Canadian Blood Services
it's in you to give

Centre for Innovation

MSM Research Grant Program
2018 Competition Guidelines

These Guidelines describe the requirements for the Canadian Blood Services MSM Research Grant program. The MSM Research Grant program terms and conditions may be altered without notice. Applicants should always refer to the latest edition of the Guidelines.

I. GENERAL INFORMATION AND PRIORITIES

In June 2016, the Minister of Health announced that Health Canada would provide Canadian Blood Services with a $3M contribution to implement an MSM Research Program in partnership with Héma-Québec. **The objective of the MSM Research Program is to ensure the generation of adequate evidence-based research for alternative screening approaches for blood or plasma donors, which could evolve the current deferral policy for men who have sex with men (MSM) while maintaining the safety of the blood supply**. As part of this initiative, Canadian Blood Services and Héma-Québec held a two-day meeting in January 2017 with national and international stakeholders to identify research priorities for closing knowledge gaps that impact donor eligibility for MSM. In addition, a research funding competition was held in 2017.

The MSM Research Grant Program provides competitive funding to research teams to address identified research priorities to close the knowledge gaps. The Program will support small (up to $50,000) and large (up to $300,000) research projects that are aligned with the objective of the program as stated above and address one or more of the research priorities listed below. For the 2018 competition, the total funding available is $850,000.

Canadian Blood Services manages the national supply of blood, blood products and stem cells, and related services for all the provinces and territories (excluding Quebec). We also lead an integrated, interprovincial system for organ donation and transplantation for all of Canada. Through our Centre for Innovation, we facilitate the creation, translation and application of new knowledge to support a safe, effective and responsive system of blood and related biological products for Canada.

Héma-Québec
Héma-Québec's mission is to efficiently meet the needs of the Québec population for safe, optimal-quality blood and blood products, human tissues, cord blood, mother's milk and cellular products; to develop and provide expertise and specialized, innovative services in the field of human biological products.

Research priorities for this competition include:

- ✓ **Research to evaluate the impact of alternative risk reduction technologies on donor screening.** For example, how would implementation of new blood manufacturing technologies (e.g., pathogen reduction) impact donor screening? How would new preventive therapies impact donor screening? How would implementation of new testing technologies (e.g., ability to detect unknown pathogens or ability to detect exposure to unknown pathogens) impact donor screening?
- ✓ **Research to evaluate operational feasibility of alternative donor deferral policies and their acceptability by Canadians.** For example, how do we ensure appropriate interpretation of screening questions and provision of truthful answers? What would the impact of changing donor screening be on the larger donor population and the sufficiency of blood products for patients (e.g., acceptability of a gender-blind questionnaire; acceptability of highly sensitive questions; use of plasma for fractionation clinics to evaluate operational feasibility of alternative donor deferral policies)? What is the public acceptance of risk?
- ✓ **Risk modeling and surveillance to assess the risk associated with alternative donor selection policies.** For example, what data are required to improve existing modeling strategies? Are there any other factors that should be considered in the model? How would one test the model? How

would implementation of alternative risk reduction technologies (e.g., pathogen reduction) impact the model?

- ✓ **Research to inform the development of an individual risk assessment donor policy (behavioural based) or to strengthen the existing policy (population based).** For example, how would one identify a low-risk population of MSM eligible to donate (e.g., new studies performed at plasma for fractionation clinics; analysis of existing MSM data with a specific focus on low-risk MSM)? How would one formulate an acceptable donor questionnaire that would prevent deferral of low-risk MSM? What would be the feasibility of a gender-blind deferral policy? Level of donor compliance vis-à-vis the donor questionnaire?

For all research priorities, close attention should be paid to study methodology and, where appropriate, feasibility and post-implementation assessment. Impact on the blood supply should be considered.

II. ELIGIBILITY

- **Principal Investigator:** The Principal Investigator must be affiliated with a Canadian academic program as a faculty member or with Canadian Blood Services or Héma-Québec. The Principal Investigator is responsible for submitting the application, managing the team members to deliver the project deliverables as approved, and reporting on project progress.
- **Team size:** There is no restriction on the number of team members (co-investigators and collaborators and partners). However, all team members must have a defined role in the project, and their expertise must be clearly required to adequately address the project goals.
- **Co-investigators:** Co-investigators must be affiliated with an academic program as faculty members or with a Blood Operator. Co-investigators are eligible for project funding. A small portion of the budget (up to 15%) may be used for co-investigators from outside of Canada, if the international investigator provides expertise not available in Canada and if the proposed work is essential to the success of the project.
- **Collaborators and Partners:** Collaborators and partners with a defined role in the project may complement the team but are not eligible for funding. Their role in the research project is to provide a specific service or expertise (e.g., access to equipment or resources, provision of specific reagents, statistical analysis, subject matter expertise, etc.) and they may be knowledge end-users.
- **Program objective and research priorities:** MSM Research Grant proposals must be aligned with the program objective and one or more of the research priorities identified in Section I. Proposals that are not relevant will not be considered for funding.
- **Budget:** The proposed project budget for a **Small Project grant** must not exceed $50,000 for a maximum duration of one year. The proposed project budget for a **Large Project grant** must not exceed $300,000 for a maximum duration of two years.
  - Funds cannot be used for salary support for investigators (i.e., individuals who are eligible to apply for operating funds from the federal agencies).
  - Funds may be used for trainee stipends, research staff salaries (e.g., research assistants, technicians), expendable materials and supplies, travel expenses and the purchase and maintenance of experimental animals.
  - The purchase of small items of equipment is permissible; however, the maximum that can be spent on equipment over the grant funding period is $8500 (exclusive of applicable taxes). Funds cannot be used towards maintenance/service contracts.
  - MSM Research Grant funds are only to be used towards the direct costs of research; no funding is to be used for indirect costs (e.g., institutional overhead).

III. APPLICATION PROCESS

The application process for the MSM Research Grant program is comprised of two phases: Registration and Application.

i) Registration Phase

- Complete the Canadian Blood Services MSM Research Grant Registration Form as per the instructions outlined in the Registration Form.
- Submit the Registration Form by email to Centre for Innovation at centreforinnovation@blood.ca on or before the deadline, as per the Instructions in the Registration Form. **No registration forms will be accepted after the deadline.**
- Canadian Blood Services will acknowledge receipt of the Registration by email. **It is the responsibility of the applicant to ensure the Registration Form has been received by Canadian Blood Services.** Please contact the Centre for Innovation if your Registration Form is not acknowledged.
- An administrative review of the Registration Forms will be performed by Centre for Innovation staff to assess that basic eligibility criteria have been met (see Section II). The information provided in the Registration Form will be used by Centre for Innovation staff to determine the expertise required to review full applications.
- Canadian Blood Services will contact all registrants and provide the full Application Form to those who meet the basic eligibility criteria. No feedback on the proposed project will be provided to registrants.
- Applicants are encouraged to submit their Registration Form in advance of the deadline; administrate review will be performed within ten (10) business days of receipt of the Registration Form.

Applicants must submit a Registration Form in order to receive the full Application Form.

ii) Application Phase

Eligible applicants who have completed the Registration Form will be invited, by email, to submit a full grant application. **Unsolicited applications will not be accepted.**

- Complete the Canadian Blood Services MSM Research Grant Program Application Form and prepare the supporting documents for the Application Package, as per the Instructions in the Application Form.
- Submit the Application Package (Application Form and supporting documents) by email to Centre for Innovation at centreforinnovation@blood.ca on or before the competition deadline, as per the instructions in the Application Form. **No applications or additional material will be accepted after the deadline**.
- The duly received MSM Research Grant Program Application Package constitutes an agreement to adhere to the conditions governing the grant.
- Canadian Blood Services will acknowledge receipt of the application by email. **It is the responsibility of the applicant to ensure the Application Package has been received by Canadian Blood Services.** Please contact the Centre for Innovation if your Application Package is not acknowledged.

IV. REVIEW PROCESS

All applications will be subjected to rigorous peer review by experts external to Canadian Blood Services and Héma-Québec. The evaluation of applications is as follows: (1) written evaluations are obtained

from subject matter experts external to Canadian Blood Services and Héma-Québec; and (2) applications and written evaluations are discussed and evaluated at a face-to-face Grant Review Panel meeting.

i) MSM Research Grant Review Panel Composition

A Grant Review Panel ("Review Panel") composed of subject matter experts will be convened by Canadian Blood Services and Héma-Québec. The Review Panel will comprise a Chair and 2 – 4 additional members, depending on the number and nature of applications received for the competition. Canadian Blood Services will make the identity of Review Panel members available to all applicants following the announcement of funding decisions.

ii) Evaluation Criteria

Applications are reviewed to identify those with the highest scientific merit and with the greatest likelihood of success in generating novel and timely knowledge relevant to the Program Objective and one or more Research Priorities.

The feasibility of the research, the relevance, significance and impact of the research, and the project team will all be considered in the application evaluation. Considerations for the criteria are as follows:

Feasibility of the Research:

- Are the overall strategy, methodology, and analyses appropriate to accomplish the specific aims of the project?
- Is existing data and knowledge clearly identified and leveraged?
- Are the timelines and related deliverables of the project realistic?
- Is the budget appropriate to accomplish the specific aims of the project?
- Does the proposal identify potential challenges and appropriate mitigation strategies?

Relevance, Significance and Impact of the Research:

- Are the objectives of the project aligned with the Program Objective and Research Priorities?
- Do the objectives respond to identified needs?
- Is the project original?
- Will the project produce new data and concepts and advance the state of knowledge?
- Are the anticipated project contributions likely to lead (in the short and/or long term) to change the blood donor deferral policy? Are they aligned with the knowledge end-users' requirements (regulators, blood operators)?

Project Team:

- The expertise of the investigator(s) in the proposed area of research and with the proposed methodology.
- The expertise of the investigator(s) as demonstrated by research productivity over the past five (5) years.
- The appropriateness of the project team to carry out the proposed research in terms of complementarity of expertise and synergistic potential.
- The level of engagement and/or commitment from the investigator(s) and the collaborator(s)/partner(s).

Applications will be assessed on a common adjudication scale:

RANGE	DESCRIPTION
4.5 – 5.0	An outstanding proposal that communicates a sound and creative research plan with a high likelihood of important knowledge generation. Short-comings are minimal.
4.0 – 4.4	An excellent proposal that communicates a sound and creative research plan with a likelihood of important knowledge generation. Improvements possible.
3.5 – 3.9	A very good proposal with meritorious aspects that should be funded if sufficient resources permit. Some improvements necessary.
3.0 – 3.4	A good proposal with deficiencies that could be improved in a resubmission but is not fundable as currently presented. Improvements necessary.
2.5 – 2.9	A fair proposal that should not be funded. Major revisions required.
0 – 2.4	A poor proposal that fails to provide convincing information and/or has serious inherent flaws or gaps.

The application's budget will also be assessed. Reviewers will be required to assess if the requested budget is appropriate to support the proposed project and is well-justified.

iii) Review Process

Canadian Blood Services will obtain up to three written reviews for each application from subject matter experts external to Canadian Blood Services, Héma-Québec, and the Review Panel.

The Chair of the Review Panel will assign two Review Panel members to review each application, one as primary reviewer and the other as secondary reviewer. Assignments will be made based on the subject matter of the applications in relation to the expertise of the Review Panel members. Both reviewers will prepare written reviews in advance of the Review Panel meeting.

The Chair will convene and oversee the Review Panel meeting. For each application, the Chair will invite the primary and secondary reviewers to announce their preliminary scores. The Chair will then invite the primary reviewer to present the salient features of their review to the Review Panel and to justify their preliminary score. The secondary reviewer will then be invited to identify any review features that differ from that of the primary reviewer and to address any additional points made in the written reviews obtained from the external reviewers. Both reviewers will also be invited to identify any budgetary concerns.

The primary and secondary reviewers will arrive at a consensus score and answer any questions from other Review Panel members. Once a consensus score is reached, all Review Panel members will score the application within ± 0.5 of the consensus score by secret ballot.

The mean scores of all Review Panel members will be used to rank the applications. Applications with a mean score below 3.5 will not be considered for funding. If there are any ties in the mean score of the applications in the fundable range, ties will be broken by consensus. The Chair will then return to the issue of budgetary concerns, to secure agreement on any financial reductions to proposals in the fundable range.

The Chair will moderate all Review Panel discussions, ensure a fair and timely process, and be responsible for communicating the final rankings and comments of the Review Panel to Canadian Blood Services and Héma-Québec. In addition, the Chair will summarize the recommended budgets for each

application. The Chair shall communicate any issues of concern raised by the Review Panel in the same manner.

The Chair's recommendations will be used to make funding decisions by Canadian Blood Services and by Héma-Québec. Decisions will be communicated in writing to all applicants in a timely manner following the Review Panel meeting. Applicants will be provided with the Review Panel's written evaluations (anonymized).

V. GENERAL TERMS AND CONDITIONS OF THE GRANT

START DATE

The MSM Research Grant should begin within three (3) months of award notification.

USE OF GRANT FUNDS

MSM Research Grant funding may be used for the payment (salary and benefits, where applicable) of research staff (e.g., research assistants or technicians), the payment (stipend and benefits, where applicable) of research trainees (e.g., post-doctoral fellows, graduate students, or summer students), the purchase of expendable materials and supplies, the purchase and maintenance of experimental animals, and the purchase of small items of equipment (totaling less than $8500 per grant). MSM Research Grant funding may also be used for the payment of contracted services on a fee for service basis (e.g., statistical support), but under no circumstances may a Principal Investigator, Co-Investigator, or Collaborator and Partner be personally remunerated. Travel expenses for the purposes of presenting research results generated from the grant at conferences or for other research purposes will be supported under the terms of the Canadian Blood Services Travel Policy.

Canadian Blood Services supports only the direct costs of research. No funding is to be used for indirect funds for institutional overhead.

CONDITIONS OF FUNDING

The grantee must respect any limitations placed on the use of MSM Research Grant funds as outlined in the formal notification of decision.

The grantee must immediately notify the Centre for Innovation, of their inability, for any reason, to carry out or complete the research for which a grant was received.

Should Canadian Blood Services funding levels not be available or are decreased due to unforeseen circumstances, Canadian Blood Services reserves the right to reduce, defer or cancel funding of grants received through this funding opportunity.

PROJECT MANAGEMENT AND PROGRESS REPORTING

Principal Investigators are responsible and accountable for project management and results. Canadian Blood Services and Héma-Québec will also have an active role in reviewing project progress and providing advice and feedback to project teams on an ongoing basis. This approach encompasses a number of features as follows:

- Principal Investigators are responsible for the allocation of funds within project teams according to ongoing progress and need. It is expected that continued funding for investigators participating in a project is contingent on reasonable progress towards stated milestones and deliverables.
- Principal Investigators will be required to submit progress reports to Canadian Blood Services Centre for Innovation.
- Principal Investigators will be required to submit a final report to Canadian Blood Services Centre for Innovation within one year of the project end date.

- Principal Investigators will be invited to attend regular meetings with Canadian Blood Services and Héma-Québec to discuss project progress.
- Continued funding of MSM Research Grant projects will be contingent on fulfilling project management and reporting requirements and on substantive progress towards milestones and deliverables. Projects that do not meet these expectations may be terminated before the end of their term and funds reallocated to other MSM Research Grant projects or MSM Research Program activities.

LICENSES AND CERTIFICATES

Canadian Blood Services attaches great importance to the ethical acceptability of experimental studies. Appropriate research ethics certificates must be obtained and documentation provided to the Centre for Innovation, prior to undertaking any parts of the research plan involving human or animal experimentation or research involving the use of biohazardous agents (especially human pathogens and toxins) or radioisotopes. In addition, should the research be conducted by or on behalf of Canadian Blood Services or involve personal information or biologic materials collected by Canadian Blood Services, researchers will be required to obtain approval from Canadian Blood Services' Research Ethics Board in addition to institutional research ethics board(s) approval(s).

PUBLICATIONS

Grantees are encouraged to publish the results of work carried out during the tenure of their grant. Any publications, reports, or public presentations resulting from work conducted during the tenure of a Canadian Blood Services MSM research grant must acknowledge the support of Canadian Blood Services and Health Canada as the source of funding. Details on how to acknowledge Canadian Blood Services in publications and presentations will be provided to grantees.

VI. FINANCIAL ADMINISTRATION OF GRANT FUNDS

Canadian Blood Services' Centre for Innovation will instruct Canadian Blood Services' Finance Services to transfer the approved funds to the grantee's institution. The grantee and its institution are responsible for administering the funds according to the guidelines set-out in this document. The grantee and its institution are responsible for financial reporting on expenditures using Form 300 or equivalent to Canadian Blood Services.

Grantees are expected to exercise appropriate stewardship over the financial resources entrusted to them from the MSM Research Grant program. In no circumstances shall the total disbursement exceed the funds available for each grant.

Funds unspent in the first year of a two-year grant shall be systematically carried over into the second year. Requests to extend resources remaining in an MSM Research Grant account beyond the original end date of the award must be made to the Centre for Innovation in accordance with Canadian Blood Services Research and Development Funding Policy.

VII. CONTACT AND ENQUIRIES

Enquiries should be addressed to the Centre for Innovation, centreforinnovation@blood.ca or (613) 739-2496.