OICR Cancer Therapeutics Innovation Pipeline

Request for Applications
Early Accelerator Projects

July 2018

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1. INTRODUCTION

1.1. 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 cancer type of interest. Currently, CTIP funds projects in two phases of preclinical drug discovery: Accelerators and Incubators (Figure 1).

- **Accelerator projects**, whose goal is to deliver an *in vitro* validated target and related Hit[1] molecules. A confirmed Hit molecule should possess features that support its potential to become a Lead[2] 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;
- **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).

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

Figure 1. OICR's Cancer Therapeutics Innovation Pipeline

1.2. REQUEST FOR APPLICATIONS: SCOPE

This RFA is **limited to Early Accelerator applications only** (see section 1.3.1.1 for more details).

The RFA process will occur in two stages:

- Letter of Intent (LOI): LOIs will be reviewed for eligibility and suitability for Early Accelerator funding and only those deemed appropriate will proceed to the full application stage;
- Full application.

OICR invites applications from investigators at Ontario academic institutions, small biotechs or start-up companies seeking support for early stage drug discovery. CTIP funding is only tenable in Ontario.

The timeline for this RFA is as follows:

- LOI deadline: August 13, 2018 by 5:00 p.m. EDT
- Response to LOI applicants: August 22, 2018
- Full application deadline: September 21, 2018 by 5:00 p.m. EDT
- Notification of results: November/December 2018
- Funding to begin: April 1, 2019

1.3. CTIP PROJECTS: OVERVIEW

Although this **RFA is limited to Early Accelerator applications only**, since successful projects have the potential to advance through the CTIP pipeline, the three stages of Early Accelerator, Late Accelerator and Incubator are described herein.

1.3.1. Accelerator projects

1.3.1.1. Early Accelerator projects: Target validation and primary assay development

The goals of an Early Accelerator project are to focus on target identification/validation experiments and to deliver a validated primary assay to enable initial screening of molecules against a defined target. 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.

1.3.1.2. Late Accelerator projects: Hit generation

At this time, OICR is not inviting applications for Late Accelerator projects.

The goals of a Late Accelerator project are to focus on screening, using validated primary and secondary assays and to deliver confirmed Hit molecules. 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.

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 against

a defined target (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, 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.

1.3.2. Incubator projects: Lead generation

At this time, OICR is not inviting applications for Incubator projects.

The goal of an Incubator project 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 molecules should be sufficiently mature to attract partnership/investment for further development and ultimately commercialization. Incubator projects will be funded to a maximum of $1,000,000 per year for a maximum of two years.

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 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.

2. LETTER OF INTENT (LOI)

At this time, OICR is inviting LOIs for Early Accelerator projects only.

The LOI (using provided **Letter of Intent Form**) will be reviewed for eligibility and suitability for CTIP funding and only those deemed appropriate will proceed to the full application stage. All sections are mandatory and must be completed using 11-point Arial font and single spacing. Margins cannot be modified and word limits must be strictly followed. Submit as one PDF to scientificsecretariat@oicr.on.ca by **5:00 p.m. EDT on August 13, 2018**. File must be labelled as follows: PI Last Name CTIP LOI.pdf.

All applicants will be advised of results and those deemed appropriate will be invited to submit a full application.

3. FULL APPLICATION

At this time, OICR is inviting applications for Early Accelerator projects only.

The full application package consists of **Form I** (Administrative information and research plan), **Form II** (Deliverables and milestones), **Form III** (Budget and justification), and **Form IV** (Biographical sketches).

All sections are mandatory and must be completed using 11-point Arial font and single spacing. Margins cannot be modified in the forms provided. Page limits must be strictly followed and **exclude** tables, figures and references.

Electronic copies of Forms I, II, III and IV must be submitted to OICR's Scientific Secretariat department (scientificsecretariat@oicr.on.ca) by **5:00 p.m. EDT on September 21, 2018.** Files must be labelled as follows:

- PI Last Name Form I – Research plan.pdf
- PI Last Name Form II – D and M.xls
- PI Last Name Form III – Budget.xls
- PI Last Name Form IV – Biographical sketches.pdf

3.1. FORM I: ADMINISTRATIVE INFORMATION AND RESEARCH PLAN

Using **Form I,** complete the following information and submit as one bookmarked PDF.

3.1.1. Contact information

Provide for the following individuals:

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

3.1.2. Research plan - Early Accelerator projects (max. seven pages)

- **Lay summary,** using simple, easy to understand, non-technical language

- **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;
  - Provide key data supporting the target's biologic and strategic rationale;
  - Describe the desired mechanism of modulation (e.g., agonist, antagonist, etc.);
  - Describe the proposed modality (e.g., small molecule, peptide, antibody, etc.);
  - Describe the intended route of administration;
  - Describe the mechanism of action (MOA), if available; and
  - Describe the feasibility as well as potential pitfalls and mitigation plans of the project.

- **Differentiation strategy:**
  - Identify the current standard of care for the target and/or the disease indication, and their limitations;
  - Describe the competitive landscape;
  - Describe issues with contemporary efforts with the target including reasons for successes or failures;
  - Describe the innovative aspects of the proposed therapeutic approach; and
  - Describe patient selection opportunities.

- **Selectivity**: Describe the desired selectivity profile, including any intentional polypharmacology

- **Safety:** Describe any known or potential toxicology considerations

- **Other considerations:** Where appropriate, describe plans to address issues associated with potency, physicochemical properties, safety, biomarker needs, and IP

- **Description of assays and flow scheme:**
  - Early Accelerator – deliver a validated primary assay to a defined target
    - Describe target identification/validation experiments, as applicable;
    - Provide a description and the development status of the primary assay to be used for

screening;
    - Clearly outline available resources such as reagents, technologies, tool molecules, and models to be used in assay development; and
    - Using a separate page, attach a flow scheme to Form I. The flow scheme must not exceed one page, which does not count towards the page limit indicated for the research plan section. It is recommended that the flow scheme is completed using a landscape orientation. Refer to **Appendix I** for an example.

- **Research environment:**
    - Summarize host/partner institutional facilities and resources available to support research execution; and
    - Where applicable, describe the expertise and capabilities that the team will enlist, including OICR's Technology Programs (Cell Screening, Diagnostic Development, Drug Discovery, Genomics, Genome Informatics, and Imaging). Click here for more information.

- **Project team:**
    - Provide an overview of the team's organizational structure, specifying the project PI, Co-PI (if applicable), Co-Investigators and other key members leading research activities; and
    - Outline necessary collaborations, highlighting the work to be undertaken by each collaborator.

- **Commercialization plan and recipient obligations:**
    - 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.

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 II**), 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 (Fight Against Cancer Innovation Trust), OICR's commercialization partner, to finalize the commercialization planning, rights and obligations, with an emphasis on Ontario-based development.

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.

3.1.3. Host Institution commitment letter(s)

The following letter(s) are to be combined with the completed **Form I** as one bookmarked PDF.

- 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 II**) and agree to abide by the policy through a funding agreement in the event of a successful application.

3.2. FORM II: DELIVERABLES AND MILESTONES (D/M)

Using **Form II**, provide D/M and submit as an excel file.

- List the ultimate deliverable of a ***validated primary assay to a defined target***;
- Specify associated milestones – **at least one milestone for every 6-month period** – that can be tracked to assess progress towards achievement of the delivery of a validated primary assay to a defined target. Specify the projected timing of each milestone. Include milestones that specify go/no go decision points whenever applicable; and
- Disbursement of funds for approved projects may be gated against the agreed-upon deliverable and associated milestones. Failure to meet the deliverable or key 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.

3.3. FORM III: BUDGET AND JUSTIFICATION

Using **Form III,** complete the project budget and submit as an excel file.

- 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;
- Funding is provided by the Government of Ontario through the Ministry of Economic Development, Job Creation and Trade. Awarded funds will be solely dispersed and administered by eligible institutions in Ontario. Funding will be contingent on availability of funds from the Government of Ontario.

The following section outlines the various cost categories that are allowed for inclusion in the CTIP application. All amounts are in Canadian dollars.

3.3.1. Overhead costs

- A maximum rate of **30 per cent** must be included 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; and
- Note that participating institutions cannot request reimbursement of overhead not covered by

OICR from another Government of Ontario funding source.

3.3.2. Project costs

3.3.2.1. Salaries and benefits

- Salaries and benefits for research associates, technicians, trainees, and other highly qualified personnel working directly on the research project 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;
- Salaries and benefits of the PI(s) or Co-Investigators are not allowable costs;
- Provision of salary increases should reflect applicable institutional guidelines;
- Budget justification should NOT contain any staff names. Instead, it should outline the job title, role, annual salary and percentage FTE;
- **Salaries and benefits at institutions outside OICR are eligible for overhead.**

3.3.2.2. 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 at institutions outside OICR are eligible for overhead.**

3.3.2.3. 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;
- **External research services are NOT eligible for overhead.**

3.3.2.4. Equipment

- Costs for equipment directly related to the 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 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 project, OICR reserves the right to relocate it;
- **Equipment is NOT eligible for overhead.**

3.3.3. Administrative Costs

3.3.3.1. 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;
- **Dissemination of research results costs are NOT eligible for overhead.**

3.3.3.2. 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 the travel policy of the individual's institution;
- **Travel costs are NOT eligible for overhead.**

3.3.3.3. 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.**

3.3.3.4. Training

- If necessary for the execution of the 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 training policy of the individual's institution;
- **Training costs are NOT eligible for overhead.**

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.

3.4. FORM IV: BIOGRAPHICAL SKETCHES

Using **Form IV,** provide biographical sketches for the following individuals and submit as one bookmarked PDF.

- PI;
- Co-PIs, if applicable; and
- Co-Investigator(s).

4. REVIEW

4.1. LOI

LOIs will be reviewed for eligibility and suitability for Early Accelerator funding and only those deemed appropriate will proceed to the full application stage.

4.2. FULL APPLICATIONS

Applications will be evaluated by the Therapeutics Pipeline Advisory Committee (TPAC), comprised of external drug development experts and *ad hoc* reviewers, as required.

The following criteria will be used to evaluate each application:

- Potential to address a well-defined unmet clinical need;
- Originality and innovativeness of the drug discovery approach;
- Strength of the target validation status;
- Strength of the target druggability status;
- Appropriateness of *in vitro* and *in vivo* cancer models to the disease;
- Feasibility of the research plan and approach;
- Likelihood of achieving the deliverable within the expected time period listed in section 1.3; and
- Strength of the project team.

The following scoring will be assigned to each application:

Table 1: Project scoring

Score	Description
4.7 – 5.0	Excellent with no weaknesses identified
4.2 – 4.6	Excellent with minor weaknesses identified
3.6 – 4.1	Very good with minor weaknesses identified
3.0 – 3.5	Very good with moderate weaknesses identified
2.4 – 2.9	Good with moderate weaknesses identified
1.7 – 2.3	Fair with moderate weaknesses identified
1.0 – 1.6	Poor with moderate to major weaknesses identified
Below 1.0	Poor with major weaknesses identified

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, 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. Project progress reporting

TPAC was established in part to provide active monitoring of CTIP projects. Twice a year, TPAC will convene to evaluate the progress of projects. Instructions and templates will be provided to project teams in advance of TPAC meetings to collect information on the status of the project, milestones and the deliverable. Feedback from the TPAC reviews will be shared with project PI(s), who will then have the opportunity to respond to TPAC's comments.

Disbursement of funds for approved projects may be gated against the agreed-upon deliverable and associated milestones. Failure to meet the deliverable or key milestones could lead to a decision to terminate and defund the project.

5.3.2. 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 2: Financial and operational status reporting*

Period covered	Responsible party and action		
	FO	**PI or Project Manager (if applicable)**	**OICR Finance and Research Operations**
Q1 Apr-Jun	Reconciliation process and financial report: ***Due Jul 31***	Review/submit quarterly financial and operational status report: ***Due Aug 15***	Review/approve quarterly report
Q2 Jul-Sept	Reconciliation process and financial report: ***Due Oct 31***	Review/submit quarterly financial and operational status report: ***Due Nov 15***	Review/approve quarterly report
Q3 Oct-Dec	Reconciliation process and financial report: ***Due Jan 31***	Review/submit quarterly financial and operational status report: ***Due Feb 15***	Review/approve quarterly report

Period covered	Responsible party and action		
	FO	PI or Project Manager (if applicable)	OICR Finance and Research Operations
Q4 Jan-Mar	Quarterly financial report, fiscal year reconciliation process and fiscal year Schedule F report: ***Due Apr 30***	• Review/submit financial and operational status report; • Review/submit financial yearly reconciliation and Schedule F report. If needed, request a budget amendment from OICR; • If applicable, submit detailed quarterly budget for the following fiscal year. ***Due May 15***	Review/approve quarterly finance report, fiscal year reconciliation, fiscal year Schedule F report, and budget amendment (where applicable)

* These are standard OICR reporting timelines and requirements. For this RFA, since projects are expected to begin in April 2019, the first required report will be after the Q1 period (April-June 2018).

5.3.3. Annual Reporting

All projects will be included in OICR's annual reporting process, as required by the Ministry of Economic Development, Job Creation and Trade according to the schedule below (Table 3).

Table 3: Annual Reporting

Report	Period covered	Due date	Action
Key Performance Indicator (KPs) Report	Fiscal year: Apr-Mar	May 15th of the subsequent fiscal year	Provide quantitative KPIs using ReportNet (OICR's online KPI reporting system; training will be provided)

5.3.4. 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

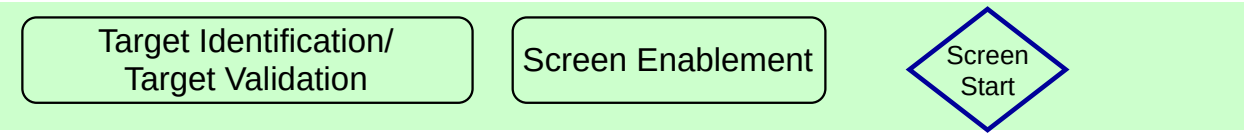
Award recipients must acknowledge and credit the contribution/support, in whole or part, of OICR and the Government of Ontario in any promotional material, including, without limitation, scientific publications of whatever nature or kind by setting out in any communication materials or publications referencing 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."

6. CONTACT INFORMATION

Email: scientificsecretariat@oicr.on.ca

7. APPENDIX I: FLOW SCHEME FOR EARY ACCELERATOR PROJECTS

Example of a flow scheme for an Early Accelerator project. Use this as a reference for your submission and include as part of Form I.



- Disease association or new therapeutic hypothesis supported by genetics
- Biochemical pharmacology or cell/molecular biology research linking target function to a physiological pathway which is abnormal in disease
- Functional genomic screens (e.g., shRNA, CRISPR)

- Material Prep (e.g., protein, antibodies, cells)
- Primary Screening Assay Development & Validation
- Secondary Assay Development & Validation

Criteria:
Validated primary assay against a defined target

KEY

Green: Assay Validated (pharmacology + stats)
Yellow: Assay in development
Red: Assay Not Ready
Critical path assay
Profiling assay

8. APPENDIX II: "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;
  - 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.
- 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.