitted to OICR's Scientific Secretariat department (<u>scientificsecretariat@oicr.on.ca</u>) by **August 15**, **2017**.

3.1 ADMINISTRATIVE INFORMATION AND RESEARCH PLAN

Using **Form II,** complete the administrative and research plan information. Submit as one bookmarked PDF document.

3.1.1 Contact information

Provide for the following individuals:

- Principal Investigator (PI):
- Co-PI(s), if applicable;
- Co-Investigators;
- Project Manager, if applicable;
- Administrative authority of the PI's Host Institution;
- Administrative authority of the Co-PI's Host Institution (if applicable).

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3.1.2 Research plan

Maximum eight pages for Accelerator Projects, **maximum twelve pages** for Incubator Projects.

• Target overview and therapeutic rationale:

- Describe the unmet clinical need;
- Describe the scientific and clinical relevance of the target as a treatment for the cancer type in the intended patient population;
- o Provide key data supporting the target's biologic and strategic rationale;
- Describe the mechanism of action (MOA), if available;
- o Provide crystallography data to support MOA, if available;
- Describe the desired mechanism of modulation (e.g., agonist, antagonist, reverse agonist, etc.);
- Describe the proposed modality (e.g., small molecule, peptide, antibody, etc.);
- Describe the intended route of administration;
- o Describe potential pitfalls of the project and mitigation plans.

Differentiation strategy:

- Identify the current standard of care for the target and/or the disease indication, and their limitations;
- Describe the competitive landscape;
- Describe the innovative aspects of the proposed therapeutic approach;
- Describe patient selection opportunities;
- Biomarker needs;
- Describe issues with contemporary efforts with the target including reasons for successes or failures.
- **Selectivity:** Describe the desired selectivity profile, including any intentional polypharmacology;
- Safety: Describe any known or potential toxicology considerations;

• Detailed flow scheme to the Hit or Lead deliverable:

- Provide descriptions and development status of the primary assay to be used for screening as well as any relevant secondary assays (e.g., biochemical assays, counter screens, cell-based assays);
- Outline available resources such as reagents, technologies, tool molecules and models to be used in the development of required *in vitro* and *in vivo* assays;
- Clearly delineate critical path and profiling assays;
- Describe the SAR plan (if applicable).

• Where appropriate, describe plans to address issues associated with potency, physicochemical properties, safety and IP;

Deliverables and milestones:

- List intermediate deliverables (e.g., completion of a functional genomic screen, establishment of a validated primary or secondary in vitro assay, establishment of an in vivo assay), as well as the ultimate deliverables of Hit or Lead. Specify the projected timing of achievement of each deliverable;
- For each deliverable, specify associated milestones and the projected timing of achievement. Milestones will be monitored to assess progress towards achievement of the deliverable. Include milestones that specify go/no go decision points whenever applicable;
- o For each deliverable, provide at least one milestone every six months.

Research environment:

 Summarize host/partner institutional facilities and resources available to support research execution;

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 Where applicable, describe the expertise and capabilities that the team will enlist, including OICR's Technology Programs (Cell Screening, Diagnostic Development, Drug Discovery, Genomics, Imaging, and Informatics).

Project team:

- Provide an overview of the team's organizational structure, specifying the project Principal Investigator (PI), Co-PI (if applicable; no more than two co-PIs per project), Co-Investigators and other key members leading research activities;
- Outline necessary collaborations, highlighting the work to be undertaken by each collaborator.

• Commercialization plan and recipient obligations:

- For Accelerator Projects: The plan must include a brief non-confidential description of any project-related IP, and any restrictions or third party rights impacting the IP development in Ontario. Beyond a description of the use of proceeds for the proposed Accelerator Project, no commercial plan is required for Accelerator Projects. It is strongly suggested that the entire commercialization section of this RFA be reviewed together with institutional Technology Transfer Officers, even if the application is not intended for Incubator funding at this time.
- For Incubator Projects: The plan must include a market analysis, competitive landscape and IP assessment. Applicants must describe any third party rights and/or constraints that could impede their use of assays, models, etc., for research purposes and/or commercial development, and how these issues would be addressed.

Since the ultimate goal of this program is to support translation of new cancer therapies to the clinical setting, the creation and protection of IP that will make drug candidates attractive to potential licensing and commercialization partners is a significant consideration in prioritizing projects for funding. CTIP is structured so that the awardee Host Institution(s) retains background IP rights. In line with OICR's "Ontario First Policy" (see Appendix I), which requires that reasonable efforts are undertaken to commercialize and manufacture a project's arising IP in Ontario, applicants will contractually agree to consult FACIT, OICR's commercialization partner, to finalize the commercialization planning, rights and obligations, with an emphasis on Ontario-based development.

Accelerator and Incubator Project award agreements will include an Option for FACIT to act as the commercial agent for any arising IP. In order to balance academic commercialization freedom and to be in line with other similar programs, the Option will be restricted to the period during the Accelerator project and a three-month period following the completion of the project. Further, should an Accelerator project evolve into an Incubator project, OICR funding of Accelerator research activities will be added to any investments made by OICR during the Incubator stage in the determination of OICR's total contributions to the Project.

OICR considers funding of an Incubator Project as an investment. Consequently, economic consideration will be required in exchange for Incubator Project funding and will also reflect any previous financial support by the CTIP program. Financial terms will be negotiated by FACIT prior to approval of Incubator awards. Unless otherwise agreed, FACIT will act as the commercial agent for Incubator projects. In this capacity, FACIT may negotiate third party rights or licenses (i.e., pharmaceutical or biotech company partnering) and co-funding arrangements as required by the CTIP program or commercialization plan. Applicants will have the opportunity to review and discuss any proposed commercial terms prior to accepting and initiating an Incubator project.

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3.1.3 Host Institution commitment letter(s)

Provide the following letters. Combine the letters with the completed Form II as one bookmarked PDF document.

- A letter from the administrative authority/high-level institutional official (i.e., President or Vice-President, Research), of the PI and Co-PI's Host Institutions must be submitted;
- The letter(s) must outline the institutional commitment to facilitate and support the research, assign space and resources, and provide other administrative support for the duration of the proposed research. The letter(s) should describe how the institution maintains accountability for promoting scientific excellence and fiscal responsibility with awarded funds. Importantly, the letters must declare that the signatories have read and acknowledged OICR's "Ontario First Policy" (Appendix I) and agree to abide by the policy through a funding agreement in the event of a successful application.

3.2 BIOGRAPHICAL SKETCHES

Use **Form III** to provide biographical sketches for the following individuals. Combine all biographical sketches in one bookmarked PDF document.

- PI;
- Co-PI, if applicable; and
- Co-Investigators.

3.3 BUDGET AND JUSTIFICATION

Use **Form IV** to complete the project budget. Line item justifications must be included. They should be brief, and provide a high level explanation of why the expenses are necessary and how they are calculated.

This section outlines the various cost categories that are allowed for inclusion in the CTIP project funding request. All amounts are in Canadian dollars.

3.3.1 Project Costs

3.3.1.1 Salaries and benefits

- Salaries and benefits for research associates, technicians, trainees, and other highly qualified personnel working directly on the research projects are allowable costs;
- Stipends for trainees (e.g., summer students, graduate students, postdoctoral fellows, medical fellows), calculated at the rate prescribed by the policies of the institution at which the research will be conducted are allowable costs. If the institution does not have written policies on rates, the rates currently in effect for similarly qualified personnel under the Canadian Institutes of Health Research's trainee programs will be used;
- Salaries and benefits of the PI(s) or Co-Investigators are not allowable costs;
- o Provision of salary increases should reflect applicable institutional guidelines;
- NOTE: Budget justification should NOT contain any staff names. Instead, it should outline the job title, role, annual salary and percentage FTE;
- o Salaries and benefits are eligible for overhead.

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3.3.1.2 Laboratory consumables

- Costs for laboratory consumables directly related to the research project are allowable;
- This category must be used for costs related to internal charge-back laboratory services within an institution (where applicable); however, internal charge-back amounts should not include overhead;
- Laboratory consumables are eligible for overhead.

3.3.1.3 External research services

- This cost category is for external costs related to research services provided by external research groups/institutions. The external group will issue an itemized purchase order/invoice that will include the full cost of the services rendered (e.g., labour, consumables, sample handling, etc.). The services will be free from any IP restrictions or restrictions on use of the data;
- o External research services are NOT eligible for overhead.

3.3.1.4 Equipment

- Costs for equipment directly related to the Accelerator or Incubator Project are allowable. Costs exceeding \$25,000 require appropriate justification and prior approval from the OICR President and/or Deputy Director. All procurement must be in accordance with the PI's Host Institution's procurement policies;
- Equipment purchased with OICR funding will belong to the recipient institution. The recipient institution is responsible for the proper functioning and maintenance of research equipment purchased using OICR funds. Final disposition of research equipment will be the responsibility of the recipient institution. However, no OICR-purchased equipment should be sold within five years of its acquisition without written approval from the OICR President and/or Deputy Director;
- Should the equipment no longer be required during the course of the Accelerator or Incubator Project, OICR reserves the right to relocate it;
- Equipment is NOT eligible for overhead.

3.3.2 Administrative Costs

3.3.2.1 Dissemination of research results

- Include costs associated with the dissemination of research results and/or specific, well-justified knowledge translation strategies including publication costs directly related to the project up to a maximum of \$4,000 per year;
- o Dissemination of research results costs is NOT eligible for overhead.

3.3.2.2 Travel costs

- Include costs for project-related travel up to a maximum of five per cent of the total project budget before overhead. All travel must be undertaken in accordance with travel policy of the traveler's institution;
- o Travel costs are NOT eligible for overhead.

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3.3.2.3 Audit costs

- The Government of Ontario may audit OICR and any of its funded projects at any time during the award, with a 48-hour advance notice and at the expense of the Government of Ontario;
- Recipients of OICR financial contributions totalling \$750,000 or more may be requested to submit an independent auditor's certificate with their year-end financial report;
- Audit costs are NOT eligible for overhead.

3.3.2.4 Training

- If necessary for the execution of the Accelerator or Incubator Project, include scientific staff training (e.g., training on a new piece of equipment, training on a protocol from a laboratory not involved with the project). Training must be carried out in accordance with the Lead or Partner Institution's policies;
- Training costs are NOT eligible for overhead.

3.3.3 Overhead costs

- A maximum rate of 30 per cent will be used for all overhead-eligible costs and will be approved as part of the budget approval process;
- When changes to funded research activities result in a reallocation of funds between sites or cost categories, the resulting calculations of overhead will require adjustments. At the time of yearly financial reporting, reported overhead will be based on actual expenditure and not budgeted amounts. Any resulting difference between the budgeted and actual amounts will require adjustments in consultation with the affected institution;
- Note that participating Institutions cannot request reimbursement of overhead not covered by OICR from another Government of Ontario funding source.

3.3.4 Non-allowable costs

- Non-allowable costs include:
 - Salaries and benefits of the PI(s) or Co-Investigator(s);
 - Benefits for trainees (i.e., undergraduate and graduate students). Note that benefits for post-doctoral fellows is an allowable cost and should be in accordance with the Host Institution's policy;
 - Funding for any project where there is significant scientific overlap (e.g., the research objective and design are identical or very closely related) with a project currently funded though other sources;
 - Insurance for equipment.

4 REVIEW

Registrations will be reviewed for eligibility and suitability for CTIP funding. Only those deemed responsive to this RFA will be invited to submit a full application.

Full applications will be evaluated by a review body comprised of external drug development experts based on the following criteria:

- Potential to address a well-defined unmet clinical need;
- Originality, innovativeness and feasibility of the drug discovery approach;

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- Strength of the target validation status and research plan;
- Strength of the target druggability status and research plan;
- Flow scheme connectivity;
- Likelihood of achieving the Hit or Lead deliverable within the expected time periods listed in section 1.3;
- Appropriateness of in vitro and in vivo cancer models to the disease;
- Potential to fill an unmet market opportunity, global competitive differentiation, which may include feedback from industry partners (if applicable);
- Commercialization potential, including the potential for industry receptor uptake.

5 AWARD PROCESS

5.1 NOTIFICATION OF AWARD

Successful applicants will be informed in writing of OICR's decision by a notification of award (NOA) letter. The NOA will announce the maximum contribution to the project and provide a description of any adjustments to the budget, if applicable.

5.2 ESTABLISHMENT OF AGREEMENTS WITH THE RECIPIENTS

Following approval of the project awards, research agreements will be established with PI Host Institutions and Partner Institutions (if applicable), and will cover the general principles regarding the conduct of research activities, eligible research expenses, terms and conditions regarding the disbursement of funds, agreements with third-party funders, financial and progress reporting, PI/Co-PI covenants, IP, commercialization, publications, and communication policies. In addition, OICR will establish a commercialization framework, which will require the recipient and OICR to set up an IP co-management plan, where applicable.

Please note that delays in execution of research agreements may impact OICR's ability to award project funding.

5.3 REPORTING REQUIREMENTS

5.3.1 Financial and operational status reporting

Host Institution Financial Officers (FO) will be required to provide quarterly updates on budget versus actual expenditures using OICR's online financial reporting system, CaAwardNet (training will be provided). When reporting on the status of a project, an explanation of variances of greater than ± 15 per cent and mitigation plans to address the budget gaps will need to be provided.

Table 1: Financial and operational status reporting*

	ACTION			
PERIOD COVERED	FO	PI or Project Manager (if applicable)	OICR Finance and Research Operations	
Q1: April- June	Reconciliation process and financial report Due: July 31	Review and submit quarterly financial and operational status report Due: August 15	Review and approve quarterly report Due: August 31	

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		ACTION		
PERIOD COVERED	FO	PI or Project Manager (if applicable)	OICR Finance and Research Operations	
Q2: July- September	Reconciliation process and financial report Due: October 31	Review and submit quarterly financial and operational status report <i>Due: November 15</i>	Review and approve quarterly report Due: November 30	
Q3: October- December	Reconciliation process and financial report Due: January 31	Review and submit quarterly financial operational status report <i>Due: February 15</i>	Review and approve quarterly report Due: February 28	
Q4: January- March	Quarterly financial report, fiscal year reconciliation process and fiscal year Schedule F report Due: April 30	 Review and submit financial and operational status report. Review and submit financial yearly reconciliation and Schedule F report. If needed, request a budget amendment from OICR. Submit detailed quarterly budget for the following fiscal year. Due: May 15 	Review and approve quarterly finance report, fiscal year reconciliation, fiscal year Schedule F report, and budget amendment (where applicable) Due: May 31	

^{*} These are standard OICR reporting timelines and requirements. For this RFA, since projects are expected to begin in December 2017, the first required report will be after the Q4 period (January-March 2018), which will include any activities in the Q3 period (October-December 2017), if any occurred.

5.3.2 Annual Reporting

All projects will be included in OICR's annual reporting process, as required by the Ministry of Research, Innovation and Science according to the schedule below (Table 2).

Table 2: Annual Reporting

REPORT	PERIOD COVERED	DUE DATE	ACTION
Annual Progress Report	Fiscal year: April-March	May 15 th of the subsequent fiscal year	 Provide brief status updates on fiscal year deliverables and milestones Provide a progress narrative for the reporting fiscal year
Key Performance Indicators (KPIs) Report	Fiscal year: April-March	May 15 th of the subsequent fiscal year	 Provide quantitative KPIs using ReportNet (OICR's online KPI reporting system; training will be provided)

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5.3.3 Communication with OICR

The obligations of award recipients to advise OICR of anticipated public dissemination, publications, and media announcements will be outlined in the research agreement.

5.4 ACKNOWLEDGEMENT AND RECOGNITION OF SUPPORT

Award recipients must acknowledge and credit the contribution/support, in whole or part, of OICR and the Government of Ontario in any promotional material, including, without limitation, scientific publications of whatever nature or kind by setting out in any communication materials or publications referencing the projects, the following statement: "This study was conducted with the support of the Ontario Institute for Cancer Research through funding provided by the Government of Ontario."

5.5 CONTACT INFORMATION

Questions should be directed to OICR's Scientific Secretariat department (scientificsecretariat@oicr.on.ca).

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6 APPENDIX I: "ONTARIO FIRST" POLICY

- In order to promote the commercialization and public availability of inventions made in Ontario by Ontario industry and, to ensure that Ontario businesses obtain sufficient opportunity to commercialize provincially-supported inventions, the Host Institution agrees that the following options to commercialize the arising intellectual property (IP) will be considered:
 - An existing organization in Ontario with receptor capacity;
 - An expansion of an existing company in Ontario;
 - o The formation of a new company in Ontario;
 - o 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.
- If reasonable efforts to grant licenses to potential licensees to commercialize and manufacture the arising IP substantially in Ontario are unsuccessful, then the Host Institution agrees that the Lead will be responsible for documenting the rationale and circumstances that led to any proposed decision or step to pursue commercialization/exploitation by a non-Ontario company, including an account of the benefits to Ontario for review by an IP Commercialization Committee prior to finalizing the decision or step. The documentation will be forwarded to OICR.

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