LeadAction Ovarian Cancer Competition

DEADLINES **Submission of Notice of Intent:** **March 17, 2020, 4:30 p.m.** **Submission of Complete Application:** **June 16, 2020, 4:30 p.m.**	For all questions related to: **IRICoR** and the Competition **Audrey Segret** Project Manager audrey.segret@umontreal.ca For all questions related to: **Ovarian Cancer Canada** **Alicia Tone** Project Manager and Scientific Advisor ovcan@ovariancanada.org

COMPETITION PROMOTERS AND CONTEXT

In an effort to develop and highlight scientific research excellence in ovarian cancer on a path towards commercialization of innovative therapeutic solutions, IRICoR and Ovarian Cancer Canada ("Promoters") are proud to announce the launch of the LeadAction Ovarian Cancer Competition (the "Competition") to support the advancement of hit-to-lead targets and novel therapeutic approaches through preclinical trials. Therapies could be targeted or immune-based and will ideally be prioritized based on existing data that indicate the probability of success, and the ability to advance the treatment into clinical trials in the shortest timeline.

IRICoR is a not-for-profit organization acting as a project maturation cluster in the field of drug discovery with the mandate to accelerate the discovery, development and commercialization of novel therapies in cancer and related fields. Since 2008, IRICoR has successfully combined industry-standard business expertise and cutting-edge research. IRICoR invests in and supports particularly innovative selected projects, ensuring an effective transition of fundamental research into innovative therapies, through either co-development partnerships with the biopharmaceutical industry or the creation of spin-off companies. IRICoR provides selected academic and industry projects with access to its drug discovery network of experts and infrastructure, including one of the largest academia-based medicinal chemistry groups in Canada. IRICoR's major funding sources for the 2018-2023 period include the Canadian government's Centres of Excellence for Commercialization and Research (CECR) Program, the Quebec government's programs, through the *Ministère de l'Économie et de l'Innovation* (MEI, previously the *Ministère de l'Économie, de la Science et de l'Innovation - MESI*), and collaborative partnerships with the biopharmaceutical industry. The Competition is a great opportunity for IRICoR to continue building a portfolio in ovarian cancer with high-value academic projects sourced from across Canada.

Ovarian Cancer Canada champions the health and wellbeing of women with ovarian cancer and others at risk of this disease while advancing research to save lives. As the only registered Canadian charity solely dedicated to overcoming ovarian cancer, the organization provides leadership in research, advocacy, and support, so that women live fuller, better, longer lives. It acts as a real scientific accelerator. To date, 6 million dollars has been allocated to research by Ovarian Cancer Canada and 10 million to advance progress on ovarian cancer research in Canada through an initiative called OvCAN. OvCAN's overall goal is to improve the outcomes of women diagnosed with ovarian cancer over the next five years.

GENERAL ELIGIBILITY CRITERIA

The main objective of the Competition is to subsidize ovarian cancer research projects led by skilled Canadian scientists. The projects must be aimed at developing highly innovative new therapies, with significant commercial potential, that will pave the way, in the long-term, towards the next generation of treatments accessible to patients.

PROJECT ELIGIBILITY

Competition objectives	Eligible projects can be related to the development of small molecules or biotherapies (antibodies, oncolytic viruses, cell products such as stem cells or T cells, synthetic peptides, ribonucleic acid (RNA)-based approaches, etc.). This list is non-exhaustive. **The Competition aims to promote projects starting at one of these following phases/stages:** • **Hit to lead transition;** • **Lead optimization;** • **Pre-clinical studies.** A few examples of fundable activities from these various phases/stages: • **Hit to lead transition/Lead optimization:** o Design of new analogs based on hit compounds series; o Structure-activity relationship analysis; o Optimization of selective compounds aimed at greater efficiency and reduced off-target activities • **Preclinical studies:** o *In vivo* evaluation of drug candidates: proof of concept, determination of the minimum effective dose and/or of the therapeutic window: o PK/PD, ADME; o Preliminary non-GLP safety studies; o Pharmaceutical aspects (i.e. initial formulation and production of preclinical material); o Identification of clinical doses **Non-Eligible:** *GLP-driven toxicology studies and manufacturing activities as well as clinical trials (phase I, II and III), are not eligible in this Competition.* Please note that in this Competition, applicants who need to use drug discovery core facilities are invited (but not obliged) to refer to the locations in the Annex of this document

APPLICANTS' ELIGIBILITY

Conditions	The grantee (Principal Investigator) must be a University Investigator or a Clinical University Investigator from an institution, center, research institute or department (hereinafter "Institution") affiliated to a Canada-based university. In this Competition, postdoctoral trainees are not eligible as Principal Investigators. The managing Institution will be the employing Institution of the funding recipient. **Research team structure** **The research team must be comprised of one (1) Principal Investigator.** The Principal Investigator will represent the project, manage the application and the internal scientific direction of the project. Along with the other members of their teams (Master's, doctoral and postdoctoral students, postdoctoral fellows, research or coordination associates, research technicians, research assistants), research teams are encouraged to include newly recruited Investigators (Junior 1), young experienced Investigators (Junior 2) or experienced Investigators (Senior). **According to the needs of the project, the Principal Investigator may complete his/her team by adding Co-investigators and /or collaborators from across Canada or internationally. No minimum or maximum is required.** The Co-investigator from Canada: • Must be from an Institution affiliated to a Canada-based university; • Must be a Canadian university faculty member; • Must contribute significantly or provide specific expertise to the research project related to the funding application; • May manage part of the funds eventually granted, following an agreement with the managing Institution. The Co-investigator from outside Canada: • Must be a university faculty member; • Must contribute significantly or provide specific expertise to the research project related to the funding application; • Will not receive funding from this grant Competition. The collaborator(s) from Canada or outside Canada: • Must be a university faculty member; • Will not have access to funds from this Competition. Investigators affiliated to federal or provincial laboratories are only eligible as collaborators in this Competition.

Professional Order for Clinical University Researcher in Canada	Individuals with the status of Clinical University Researchers must prove that they are members in good standing of the professional order governing them in Canada, have a valid license to practice in Canada and have professional liability insurance.
Multiple applications	An Investigator: • May only submit one project to this Competition as a Principal Investigator; and • May participate in a maximum of two (2) projects as a Co-investigator or collaborator. Therefore, an Investigator may participate in a maximum of three (3) projects in this Competition.
Research ethics codes and institutional policies	The Principal Investigator must have his/her project evaluated with respect to ethics and obtain the approvals of the research ethics committees concerned before the research involving the funded project can begin. It remains the responsibility of the Principal Investigator to obtain the certification required for the project and to provide it to the departments concerned in his/her Institution. It remains the responsibility of the Principal Investigator, Co-investigators and collaborators to respect institutional rules and policies of their institutions.

REQUIRED DOCUMENTS – NOTICE OF INTENT

IRICoR and Ovarian Cancer Canada handle the management of the Competition.

The first step of the competition is a 'Notice of Intent' followed by the 'Complete Application'.

All correspondence with IRICoR or Ovarian Cancer Canada may be conducted in French or in English. However, **please note that in cases where the application is drafted in French, IRICoR and Ovarian Cancer Canada, may request that the applicant provide an English translation for evaluation purposes.**

Transmission of documents:

All documents described below must be sent by e-mail to Audrey Segret, Project Manager at IRICoR (audrey.segret@umontreal.ca).

Missing documents or forms that do not comply with the Competition rules, within the deadlines indicated, will result in the file being ineligible and will be automatically rejected. No extensions will be permitted.

All documents must be integrated into a single (1) PDF document. The Principal Investigator's CV, including detailed contributions, should be part of the PDF document.

The date and time of the transmission of the e-mail

is proof of the date and time of the document's filing.

Principal Investigator	**The Notice of Intent should be submitted by the Principal Investigator managing the project and must include:** • Notice of Intent form; • Free format CV (last update between July 2019 and the Competition deadline); • Detailed contributions (last update between July 2019 and the Competition deadline); • Letter of support from the university technology transfer unit (or any other equivalent entity) to which the Principal Investigator is affiliated, indicating having been made aware of the project submission. Only Investigators whose Notices of Intent were considered to be eligible will be invited to submit a Complete Application (see the "Evaluation" Section). IRICoR will send an e-mail confirming the acceptance or rejection of the Notice of Intent to each applicant.

REQUIRED DOCUMENTS – COMPLETE APPLICATION

Transmission of documents:

All documents described below must be sent by e-mail to Audrey Segret, Project Manager at IRICoR (audrey.segret@umontreal.ca).

Missing documents or forms that do not comply with the Competition rules, within the deadlines indicated, will result in the file being ineligible and will be automatically rejected. No extensions will be permitted.

All documents must be integrated into a single (1) PDF document. The CV of all Investigators, **including detailed contributions**, should be inserted one after the other in the PDF document.

The date and time of the transmission of the e-mail is proof of the date and time of the document's filing.

Principal Investigator	**The Complete Application must be submitted by the Principal Investigator of the managing Institution and must include:** • Complete Application form; • Free format CV (last update between July 2019 and the Competition deadline); • Detailed contributions (last update between July 2019 and the Competition deadline); • Letter of support from the administrators of the Institution or university department in which the Principal Investigator's research will be carried out, indicating the commitment towards the Principal Investigator and the project; • For clinicians: a letter from the administrators of the clinical department or the dean of the faculty specifying the number of hours for which the applicant will be released from his/her

	clinical obligations to carry out the research project; • A quote presenting the costs associated with the services to be provided by the drug discovery core facilities.
Co-Investigator	• Free format CV (last update between July 2019 and the Competition deadline); • Detailed contributions (last update between July 2019 and the Competition deadline); • Letter of support from the administrators of the Institution or university department in which the Co-Investigator research work will be carried out, if necessary; • For clinicians: a letter from the administrators of the clinical department or the dean of the faculty specifying the number of hours for which the applicant will be released from his/her clinical obligations to carry out the research project.

RESEARCH LOCATION

Choice of the Principal Investigator's research location	A public or parapublic sector institution, excluding private companies.
Change of research location	IRICoR and Ovarian Cancer Canada expect that the grantee will conduct his/her project at the same Institution or university that initially endorsed the application throughout the entire grant period. The grantees who wish to change their research location must submit an official letter of request by e-mail to IRICoR. The request must detail the reasons for the change and describe all possible consequences on his/her research project. University or institutional authorities must also approve the change by notifying IRICoR in writing. The administration of the new research center must also notify IRICoR in writing that they accept to host the grantee and accept rules and terms of the LeadAction Ovarian Cancer Competion as well as the funding agreement signed by contracting parties.
Choice of the Co-investigator and collaborator's research location	A public or parapublic sector institution, excluding private companies.

TERM OF THE GRANT

Term	Two (2) years, non-renewable
Funding start date	October, 2020

AMOUNT OF THE GRANT

Amount	The total budget for the Competition is $4M (50% IRICoR – 50% Ovarian Cancer Canada). **Hit to lead transition and/or lead optimization activities will benefit from a maximum amount of $250,000 per year within this Competition.** **Pre-clinical research activities will benefit from a maximum amount of $500,000 per year within this Competition.** **NOTE: The maximum amount granted in this Competition is $1,000,000 per project over 2 years.** **NOTE: The allocated funds must be spent in Canada.** The managing Institution will handle the transfer of funds, if necessary. Co-funding from other partners is not mandatory. For this purpose, you will be asked to declare in your submission any additional funding by private or public bodies, and conditions related to the commercialization or management of intellectual property to third parties. Payment for the second year of funding will only take place after evaluation and validation of the achieved deliverables by the LeadAction Ovarian Cancer Review Committee (see the "Evaluation" Section for more details). It should be noted that when this Competition's project funding comes to an end, IRICoR may continue to invest in selected projects based on their progression and achieved deliverables.
Indirect research costs	The amounts granted to research teams for this Competition (direct costs) do not include indirect research costs payable to the Institutions. Thus, research teams do not need to include indirect research costs in their budget. Depending on the funding sources that will be used by IRICoR, it is possible that indirect costs will be paid to the Institution in addition to the direct costs.

ELIGIBLE EXPENDITURES

Eligible expenditures for the Competition	• Scholarships, scholarship supplements and salary support (where applicable) to undergraduate, Master's, and doctoral students, and postdoctoral fellows; • Salaries and social benefits to research or coordination associates, research technicians or research assistants; • Research material (including the purchase and housing of animals) and all other expenses required to carry out the research project, conditional upon adequate justification in the application; • Costs related to the use of drug discovery core facilities (academic or private setting in Canada). • Costs related to consultation fees related to specific subjects

	(i.e. chemistry, preparation of IND-enabling studies, etc) • Travel and accommodation costs within the framework of the funded project such as field work, collaborations/consultation (up to 1% of the total budget); • Costs related to the acquisition of biological material from biobanks (up to 1% of the total budget); • Expenses related to the protection of intellectual property (i.e. patent filing and prosecution costs, license fees or patent agent fees). **NOTE :** If IP will be generated, please include in your budget the costs associated : - *US provisional patent application: $4-$7k* - *PCT (international) patent application (>12months): $8-$13K*
Non-eligible expenditures for the Competition	• Remuneration of the Principal Investigators and collaborators; • Purchase of equipment, costs of leasing (or purchasing) facilities; • Participation in conferences and conventions; • Costs related to organizing knowledge mobilization activities; • Research activities that have already been the subject of funding will not be funded if an award has been previously granted.

EVALUATION

Notice of Intent	The Notice of Intent will be used to determine the Principal Investigator's eligibility. It will also allow the Promoters of the Competition to evaluate the administrative and scientific eligibility of the grant application in view of the Competition's objectives and identify any potential conflicts of interest. Promoters will pay particular attention to: - Any funding overlap with grants obtained or applied for by the principal investigator and co-applicants/collaborators of the proposals; - If this project has been or is subject to additional funding by private or public organizations, and conditions related to the commercialization or management of intellectual property allowing certain rights to third parties. Any overlapping funding issues and management of the commercialization or the management of the intellectual property by a third party will be addressed jointly by IRICoR and OCC to confirm if applicants are deemed eligible to submit a Complete Application. The Notice of Intent will enable the Promoters to select the LeadAction Ovarian Cancer Review Committee Members (see below for details). The Chair of the LeadAction Ovarian Cancer Review Committee will validate the eligibility of the reviewers selected. Only applicants whose Notices of Intent are deemed eligible will be

	invited, by e-mail from IRICOR, to submit a Complete Application.
Complete Application	The Principal Investigator for the grant application, as well as the managing Institution, and co-investigators/collaborators must remain the same as those included in the Notice of Intent.
LeadAction Ovarian Cancer Review Committee	The Complete Applications will be evaluated by the LeadAction Ovarian Cancer Review Committee (hereinafter the "Committee") in plenary session. The Committee will comprise both scientific and industry independent experts from the ovarian cancer field. The scientific experts sitting on the Committee will come from Canadian and international academic and clinical settings. Expert members from industry will come from Canada and international and from the following fields: finance, biopharmaceutical industry, business development and entrepreneurship. The Committee will also comprise a patient/advocate as observers to share their vision of the impact on the patient population of each Complete Application submitted. The selection of all Committee members will be made in compliance with IRICoR's conflict of interest policies and guidelines. All projects evaluated by the Committee will be processed with complete confidentiality, in compliance with the policies of IRICoR. At the end of the first and second years of investment, the selected projects will be evaluated by Committee members.
Evaluation criteria of the Complete Application	Complete Applications will be evaluated according to well-defined criteria as follows: • **Project positioning and scientific excellence:** o Context, preliminary results and relevance of the problem; o Clarity of scientific objectives; o Innovative character; o Development stage of the project to be funded; o Extent of link between target and the clinical application sought. • **Scientific and technical feasibility:** o Quality of the applied research methodology; o Relevance of the technological core facilities used in the project; o Identification of risks and mitigation plan; o Expected milestones/deliverables: specific, measurable, realistic, and timely. • **Experience and expertise of the research team:** o Achievements and scientific level of the research team (outreach at the Canadian and/or international level, etc.); o Involvement of early career Investigators (Junior 1 and

	Junior 2) (an asset). • **Commercial potential:** o Ability to respond to an unmet medical need; o Business opportunity/market size; o Discussions already underway with potential private partners. • **Competitive environment and intellectual property:** o Competitive advantage (direct and indirect) of the project; o Status of the intellectual property, if already generated; o Potential for creating new intellectual property. • **Detailed budget:** o Adequate budget justification in line with the proposed project; o Financial leverage (if applicable). NOTE: Investigators are recommended to consult the technology transfer unit of their Institution or any equivalent structure in order to properly describe the project's potential commercialization strategy in view of the Competition's objectives.

MANAGEMENT OF THE AWARD AND KNOWLEDGE MOBILIZATION

Conditions for releasing the allocated funds	If a positive funding decision is made, the Principal Investigator will receive an award letter, with a copy to the managing Institution's Research Bureau, on behalf of IRICoR and Ovarian Cancer Canada. The award letter will present the specific conditions of the award as well as the project plan, as approved/modified by the Committee. The Principal Investigator will then have no more than two (2) weeks to accept or reject the grant under the conditions set forth by sending back the Acceptance Form to IRICOR. **If any conflicts of interest arise from prior agreements, additional public or private funding, conditions related to the commercialization or management of intellectual property, IRICoR and Ovarian Cancer Canada reserve the right to modify or cancel the grant.** The list of these additional funds will be mentioned in the Acceptance Form. A funding agreement, between IRICoR, the Institution of the Competition grantee and affiliated institutions of the Co-Investigators and / or collaborators, must also be signed before the funds are released. If the conditions for releasing the funds allocated are not met (acceptance of the award by the Investigator and signing of the funding agreement) within three (3) months, the award could be cancelled. The releasing of the allocated funds during the two years of Competition funding is conditional on the submission of the required reports in this Competition (See the section Management of the award by Promoters and reporting).
Management of the award by Promoters and reporting	An official project launch meeting will be set up between the research team and IRICoR.

	Project follow-up will be ensured through meetings with the research team **every four (4) months** throughout the period of the award. Annual scientific and financial progress reports must be completed within the agreed timelines. After the 1st year of funding, if the project has not achieved the expected milestones, in keeping with the recommendations of the Committee, IRICoR and Ovarian Cancer Canada reserve the right, within one (1) month of receiving the report, to reduce or to terminate the funding granted for the 2nd year of the project. Following approval of the reports by the Committee, 90% of the funds allocated for the 2nd year of funding by IRICoR and Ovarian Cancer Canada will be paid. When accepting the grant, the Investigator agrees to provide, not more than three (3) months after the end of the grant, namely at the end of the two (2) years of allocated funds, a final scientific report and a final financial report. If those two reports have not been received, IRICoR and Ovarian Cancer Canada reserve the right to withhold the final payment (the remaining 10% of the allocated funds). By accepting the grant, the Investigator also agrees to share the key findings of the study at the 2024 Canadian Conference on Ovarian Cancer Research. Please note that Investigators who have been awarded funding will benefit from IRICoR's established expertise in milestone-based project management and strategic oversight of intellectual property throughout the course of the project.
Intellectual property (IP) and sharing of commercialization revenues	There is no obligation to hold patents or patent applications to file an application for this Competition. However, the intent of IP generation is strongly encouraged. The Background IP (BIP), including all know-how developed by an Institution and required for the successful execution of the project, will remain property of the Institution. IRICoR and all project participants (research teams and their Institutions of affiliation) will need to have access to that BIP for the sole purpose of the project's development. As for the IP generated during the course of the project (Foreground IP (FIP)), the IP generated by the Institution where the Investigator(s) work(s) will be the property of that Institution and will be governed by the IP policy that prevails in that Institution. IP generated by multiple Institutions will be considered as joint IP in proportion to the inventive contribution of each Institution. Funding agreements between IRICoR and the Institutions involved will integrate each Institution's IP policy and practices and will mandate **IRICoR as a commercialization agent** in collaboration with the technology transfer unit (or any other equivalent entity) recognized by the Institution. During the funding period projects will benefit from IRICoR's expertise in all aspects of drug development (CMC, preclinical, regulatory, etc) and once reaching their milestones, theywill benefit from access to IRICoR's business network, thus facilitating their commercialization.

	Terms of potential revenue sharing between the Institutions involved, IRICoR and Ovarian Cancer Canada will be negotiated on a case-by-case basis according to the projects funded and will comply with the relevant regulations of the CECR Program Guide governing IRICoR funds.
Publications by the Investigators	The grantees agree to thank/recognize the contribution of IRICoR and Ovarian Cancer Canada in every scientific or electronic publication that will present the outputs obtained through work subsidized by IRICoR and Ovarian Cancer Canada. The grantees agree to inform IRICoR and Ovarian Cancer Canada of all scientific or electronic publications.
Dissemination and use of the results by the Competition Promoters	The grantees agree to authorize the Promoters to use reports and research outputs that have been disseminated to the public by the Investigator (as part of a scientific or electronic publication, conference, symposium or other), notably for reproduction, translation, execution or public communication purposes through any means, as well as any other form of use, provided there is no infringement of copyright law and solely for non-commercial purposes.
Knowledge mobilization by Investigators	The Promoters encourage grantees to participate in knowledge mobilization activities (transfer, sharing, development, promotion and dissemination) within the practice settings and the general public, whenever such activities are relevant.

APPLICANT'S AGREEMENT

In submitting his/her application, **the Investigator** must, among other things:

- Comply with regulations governing IRICoR's activities, as outlined in the CECR Program Guide;
- Comply with all of the conditions and requirements outlined in the Competition rules and forms;
- Submit certain additional documents related to the use of the grant, if requested by IRICoR or Ovarian Cancer Canada;
- Obtain the certification required for the project and provide it to the departments concerned in his/her Institution before beginning the project;
- Authorize IRICoR and Ovarian Cancer Canada to retain and use all personal and scientific information contained in the file, provided that individuals who are granted access to personal information respect its confidentiality.

RESEARCH INSTITUTIONS' AGREEMENT

The institutions hosting the Principal Investigator and the Co-investigators and/or collaborators are required to provide the basic equipment, research facilities and administrative services required to carry out the research project.

TIMETABLE FOR THE EVALUATION PROCESS

Steps	Period	Dates
Competition launch	N/A	February 4, 2020
Deadline for submitting a Notice of Intent	6 weeks	March 17, 2020
Invitation to submit a Complete Application	4 weeks	April 14, 2020
Deadline for submitting a Complete Application	9 weeks	June 16, 2020
Evaluation by the Committee		September, 2020
Announcement of results		October, 2020

ANNEX: Locations offering drug discovery services

Please note that in this Competition, applicants who need to use drug discovery core facilities are invited (but not obliged) to refer to the following locations:

- Institute for Research in Immunology and Cancer (IRIC) - Université de Montréal (UdeM).
- The Biopharmacy platform of the Faculty of Pharmacy of the Université de Montréal (UdeM);
- The Goodman Cancer Research Centre (GCRC) – McGill University;
- The Research Institute of the McGill University Health Centre (RI-MUHC);
- The Pharmacology Institute of Sherbrook (IPS);
- Le Centre de recherche du Centre hospitalier de l'Université de Montréal (CRCHUM);
- Le Centre hospitalier universitaire de Québec – Université Laval;
- Research Centre – Québec Heart and Lung Institute;
- The MILA-Institut québécois d'intelligence artificielle;
- The Lunenfeld-Tanenbaum Research Institute – Mount Sinai Hospital (Toronto).
- Ontario Institute for Cancer Research Collaborative Research Resources.

Additional references may be provided by IRICoR upon request.

NOTE: Please note that the core facilities' services facilitate and accelerate the development of small molecules or biotherapies. The expertise of a laboratory cannot therefore replace the services proposed by specialized drug discovery core facilities.