

**TERMS AND CONDITIONS
BLOOD SAFETY CONTRIBUTION PROGRAM**

**CONTRIBUTIONS TO CANADIAN BLOOD SERVICES, HÉMA-QUÉBEC AND/OR
OTHER
DESIGNATED TRANSFUSION/TRANSPLANTATION CENTRES TO SUPPORT
ADVERSE EVENT SURVEILLANCE ACTIVITIES**

(1) Introduction

These Terms and Conditions apply to the financial assistance provided through contributions to Canadian Blood Services (CBS), Héma-Québec and/or other designated transfusion /transplantation centres to support adverse event surveillance activities through the *Blood Safety Contribution Program* (BSCP).

The BSCP formed part of Health Canada's *Strengthening Health Canada's Blood Safety Program* (Blood '98) approved in October 1998 with a funding commitment of \$17.5 million to \$29.6 million annually for the overall effort in the years to follow. Of this, an annual budget of \$4 million - including \$2.4 million in contributions and \$1.6 million in salaries, operations, and maintenance - is allocated to the BSCP.

(2) Legal and Policy Authority

The *Department of Health Act (1996)* confers federal powers to the Minister of Health related to the promotion and preservation of the health of the people of Canada.

The *Public Health Agency of Canada Act (2006)* was established "to contribute to federal efforts to identify and reduce public health risk factors and to support national readiness for public health threats".

The Public Health Agency of Canada (PHAC) complements the efforts of Health Canada, the Canadian Institutes of Health Research, and all other members of the Health Portfolio.

(3) Objectives, Purpose, Performance Measurement Strategy and Links to Program Activity Architecture

A. Objectives:

To support provincial and territorial transfusion and/or transplantation adverse event surveillance activities.

B. Purpose:

The purpose of the BSCP is to implement the *Canadian Strategy on Post-Market Surveillance for Blood, Cells, Tissues and Organs* to develop, enhance, implement and augment transfer of knowledge, expertise and best practices in acute healthcare settings.

Recipients will develop projects to establish systems to monitor adverse events associated with the transfusion of blood, blood products and cells/tissues/organ transplantation which could include infectious diseases, and allergic and immune-mediated events. Recipients will develop and enhance surveillance and support targeted research activities to identify and define risks associated with the use of blood products, cells, tissues and organs. As part of the Contribution Agreement, the recipient will be required to report these adverse events and outcomes to Health Canada as the regulator.

The capability to monitor these events and receive reports in a timely manner will enhance PHAC's ability to detect and prevent transfusion- and transplantation-associated adverse events and allow PHAC to develop appropriate management strategies for managing these risks.

C. Performance Measurement Strategy:

Blood Safety Contribution Program (BSCP)		
Performance Measurement Strategy (PMS) -		
Objective: To support provincial and territorial transfusion and/or transplantation adverse event surveillance activities		
Components	Description	Performance/Output Indicators
Inputs	Resources Invested	<p>\$/% of resource disbursements by component.</p> <p>% variance of disbursements with budgetary allocation by component.</p>
Activities	<p>1) Set, conduct, design and/or facilitate provincial and territorial adverse event surveillance initiatives;</p> <p>2) Build, strengthen and maintain error surveillance related to blood transfusions;</p> <p>3) Conduct cells, tissues and organ transplant surveillance;</p> <p>4) Develop data linkages and communication and dissemination of information; and</p> <p>5) Conduct surveillance of high-risk populations</p>	

Blood Safety Contribution Program (BSCP)		
Performance Measurement Strategy (PMS) -		
Objective: To support provincial and territorial transfusion and/or transplantation adverse event surveillance activities		
Components	Description	Performance/Output Indicators
	and emerging pathogens.	
Outputs	<p>1) Create a blood surveillance system based on a mandated post-market surveillance and CBS database management system;</p> <p>2) Study the most vulnerable populations and conduct outbreak investigations;</p> <p>3) Conduct public health investigations and establish coordinated research thrusts into emerging blood-borne pathogens; and</p> <p>4) Link with public health information networks and develop linkages with appropriate partner organizations.</p>	<p># of proposals received and negotiated by type and component.</p> <p># of contribution agreements signed by component.</p> <p>Presence of national tools, standards by type and component.</p> <p>Presence of pilot studies and feasibility reports by component.</p>
Short-Term Key Expected Results (ER):	1) A fully operational adverse event surveillance system in each province and territory;	<p># of provinces/territories capturing adverse events.</p> <p>% of transfusions captured by adverse event surveillance systems by province/territory.</p> <p>% of adverse events captured by province/territory.</p>
	2) A fully operational national error surveillance system;	% of transfusions covered by error surveillance system.
	3) A fully operational national cells, tissues and organ transplant surveillance system;	% of transplants captured by the surveillance system.
	4) The establishment of linkages with public health information networks;	# of provinces/territories with established linkages to public health information on delayed adverse events.
	5) The establishment of a blood sample archive for high-risk populations; and	Presence of blood sample archives for high-risk populations.

Blood Safety Contribution Program (BSCP)		
Performance Measurement Strategy (PMS) -		
Objective: To support provincial and territorial transfusion and/or transplantation adverse event surveillance activities		
Components	Description	Performance/Output Indicators
		Presence of sample blood collection system (for placement in/update of archive).
	6) The establishment of risk identification strategies for high-risk populations.	% of individuals studied within each identified high risk group. Extent to which risks faced by high-risk groups are identified.
Intermediate Key Expected Results (ER):	1) An enhanced capacity to identify and assess the risks associated with the use of blood, blood products or transplantation of cells, tissues and organs;	Frequency/timeliness of data export to Health Canada. National % of transfusions captured. National % of immediate and delayed adverse events captured. % of transfusion errors captured by surveillance. % of adverse events captured by transplantation surveillance. Quality of epidemiological analysis.
	2) An enhanced capacity to survey and assess risks for high-risk populations	% of individuals in high-risk populations whose blood samples are contained in archives. Extent of use of archives. Extent of ability to predict risks of viral transmission to

Blood Safety Contribution Program (BSCP)		
Performance Measurement Strategy (PMS) -		
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Components	Description	Performance/Output Indicators
		high-risk populations.
Long-Term Key Expected Results (ER):	1) An enhanced capacity to develop mitigation strategies for risks associated with the use of blood, blood products or transplantation of cells, tissues and organs.	Availability of comprehensive data from surveillance systems. Availability of PHAC/participant epidemiological expertise/skill set.

Source: Treasury Board Submission for the renewal of the Terms and Conditions of the Contribution Program under Health Canada's Blood Safety Program (March 8, 2004) and the PHAC Integrated Results-based Management and Accountability Framework & Risk Based Audit Framework (RMAF/RBAF) for the Blood Safety Contribution Program (BSCP) including Transfusion Transmitted Injuries Surveillance Systems (TTISS) Cell, Tissue and Organ Surveillance System (CTOSS) Revised: March 3, 2008

D. Links to Program Activity Architecture (PAA)

The BSCP supports the sub-activity program *Health Care Associated Infections*; to reduce the risk of healthcare-associated pathogens and biological injuries due to blood transfusion/cell, tissue and organ transplantation in both institutions and community healthcare settings.

Program activities have clear linkages to PHAC's Program Activity: Infectious Disease Prevention and Control, and is aligned with PHAC's strategic outcome: "...to promote health, reduce health inequalities, and prevent and mitigate disease and injury."

(4) Eligible Recipients

Eligible recipients are those capable of advancing program objectives, and include provincial and territorial governments; transfusion and/or transplantation centres and agencies and/or groups designated by provincial and territorial Ministries of Health to undertake surveillance for blood/cell/tissue/organ-associated adverse events; and Canadian not-for-profit organizations which support transfusion adverse event surveillance activities in the provinces and territories.

(5) Eligible Initiatives and Projects

Eligible initiatives and projects are those which increase and/or enhance surveillance and targeted research activities in order to identify and define risks associated with the use of blood products, cells, tissues and organs.

Eligible initiatives and projects are as follows:

- set, conduct, design and/or facilitate provincial and territorial transfusion adverse event surveillance initiatives;
- build, strengthen and maintain error surveillance related to blood transfusion surveillance;
- conduct cells, tissues and organ transplant surveillance;
- develop data linkages, communication, and dissemination of public health information; and
- conduct surveillance of high-risk populations and emerging pathogens.

Eligible activities include the following:

- regular monitoring of transfusion and transplantation recipients at hospitals for transfusion- and transplantation-associated adverse events;
- collection of this information using standardized reporting forms; and
- data analysis and the reporting of this information to Health Canada.

Eligible activities could also include the following:

- the funding of a regional/provincial/territorial coordinator to perform these activities; and
- targeted research activities to identify and define risks associated with the use of blood products, cells, tissues and organs.

(6) Assessment Criteria

Projects will be screened for eligibility and assessed for merit in terms of the relevance and quality of the proposal.

Programs operating under these Terms and Conditions will meet the following criteria:

- objective/rationale;
- scope of programs and time frame of these authorities;
- relevance to the objectives of the BSCP;
- relevance to the directions and objectives of PHAC; and
- compliance with these Terms and Conditions.

(7) Type and Nature of Eligible Expenditures

Expenditures directly related to approved projects are defined in the Contribution Agreement. The eligible expenditures under the Contribution Agreement will include direct and indirect costs such as:

- salaries and wages of individuals, including employee benefits;
- travel and accommodation;

- costs of renting or leasing meeting and conference facilities;
- services provided under contract by a private contractor, consultant, Canadian university or institute, or community-based organization;
- all reasonable operating expenses including, but not limited to, office supplies, printing, publishing, distribution, promotion, utilities, telephone, insurance, and computer service rentals, repairs and maintenance; and
- contracting for the audit requirements of this contribution, if included in the Contribution Agreement.

(8) Stacking Provisions

Assistance is provided for projects at the minimum level necessary to further the attainment of the BSCP objectives and expected results.

The maximum level (stacking limit) of Total Government Assistance (TGA) (federal, provincial, territorial and municipal assistance for the same eligible expenditures) for a project will not exceed 100% of eligible expenditures.

In the event that actual TGA to a recipient exceeds the stacking limit, PHAC will adjust its level of assistance and seek reimbursement so that the stacking limit is not exceeded. This repayment provision applies only to contributions that exceed \$100,000. The repayment of any amount exceeding the TGA limit will be calculated on a pro-rated basis (based on TGA received toward the same eligible expenditures).

Proposals must disclose all additional sources of funding, i.e. funds from other PHAC programs, other federal departments, other levels of government, charitable foundations etc. In the course of the project, recipients are required to report to PHAC any additional funds received from any and all sources to support the approved project or to augment activities of the project.

(9) Method for Determining the Amount of the Contribution

Proposals will be screened for completeness, eligibility, and program relevance. Proposals will undergo a quality assessment, which may include internal and/or external reviewers. Proposals recommended for approval will be forwarded to the appropriate departmental authority for final decision.

Funds are provided to cover PHAC's projected share of the costs of approved project expenditures.

(10) Application Requirements

Proposals may be solicited or directed by PHAC. Detailed instructions on how to apply for funding, as well as a list of priorities and time frames, are contained in the guides to applicants or individual program guidelines. Projects must establish eligibility, relationship of the project to program objectives and priorities, and include a work plan, budget, and evaluation plan. Proposals are screened for eligibility and reviewed for merit.

The programs will operate within the scope of the *Conflict of Interest and Post-Employment Code for Public Office Holders*, and the *Conflict of Interest Act and the Values and Ethics Code for the Public Service*.

(11) Maximum Amount Payable

PHAC may use a multi-year Contribution Agreement which respects provisions of the *Treasury Board Policy on Transfer Payments* and these approved program Terms and Conditions.

The maximum amount payable to a recipient in any one fiscal year is set at \$600,000.

Multi-year funding will be approved subject to an annual appropriation made for that purpose by Parliament and may be cancelled or reduced in the event that departmental funding levels are reduced by Parliament.

(12) Basis and Timing of Payment

The basis and timing of payments, including advance and progress payments and applicable holdback provisions (i.e. 10%), will be consistent with the *Treasury Board Policy on Transfer Payments*.

Contribution progress payments may be made in the following manner:

- Reimbursement of eligible expenditures; or
- Achievement of pre-determined performance expectations or milestones as identified in the project work plan.

Advance payments are limited to the immediate cash requirements for approved activities and budgeted amounts based on periodic cash flow forecasts.

Holdbacks will be applied to manage the risk of non-performance or overpayment to a recipient and are to be based on prudent cash management practices.

Final payments will be made once all funding agreement requirements are completed.

(13) Repayable Contributions

Not applicable.

(14) Duration of Terms and Conditions

These Terms and Conditions, unless otherwise revoked or amended, shall be in effect from the date of approval of this amendment.

(15) Contribution Agreements

Contribution Agreements will adhere to the requirements set out in Appendix G of the 2008 *Treasury Board Policy on Transfer Payments*. The Contribution Agreement establishes the terms of the agreement between PHAC and the recipient. The Contribution Agreement will contain details of financial obligations, record-keeping requirements, progress and evaluation reporting requirements, and other related matters.

(16) Monitoring and Reporting

Departmental systems (i.e. Grants and Contributions Lotus Notes Database and the Framework for Integrated Resource Management Systems), procedures and resources are in place to ensure due diligence in approving transfer payments, verifying eligibility, and managing and administering the contribution program. Funded initiatives will be monitored by PHAC staff who are responsible for the following:

- assist funded organizations by providing advice or expertise, where required and as appropriate;
- monitor progress towards identified objectives; and
- ensure accountability for public funds.

In cases where financial assistance has been provided, and it is deemed likely by the Program that the objectives of the BSCP will not be met based on a record of performance, project reports and financial statements, a recommendation to terminate the project may be made. Moreover, PHAC may seek repayment, in full or in part, when the recipient cannot demonstrate the relationship between the funding and the capacity to meet stated objectives and goals. This cancellation provision will be reflected in all Contribution Agreements.

To ensure transparency, PHAC will keep proper records and documentation of key decisions taken and results achieved.

The Minister, in the administration of the Terms and Conditions may, from time to time, prescribe such definitions, standards, terms and conditions, procedures and forms as are consistent with these Terms and Conditions, or with any relevant Act of Parliament.

(17) Third Party Delivery

PHAC may provide contributions to recipients who in turn further distribute payments to ultimate recipients. Initial recipients will have full independence and responsibility in the

selection of ultimate recipients and will not act as an agent of the government in making such distributions.

(18) Intellectual Property

Intellectual property relating to research and/or development activities undertaken by a recipient or an ultimate beneficiary with funding provided by PHAC under a contribution program will vest in the recipient or the ultimate beneficiary.

(19) Official Languages

PHAC is committed to providing services in both official languages in accordance with the *Official Languages Act*; enhancing the vitality of the English and French linguistic minority communities in Canada; and fostering the full recognition and use of both official languages in Canadian society. Provisions of the *Official Languages Act* will be respected including communication about the program. Invitations to submit applications for example, will be provided in both official languages and communication with PHAC, both written and oral, will be the choice of the applicant.

(20) Disclaimer

Funding under this contribution program does not imply any commitment, financial or otherwise, by any federal government department or agency beyond the approved funding level and the approved period.