

SUPPORT FOR PEOPLE AND PATIENT-
ORIENTED RESEARCH AND TRIALS
(SUPPORT) UNITS

APPLICATION INSTRUCTIONS

Revised December 2013

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1. BACKGROUND

Patient-oriented research, the cornerstone of evidence-informed health care, refers to a continuum of research, from initial studies in humans to comparative effectiveness and outcomes research, and the integration of this research into the health care system and clinical practice.

Canada's Strategy for Patient-Oriented Research (SPOR) is a pan-Canadian research strategy that puts patients first. It was created after extensive consultation with national and international partners and is led by the National Steering Committee: a coalition of federal, provincial and territorial partners with broad representation from patient advocates, policy makers, researchers and clinicians. SPOR reflects a commitment to deliver high quality care in Canada by providing patients, health professionals and policy makers with the best available information to make decisions about health care. It aims to strengthen support for clinical trials and intervention studies as well as research that compares the effectiveness, benefits and harms of existing treatment options. The strategy also endeavours to improve the translation of innovative preventative, diagnostic and therapeutic approaches into the health care setting by expanding research in implementation science and incorporating these methods into day to day practice.

The vision of the strategy is that Canada will demonstrably improve health outcomes and enhance the health care experience for patients through the integration of evidence at all levels of the health care system.

Two key components of the SPOR strategy are: National Research and Knowledge Translation Networks and nationally distributed specialized support units called Support for People and Patient-Oriented Research and Trials (SUPPORT) Units. The focus of this document is the creation of the SUPPORT Units.

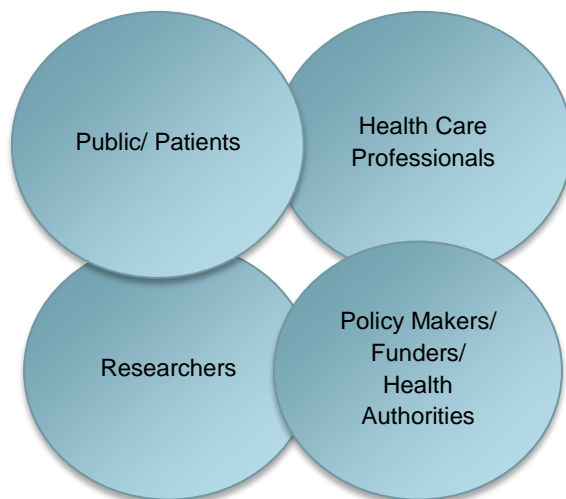
2. OVERVIEW

SUPPORT Units will develop jurisdictional centres of expertise to enhance patient-oriented research and facilitate studies involving patients and/or patient records.

SUPPORT Units are intended to:

- Identify the needs of patients and knowledge users and facilitate research that addresses these needs.
- Provide a critical mass of highly specialized and multi-disciplinary methodological expertise in patient-oriented research and its application.
- Assist decision makers and investigators to identify and design relevant research studies, conduct biostatistical analyses, manage data, provide and teach project management skills and ensure studies meet all relevant regulatory standards.

- Advance methods and training in comparative effectiveness research and develop the next generation of methodologists.
- Provide timely access to linked data and integrate existing or new databases.



3. VISION

The vision is that SUPPORT Units will:

- Support the priority setting mechanism for the jurisdiction.
- Conduct and support implementation science and integrated knowledge translation (KT) approaches.
- Support the design and conduct of clinical and health services studies that address jurisdictional priorities.
- Support systematic evidence reviews.
- Have data systems in place to accelerate the conduct of clinical and health services research.
- Develop new and innovative methods.
- Provide training and career development in health services research methods.
- Leverage and integrate existing SUPPORT-related resources.

4. DESCRIPTION

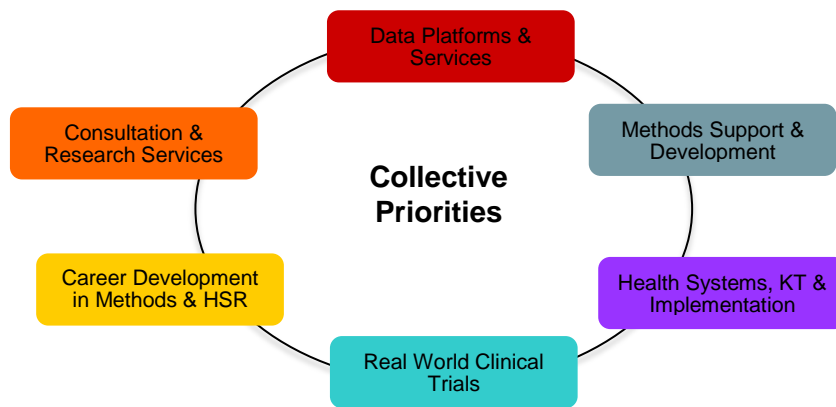
SUPPORT Units will be established across Canada to develop jurisdictional centres of expertise to enhance patient-oriented research and facilitate large-scale national and international studies involving patients and/or patient records. Working collaboratively with their knowledge user partners, the SUPPORT Unit should help to address the research questions/knowledge needs of the knowledge users by producing solutions-focused answers and supporting the knowledge users to apply these solutions. Examples include policy makers at the provincial/territorial or federal level; managers and administrators of the health care

system/ jurisdictional health authority/ hospital or community sector, health care providers; patients and the public.

Each SUPPORT Unit will be developed in partnership with the jurisdictional partners to ensure that the design is appropriate to the jurisdiction and capable of achieving the intended impact. The proposal process will commence based on the 'readiness' of the jurisdictions and it is anticipated that funding will begin in fiscal year 2013-14.

5. CORE COMPONENTS

The SUPPORT Units are each expected to include six components covering core functions. Jurisdictions will be asked to demonstrate how the core components are expected to meet their needs and how existing resources will be leveraged and integrated. It is expected that some core components may be phased in over time.



1. DATA PLATFORMS AND SERVICES

Proposed requirements for this component includes linkage of administrative data to clinical data, linkage of clinical feeder system to consent-based and legislated registries and providing timely access to usable data within a three to four month timeframe. More specialized services may include use of electronic health/medical records, computerized clinical decision support protocols, linking biobanks and clinical registry and administrative data systems, and advanced technologies and methods including qualitative and patient-reported outcomes.

2. METHODS SUPPORT AND DEVELOPMENT

This component would provide timely services in areas such as biostatistics, epidemiology and health economics to the community in the jurisdiction. Scientific leadership in applied methods could focus on a pre-determined priority area, develop advanced methods and provide leadership and mentorship for students. Services could also include data management and computing for small to moderate scale databases, cohorts and multi-site studies. More specialized services could focus on advanced methodological innovations and services, e.g. for genetic bioinformatics, adaptive clinical trials, high content trials, patient-reported outcomes, international cohorts and multi-site studies.

3. HEALTH SYSTEMS RESEARCH, IMPLEMENTATION RESEARCH AND KNOWLEDGE TRANSLATION HEALTH SYSTEMS RESEARCH

SUPPORT Unit funding will support Applied Health Services Research (HSR) scientific leadership to lead the engagement of decision-makers and build HSR research capacity. Areas of focus may include evaluation of clinical and program interventions, financing and funding models and governance/accountability mechanisms; comparative effectiveness research, comparative policy and health systems research. Programs would take into account the jurisdictional or local needs of knowledge users and support decision making within the catchment area.

KNOWLEDGE TRANSLATION (KT) – KT will be a requirement of SUPPORT Units.

Specialized functions could include conduct of knowledge synthesis and/or science of knowledge synthesis, and primary implementation studies on the science of KT.

IMPLEMENTATION RESEARCH - is critical to promote the discovery of more effective approaches to implement clinical and health research findings and other evidence-based practices into routine practice, and hence to improve the quality (effectiveness, reliability, safety, appropriateness, equity, efficiency) of health services.

4. REAL-WORLD CLINICAL TRIALS AS PART OF A STRATEGY TO CHANGE HEALTH OUTCOMES

As a core service, SUPPORT Units will provide expert assistance in areas such as innovative trial design, data management, statistical analysis, ethics approvals and multi-site management for clinical trials that change health outcomes and can support decision-makers in all aspects of Canadian healthcare. In particular, clinical trials that compare effectiveness and/or the comparative safety of treatments in the real-world healthcare environment will be emphasized.

Outcomes of such trials will be used as inputs into clinical practice guidelines, computerized decision-support tools, cost-effectiveness economic models, educational modules for healthcare providers, and by other decision-makers, from patients and their caregivers to provincial reimbursement plans. Partnerships may allow for clinical trials supporting commercialization of products; however, emphasis is placed upon clinical trials supporting improvements in real-world health outcomes.

5. CAREER DEVELOPMENT IN METHODS AND HEALTH SERVICES RESEARCH

Training, mentoring and career development for clinical, health services and systems research and methodological patient-oriented researchers is a core responsibility of SUPPORT Units.

SUPPORT Units will be expected to provide an environment that will foster the development of the next generation of specialized and multi-disciplinary methodological expertise, and clinical, health services and systems researchers engaged in patient-oriented research.

It is expected that research institutions would be essential partners in the SUPPORT Unit training and mentoring program and would be involved in the development of a sustainability plan for long-term innovative training and mentoring.

6. CONSULTATION AND RESEARCH SERVICES

Consultation services could focus on design, measurement, methods development, data analysis, economic evaluation, literature review and scientific writing. Services could also include data management and computing for small to moderate scale databases, cohorts and multi-site studies. Clients of the SUPPORT Unit could have access to highly qualified research personnel including data managers, data analysts, research coordinators and nurses. These services could be contracted by teams or individual investigators to assist in the management and conduct of health systems research and multi-site clinical trials.

In addition, project management services of a SUPPORT Unit could provide expertise related to the management of small-scale to multi-site study teams such as development of business plans, tracking/evaluation of deliverables, and coordination of project components, communications strategies and project implementation. More specialized services could include a comprehensive (turnkey) service to develop and manage projects on a large national & international scale and could include, for example, qualitative research methods, survey methods, adaptive assessment of patient-reported outcomes and meta-analysis. The consultative services could be provided on a fee-for-service, which could generate infrastructure and operational funds for the unit.

6. GOVERNANCE

Integral to the success of a SUPPORT Unit, it is expected that a collaborative leadership and governance approach will be used to integrate all individuals crucial for changing practice, implementation of evidence and sustainability. This would include the involvement of knowledge

users such as policy makers at the provincial/territorial or federal level; managers and administrators of the health care system/ jurisdictional health authority/ hospital or community sector, health care providers; patients and the public.

7. PERFORMANCE MEASUREMENT

Preliminary discussions on performance measurement were held at the *Strengthening and Development Workshop (January 2013)*. A core set of performance measurement indicators, covering all six core components, will be jointly developed and discussed by CIHR and representatives from each jurisdictional SUPPORT Unit.

Based on jurisdictional needs, jurisdictions will also be required to develop a performance measurement framework, including relevant indicators and milestones across the six components to be reported throughout and at the end of the funding period.

8. ITERATIVE REVIEW PROCESS

Business plans will be evaluated using a two-phase, iterative review process, designed to provide jurisdictions with feedback during business plan development and implementation. This will be followed by a third phase designed to facilitate networking and continuous improvement of SUPPORT Unit activities.

In addition, all jurisdictions were invited to present their vision for their SUPPORT Unit at a Strengthening and Development Workshop in January 2013. The goal of the workshop was for jurisdictions to learn from each other, share ideas and best practices and strengthen business plan proposals.

Intended outcomes resulting from the workshop were:

- Improved understanding of the vision, aims and jurisdictional priorities.
- Strengthening of initial ideas leading to stronger final business plans.
- Emergent learning, monitoring and evaluation framework.

PHASE 1 – DRAFT BUSINESS PLAN

Jurisdictions will have the opportunity to submit a draft business plan from **November 1, 2012** onwards. Once submitted, an internal CIHR review of the draft business plan will be conducted by CIHR. Follow up via telephone with the jurisdictions will occur with the goal of providing preliminary feedback in order to assist in the preparation of the final business plan.

PHASE 2 – FINAL BUSINESS PLAN

Through an iterative review process, an expert international panel will evaluate the final business plans. Jurisdictions will have the opportunity to answer questions raised by the panel during the evaluation process.

Jurisdictions may submit their final business plans when they are ready to do so.. Funding decisions will be available 6-12 weeks after submission.

Once a business plan is endorsed by the adjudication panel and recommended for funding, the grant agreement development process will begin. A portion of year-one funding will be made available as a start-up grant (up to \$250,000) to help catalyze activities while the grant agreement is finalized.

PHASE 3 – CONTINUOUS DEVELOPMENT

To ensure continuous improvement and on-going learning, jurisdictions will have the opportunity to network and share ideas on a regular basis. It is anticipated that this will occur annually.

9. AVAILABLE FUNDING

The total annual budget for a SUPPORT Unit is likely to vary depending on the needs and capacity of the jurisdiction. CIHR will match financial commitments invested by the jurisdictions with an estimated range of \$2-10 M per year per SUPPORT Unit over a period of five years.

10. BUSINESS PLAN REQUIREMENTS

To ensure proposals contain all pertinent information, jurisdictions are asked to include the following sections in their business plan:

1. Overview of Vision
2. Description of Key Components of the Support Unit
3. Summary of Participants
4. Alignment with Jurisdictional Priorities and National SPOR Strategy
5. Governance
6. Performance Measurement
7. Stakeholder Engagement
8. Appendices
 - a) Expenditure Requirements
 - b) Governance Chart
 - c) Bio-sketches of key participants
 - d) Letters of Participation and/or Support

SECTION INSTRUCTIONS

Once completed, the following sections will make up the business plan for the SUPPORT Unit. The number of pages specified for each section is intended as a guide rather than a prescriptive instruction.

SECTION 1: OVERVIEW OF VISION (1 PAGE FREE FORM)

In the form of an executive summary, describe the jurisdiction's vision and expected outcomes for the SUPPORT Unit.

ASSESSMENT CRITERIA:

- To what extent are the vision and expected outcomes focused, clear and appropriate? The vision should describe the end-results and impacts within the timeframe of the proposed funding cycle, especially with respect to the expected outcomes and impacts on partners and the user sector for the benefit of Canadians.

SECTION 2: DESCRIPTION OF KEY COMPONENTS OF THE SUPPORT UNIT (MAXIMUM 10 PAGES FREE FORM)

Provide information on how the jurisdiction is going to establish and implement the six core components of the SUPPORT Unit. If it is not feasible to establish all six at the time of submission, include a plan for future attainment.

For each of the six core components, provide:

- details of the proposed activities and/or services;
- an overview of the budget requirements for the proposed activities (see appendix)
- a summary of how these core components will meet the needs of the jurisdiction;
- a description of how existing resources will be leveraged and integrated;
- a scalability plan (adaptability to increased or decreased demand and or for core components that are not fully developed a plan/approach that will be taken to phase them in over time);
- an overview of key risks to the successful realization of the described activities and/or services in the core component, including a risk mitigation strategy; and
- a sustainability plan.

ASSESSMENT CRITERIA:

- Is there evidence that the business plan proposed will lead to the successful development, implementation and on-going management of the SUPPORT Unit?
- Do the proposed core components detailed in the business plan meet the minimum requirements for a SUPPORT Unit?
- Is there evidence that the core components will contribute significantly to achieving:
 - The overall objectives of the SUPPORT Unit initiative?
 - Enhanced patient-oriented research capacity at the jurisdictional, national and international level?
- To what extent is the budget estimate appropriate and justified in relation to the proposed activities? Is there evidence of a reasonable and realistic ramp-up period?
- Are key risks clearly articulated? Is there a suitable mitigation strategy?
- Is the sustainability plan robust and realistic? Likely to be realized?

SECTION 3: SUMMARY OF PARTICIPANTS (MAXIMUM 4 PAGES FREE FORM)

In table format, provide a list of all jurisdictional participants, including their expertise, planned activities and role in ensuring the success of the SUPPORT Unit. Bio-sketches should be provided in the appendix.

To facilitate communication with CIHR, a primary contact representing the jurisdiction must be identified. The contact must be designated by and endorsed by the jurisdiction.

ASSESSMENT CRITERIA:

- Is there evidence that the qualifications and experience of the SUPPORT Unit participants leaders will contribute significantly to the likelihood of successful development, implementation and on-going management of the SUPPORT Unit?
- Are the roles and responsibilities of participants including the ministry/health authority and other decision/policy makers, researchers and other partners and stakeholders clearly identified?
- Is the composition of the proposed operational management team appropriate?

SECTION 4: ALIGNMENT WITH JURISDICTIONAL PRIORITIES AND NATIONAL SPOR STRATEGY (2 PAGES FREE FORM)

Describe the value added of establishing a SUPPORT Unit in the jurisdiction based on jurisdictional needs and priorities. Include how existing projects can access the SUPPORT Unit.

Describe how the vision and expected outcomes of the SUPPORT Unit align with the National SPOR strategy.

ASSESSMENT CRITERIA:

- To what extent does the proposal justify the value added for establishing the SUPPORT Unit in the context of jurisdictional needs and priorities as well as existing structures available in Canada and/or internationally?
- To what extent does the SUPPORT Unit show evidence that it can be initially accessed by existing projects?
- To what extent does the SUPPORT Unit align with the National SPOR strategy

SECTION 5: GOVERNANCE (2 PAGES FREE FORM)

Provide a governance structure including key roles and decision-making processes. It should be noted that the model should be based on a collaborative leadership approach, including key decision makers, designed to support the achievement of the SUPPORT Unit's vision. A governance chart should be provided in the appendix.

ASSESSMENT CRITERIA:

- To what extent is the proposed SUPPORT Unit governance structure and decision making-process appropriate?

SECTION 6: PERFORMANCE MEASUREMENT (2 PAGES FREE FORM)

Propose a performance management framework for the SUPPORT Unit to assist in the monitoring and evaluation of key outcomes.

ASSESSMENT CRITERIA:

- To what extent does the performance framework align with outcomes described in the vision?
- Are the proposed performance measures: Relevant? Robust? Feasible? Measurable? Likely to be realized?

*Note: In addition to the framework being proposed by the jurisdiction, a core set of performance measurement indicators, covering all six core components, will be jointly developed and discussed by CIHR and representatives from each SUPPORT Unit.

SECTION 7: STAKEHOLDER ENGAGEMENT (2 PAGES FREE FORM)

Provide an overview of the stakeholder engagement and collaboration plan. The plan should include patients and the public.

ASSESSMENT CRITERIA:

- How appropriate is the engagement and collaboration plan? Is there evidence that the approach proposed plan will contribute significantly to achieving appropriate engagement of patients and the public?

SECTION 5: APPENDICES

APPENDIX A: EXPENDITURE REQUIREMENTS

Using the table provided as a guide, include budget expenditures required from all sources of funding (per funding year). **All expenditures entered into the table must be justified in detail in the business plan.**

Below are details related to eligible and ineligible expenses for the CIHR contribution:

1. CIHR funding for the Unit cannot be used towards infrastructure and capital equipment.
2. CIHR funds may be used to cover operating expenses directly necessary for managing and operationalizing the SUPPORT Unit, such as office supplies and other necessary provisions required for the on-going support of SUPPORT Unit activities. CIHR funds cannot be used for expenditures normally covered by the host institution of a researcher and/or other federal funding programs (e.g., indirect costs program). Such ineligible expenditures include those that are capital in nature (e.g., building construction, renovations, improvements); those related to overhead (e.g., rent, electricity); or those related to administration (e.g., flat charges for management of funds by host organization).
3. Subject to 2, CIHR funding will comply with the requirements set out in the Use of Grant Funds section of the [Tri-Agency \(CIHR, NSERC and SSHRC\) Financial Administration Guide](#).

APPENDIX B: GOVERNANCE CHART

Illustrate the organizational governance structure for the management of the SUPPORT Unit activities.

APPENDIX C: BIOSKETCHES OF KEY PARTICIPANTS (FREE FORM – 2-4 PAGES PER BIO-SKETCH)

Provide bio-sketches of all key participants. This may include Board and Subcommittee members (or equivalents), operational management personnel, scientific leaders, subject matter experts, etc.

APPENDIX D: LETTERS OF PARTICIPATION AND/OR SUPPORT (NO LIMIT)

Letters of participation and/or support confirm the commitment of participants and partners to the SUPPORT Unit and its activities. It is expected that the SUPPORT Unit will receive letters of participation and/or support from key participants, relevant stakeholders and partners detailing support and/or commitments (including financial, if applicable). It is vital to the success of the SUPPORT Unit that the ministry/health authority and other decision/policy makers are included as key participants.

CONTACT INFORMATION

Please send your business plan via email to the coordinates listed below. In addition, for questions on this initiative, application instructions and the adjudication process, please contact:

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