



Michael Smith Foundation for
Health Research

2010

**BC Ethics
Harmonization Initiative:**

Request for Proposals

&

Proposal Guidelines and Template

Table of Contents

Part 1	4
Request for Proposals.....	4
Introduction & Background	4
Scope.....	5
Eligibility Criteria	5
Key Competition Dates.....	5
Proposal Submission.....	6
Proposal Review.....	6
Step 1: External Review.....	6
Step 2: Reverse Site Visit	6
Step 3: Approval by MSFHR Board of Directors.....	7
Accountability and Reporting.....	7
Notification of Changes.....	7
Inquiries & Further Information	7
Part 2	8
Proposal Guidelines and Template.....	8
Definitions and Abbreviations	8
Award Term and Amount.....	9
Application Format.....	10
Proposal Evaluation Criteria	10
Governance.....	10
Management	11
Quality	11
Proposal Content.....	11
Section A – General Information	11
A.1 Contact Information	11
A.2 Résumés of Co-Applicants and Management Team Members	12
A.3 Letters of Support	12
Section B – Proposed Consortium and Team.....	12
B.1 Organizational Chart.....	12
B.2 Description of Key Roles	13
B.3 Governance and Accountability Structures and Processes.....	13
Section C – Proposed Initiative	13
Section D – Initiative ROI/Value Add	14
Section E – Financial Planning	15
E.1 Activities and Status of Development to Date.....	15
E.2 Initiative Plan	15
E.3 Initiative Schedule and Milestones	15
E.4 Space.....	15
E.5 Human Resources Plan.....	15
E.7 Key Success Factors	16
E.8 Upgrade Plan.....	16
Section F - Budget Documentation	16

F.1	Eligible and Ineligible Expenses	16
	Eligible Expenses.....	16
	Ineligible Expenses	17
F.2	“Uses of Cash Statement” template in Appendix C	18
F.3	“Incremental Institutional In-Kind/Funding Contributions Statement” template in Appendix D	18
	Section G – Risk Analysis	18
	G.1 Risk Identification.....	18
	G.2 Risk Mitigation Strategies	19
	Section H – Evaluation.....	19
	H.1 Baseline Evaluation Measures	19
	H.2 Follow-up Evaluation Measures.....	19
	H.3 Specification of Milestones	19
	Checklist for Application Submission	20



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Part 1

Request for Proposals

Introduction & Background

The BC Ethics Harmonization Initiative – Phase One

Health research stakeholders across British Columbia (BC) have identified the need for an effective, coordinated, value-add provincial approach to ethical approval – one that improves quality, access, consistency, efficiency and capacity for ethical review of research involving human subjects. A survey of researchers conducted by the Michael Smith Foundation for Health Research (MSFHR) in 2007 revealed that the need for multiple reviews of multi-centre studies was seen as a major impediment to research in the province. At the same time, a survey conducted by MSFHR of the ethics review committees across BC revealed that most committees were significantly challenged by large workloads and by turnover of qualified reviewers.

In November 2007,¹ MSFHR convened a workshop involving the Research Ethics Boards' (REB) Chairs and Managers, VPs or Directors of Research of the Provinces' higher institutes of learning, and representatives of the research community from across the province. The workshop attendees strongly recommended that a collaborative ethics review process supported by common tools and processes be developed in BC rather than a single, centralized review process. Key deliverables would need to include the following:

- Creation of common forms (e.g. application forms, informed consent);
- Development of a shared/common IT platform and tools accessible to researchers and institutions in BC at which human subject research is undertaken;
- Exploration of how ethics review for multi-centre trials could be more efficient, consistent and timely, possibly with some degree of inter-institutional reciprocity; and
- Development of common educational and training resources to be shared by research ethics boards.

Such an initiative was determined to best enable BC to meet its goals for ethics review reform. The recommendation and key deliverables were subsequently endorsed by the BC Ethics Harmonization Initiative Task Force², which provided guidance to MSFHR in planning the surveys and workshops.

¹ See http://www.msfhr.org/special_initiatives/ethics_harmonization for additional background information regarding the BC Ethics Harmonization Initiative.

² For Task Force members see http://www.msfhr.org/resources/public/Special_Initiatives/BC_Ethics_Task_Force_Members_2007.pdf.

The BC Ethics Harmonization Initiative – Phase Two

To build on the work outlined above, MSFHR is launching phase two of the BC Ethics Harmonization Initiative, which will provide up to \$1,000,000 over five (5) years to implement a harmonized approach to human subject ethics review in BC. Funding available through this initiative must be directed to the incremental costs of implementing a provincial collaboration; it may not be used to offset costs related to each participating organization's ethics reviews.

Scope

- The initiative is meant to incorporate the ethics reviews of research involving human subjects in BC. It is not meant to include other forms of research that do not involve human subjects such as animal research.
- The initiative is focused on ethics reviews. MSFHR recognizes that organizations (e.g. hospitals, health authorities) have additional types of reviews (e.g. resource reviews) that they may wish to conduct with respect to research proposals. These are not covered under this initiative.

Eligibility Criteria

For the purposes of this Proposal, we use the term “organization” to refer to publicly funded institutions and health authorities in BC that conduct human subject research that is subject to ethics review, and the term “investigator” to mean an investigator within one or more of the organizations participating in the Consortium.

- There must be one Co-Leader from each participating organization who acts as the signatory for that organization. The Co-Leader must be the highest-ranking individual responsible for research conducted within each participating organization. Normally, this will be the Vice-President Research or equivalent.
- While the ultimate goal is to include all BC organizations that conduct human subject research, MSFHR recognizes that this may not be possible at the outset. However, in developing the Proposal, the applying Consortium must demonstrate that it conducts 80 percent or more of human subject ethics reviews in BC and that it will be proactive in bringing new organizations into the Initiative. (For additional information on REBs in BC see http://www.msfhr.org/resources/public/Reports/BC_Scan.pdf)

Key Competition Dates

Request for Proposal	January 27, 2010
Proposal Submission Deadline	April 16, 2010
External Review Panel/Reverse Site Visits	May 2010
Approval of Award and Funding Level by MSFHR Board of Directors	June 25, 2010
Announcement of Funding Decisions	June 28, 2010
Commencement of Funding	July 1, 2010 onwards

Proposal Submission

Applicants must submit a single Proposal to MSFHR by the deadline of 4:30 pm, April 16, 2010 to the following:

Dr. Sharon Mortimer
Senior Director, Programs
Michael Smith Foundation for Health Research
Suite 200, 1285 West Broadway
Vancouver, BC V6H 3K8

The submission must be clearly marked, "BC Ethics Harmonization Initiative". Three original unbound copies and one CD copy shall be provided. Fax or email submissions will not be accepted.

MSFHR will **not** accept a late submission.

Upon receipt, the Proposal will be reviewed for completeness. *An incomplete Proposal will not be reviewed further.*

Proposal Review

In order to evaluate the detailed Proposal with all due diligence, a three-step review process will be implemented.

Step 1: External Review

May 2010

- The Proposal will be forwarded to an External Review Panel for consideration. The Panel will consist of experts from outside BC with specific expertise in the initiative area. Reviewers will sign non-disclosure agreements and will have to declare all potential conflicts of interest.
- Each reviewer will independently review the Proposal and provide a score of between 0 (low) and 4.9 (high) against the review criteria and submit these scores to MSFHR.
- The External Review Panel will meet by teleconference to review the scores and come to a consensus about the scoring; they will also generate a list of questions that will be forwarded to the Applicants for response, as outlined in Step 2, below.

Step 2: Reverse Site Visit

The Applicants will be invited to a formative review to give a 30-minute presentation to the External Review Panel on their proposed initiative followed by a 90-minute Q & A period. At this time, Applicants will be expected to address any concerns and questions raised by the External Review Panel.

- The External Review Panel will then determine if the Proposal is ready to proceed, requires major changes, or should be rejected.

- Based on their assessment of the budget and budget justification, the External Review Panel will recommend an initial award amount of up to \$250,000 to support the initial period of the Initiative (July 2010 to March 2011) for approval by the MSFHR Board of Directors.

Step 3: Approval by MSFHR Board of Directors

June 25, 2010

Outcome of Proposal Review

Following the funding decision, Applicants will be provided with the decision of the MSFHR Board of Directors and a written evaluation of the strengths and weaknesses of the Proposal. The decision will be final and appeals will not be considered.

Accountability and Reporting

A face-to-face 'status up-date' meeting with MSFHR staff will be conducted six months post start of funding. Additional face-to-face meetings with MSFHR staff may be sought from time to time thereafter.

The Initiative will be required to submit a written progress report at the end of each funding year. The written report will include progress measures as specified in Section H of the Proposal guidelines and template, a financial statement issued by the Initiative's host institution for the previous 12 month funding period that details utilization of expended funds, and any other requirements as specified by MSFHR.

Notification of Changes

The Co-Leaders are required to notify MSFHR in writing of changes of a material nature, as soon as practical. Such changes may include but are not limited to a change in Co-leaders, or the nature of their roles, to the Initiative, major changes or deviations from the approved Proposal activities, and significant variations in the budget (defined as +/- 20% of any approved line item or the addition of any new line item). Changes of a material nature will trigger a review by MSFHR that may include external peers.

Inquiries & Further Information

For inquiries and information about the Initiative, please contact:

Dr. Martin Schechter

Chief Scientific Officer

Michael Smith Foundation for Health Research

Suite 200, 1285 West Broadway

Vancouver, BC V6H 3X8

(604) 714-6334

mschechter@msfhr.org

Dr. Sharon Mortimer

Senior Director, Programs

Michael Smith Foundation for Health Research

Suite 200, 1285 West Broadway

Vancouver, BC V6H 3X8

(604) 714-2777

smortimer@msfhr.org



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Part 2

Proposal Guidelines and Template

Definitions and Abbreviations

For the purpose of the BC Ethics Harmonization Initiative, the following definitions and abbreviations apply.

Organization

Refers to publicly funded institutions and health authorities in BC that conduct human subject research that is subject to ethics review.

Consortium

Refers to the group of organizations who are participating in the Initiative.

Proposal

The overall Proposal for the Initiative submitted by the Consortium, which is comprised of all required sections and detailed plans including a financial analysis and budget justification.

Co-Leader

The highest-ranking individual responsible for research conducted within each participating organization. Normally, this will be the Vice-President Research or equivalent.

Co-Applicant

The senior person responsible for the implementation and operation of the Initiative (e.g. Director, Research Services; Manager, Ethical Reviews) at each participating organization; a member of the Management Team.

Governance Oversight Committee

All the Co-Leaders together with other stakeholders of their choosing will form the Governance Oversight Committee (GOC). Thus, each participating organization will be represented on the GOC. Its mandate is to oversee, advise, and provide final approval on all major strategic and financial management decisions of the Management Team. *Management Team Members cannot be voting members of the Governance Oversight Committee*, but can attend meetings as observers or presenters.

Management Team

The Co-Applicant and/or senior officials within each participating organization, who, as a group, will manage the overall development, implementation, and operation of the Initiative. The Management Team must have at least one but not more than two representatives from each participating organization. The Management Team as a whole should include at least one individual who has the necessary credentials to provide financial management for the Initiative. Management Team members may include Director, Research Services; Manager, Ethical Reviews, etc but excluding the Vice-Presidents Research or equivalents.

Host Institution

One of the participating organizations will be required to act as the Host Institution on behalf of the Consortium. This must be an organization that a) agrees to receive and manage grant funds provided by MSFHR, b) meets the requirements for eligibility to receive funding set out in guidelines issued by MSFHR, c) has signed an MOU on Roles and Responsibilities in the Management of Agency Grants and Reward with MSFHR, d) is publicly-funded by the BC Government, wholly or partially, and e) is an incorporated entity governed by an external board of directors with the right to hire and terminate employees. The host institution must be identified by the Consortium.

Contact Person

An individual who is a Co-Leader or Management Team member and is identified by the Consortium as the individual with whom MSFHR conducts all correspondence regarding the Proposal.

MSFHR

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Award Term and Amount

Subject to the availability of funds, the full term of the award is July 1, 2010 to March 31, 2015 (five years). Funding beyond March 31, 2011 of the award term is contingent upon continued successful review of the Initiative's annual progress against approved milestones, the availability of funding and approval by the MSFHR Board of Directors. Failure to meet or to demonstrate sufficient progress towards annual project milestones may result in adjustment of the budget for the subsequent year or award termination by MSFHR, at its sole discretion.

In recognition of the significant up-front costs involving information technology and legal agreements, the maximum award has been set out as follows:

Year 1 (July 2010 – March 2011)	\$250,000
Year 2 (April 2011 – March 2012)	\$300,000
Year 3 (April 2012 – March 2013)	\$200,000
Year 4 (April 2013 – March 2014)	\$150,000
Year 5 (April 2014 – March 2015)	\$100,000

It is expected that the initiative will be an integrated part of ethics review throughout the Consortium on or before the end of year five (5) and will require no MSFHR funding beyond that time.

Application Format

The following table lists the required sections of a full application.

Section	
	Cover Letter
	Application Cover and Signatory Forms
	Table of Contents
	Sections A through H
App A	Résumés Co-Applicants / Management Team
App B	Letters of Institutional or Other Support
App C	Uses of Cash
App D	Incremental In-Kind Contributions

To be eligible for review, the Proposal **must** adhere to the instructions for presentation and content, and use the numbering system provided (e.g. Sections A - H). The Applicants are permitted to use sub-sections as appropriate. Except for the appendices, all materials must be presented as follows:

- Arial font (regular), minimum 11-point
- Text printed single-spaced
- Each page printed single-sided
- One-inch margin on all sides of each page
- A header on each page with the Initiative name in the bottom left-hand corner, and the section number and page number in the top right-hand corner
- The maximum page count for the full Proposal must not exceed 20 pages including the content pages but not including the specified appendices, cover letter, application cover and signatory form, or table of contents. Additional pages beyond the maximum will be removed and shredded by MSFHR prior to further processing.

Proposal Evaluation Criteria

The application will be evaluated against the following criteria:

Governance

- The participating organizations have each documented their support for the goals and objectives of the Initiative.
- A governance structure has been defined that is representative of the participating organizations and will ensure appropriate stewardship and oversight of the Initiative, and transparency and accountability for the Initiative operationally and financially.
- The participating organizations have committed additional resources and/or infrastructure to deliver on the Initiative's objectives.
- The participating organizations have demonstrated they collectively provide at least 80 percent of human subject ethic reviews in BC.

- The Consortium has processes in place to bring new organizations into the Initiative.

Management

- An operational Management Team has been clearly identified to implement and manage the Initiative.
- The Management Team has demonstrated success in leading and sustaining other major, province-wide new ventures.
- The Management Team has demonstrated the range of expertise required to implement all the components of the Initiative.
- The Management Team has an established record of experience specific to the Initiative's work.

Quality

- The Proposal is innovative and demonstrates a commitment to the highest standards of excellence.
- The Proposal successfully addresses all required components of the Initiative.
- The Proposal incorporates technologies and/or methodologies that will be at the cutting edge over the next five to ten years.
- Tracking mechanisms have been defined to gather, analyze and report on data relevant to specific milestones and metrics.
- Tracking mechanisms have been defined to gather, analyze and report on relevant data measuring the impact that the Initiative has had on human subjects ethics review in BC.
- The successful implementation of this Initiative will add value and competitive advantage to BC for national and/or international research funding.

Proposal Content

The Proposal must demonstrate how the Initiative will meet the objectives of the Initiative, as articulated in the [Proposal Evaluation Criteria](#), over a five (5) year time frame. Use the [BC Ethics Harmonization Initiative Application Template](#), to structure the Proposal under 8 sections (Sections A – H), plus four appendices (Appendices A – D), as described below.

Section A – General Information

A.1 Contact Information

Include all information necessary to contact the designated Contact Person and a back-up person in case MSFHR cannot reach the designate. Both contacts must be available during business hours throughout the period of review (April – June 2010). Contact information at minimum must include the following:

- Name
- Title
- Organization
- Street address

- Postal address
- Phone number (Office)
- Phone number (Cell), if available
- Fax number
- Email address

A.2 *Résumés of Co-Applicants and Management Team Members*

Résumés for Co-Applicants and Management Team Members should be a maximum of two pages in length and demonstrate that they have the educational, professional and/or other requirements necessary to fulfill their roles as Co-Applicants and/or Management Team Members. Note that résumés are not required for the Co-Leaders.

A.3 *Letters of Support*

Include the following letters, as appropriate, indicating support and commitment to the goals and objectives of the Initiative:

- Institutional (required)
- Cash Contribution (funding sources other than MSFHR)
- In-kind Contribution (funding sources other than MSFHR)

MSFHR reserves the right to withhold award funds until such letters of confirmation are provided.

Section B – Proposed Consortium and Team

Provide a description of each participating organization within the Consortium and their current level of activity with respect to human subject ethics reviews, e.g. committee description, frequency of meetings, numbers of reviews, etc. Demonstrate that the Consortium collectively conducts at least 80% of human subject ethic reviews in BC.

Provide a description of how the team will be able to develop and implement the proposed Initiative successfully. In particular, the Proposal should demonstrate that the Co-Leaders and Management Team Members:

- have demonstrated leadership experience, particularly in large scale and/or innovative initiatives;
- as a group, are well integrated into the operation of the Initiative;
- have demonstrated skills in successful collaboration;
- have credibility and experience relevant to their roles in the Initiative; and
- represent the appropriate stakeholder groups.

B.1 *Organizational Chart*

Provide an organizational chart that clearly shows the reporting relationships and lines of authority for the development and operation of the Initiative. At a minimum, include the Governance Oversight Committee and Management Team.

B.2 Description of Key Roles

Provide a description of key responsibilities and authorities of the major groups within the organization chart and for each individual on the Management Team.

B.3 Governance and Accountability Structures and Processes

Provide a description of the governance and accountability structures and decision-making processes of the Initiative. Demonstrate that they are representative of the Consortium; transparent; are accountable both operationally and financially; and can ensure the appropriate stewardship and oversight of the Initiative. For example, this section may include a description of approval processes for strategic, financial, and operational decisions. The Host Institution should be identified here, and the process for approving expenditures should be described.

In addition, demonstrate that the Consortium has committed additional resources and/or infrastructure to deliver on the Initiative's objectives and is open and proactive in bringing new organizations into the Initiative.

Section C – Proposed Initiative

Provide a description of the Initiative and how it will integrate, support and provide timely and efficient access to human research application ethics reviews beyond what is currently available today. Elements that **must be addressed** include but are not limited to:

<p>1. Shared IT platform / Creation of Common Forms</p>	<ul style="list-style-type: none">• Development and implementation of a shared Information Technology (IT) platform and tools for the submission, review and tracking of applications; the IT platform should be accessible to researchers and institutions, and used in common by all participating organizations in the Consortium• The IT platform will require an investigator to complete one and only one electronic form no matter how many participating organizations are involved in the research• The IT platform will direct ethics applications to any of the participating organizations and allow them to conduct the primary review• The IT platform will assist each participating organization to meet its workload more effectively
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<p>2. Consortium Reciprocity Agreements</p>	<ul style="list-style-type: none"> • Development and implementation of legal agreement(s) whereby participating organizations agree to accept each other's primary reviews (inter-institutional reciprocity) in order that ethics review for multi-centre studies can be more efficient, consistent and timely <ul style="list-style-type: none"> ○ Illustration: Suppose A is the primary organization where the principal investigator is located, and B is another member of the Consortium where the research will also be conducted. In one model, B would simply accept the primary review conducted by A. In another model, B would receive A's review and would provide a rapid yes or no response on whether B will participate (without revision). In either model, the goal is to avoid the situation where an ethics application receives multiple in-depth reviews by multiple committees.
<p>3. Shared Education Resources</p>	<ul style="list-style-type: none"> • Development of shared educational and training materials, resources and initiatives to train qualified reviewers • Plans for shared efforts to educate investigators about ethics review (e.g. development of a common model for informed consent forms)

Section D – Initiative ROI/Value Add

The purpose of this section is to demonstrate how the proposed Initiative will provide return on investment (ROI), value add and competitive advantage for the BC research community including, but not limited to, academia, health, health system, and industry/economic development. The ROI, value-add and competitive advantage can be quantifiable or qualitative in nature. The Initiative must create something that is different from and/or additional to what is currently available provincially and potentially nationally.

Areas that may be addressed include:

- ability of the Initiative to support a broad range of health research applications;
- contribution to academia, health/health system outcomes, and/or economic development;
- contribution to likely/foreseeable future needs;
- contribution to economies of scale, increased efficiency, and user productivity;
- role of the Initiative in educating trainees, young investigators and other users about ethics reviews (e.g. development of common model informed consent forms);
- role of the Initiative in training qualified reviewers;
- role of the Initiative in promoting the highest ethical standards in BC;
- advancement of innovation in the health system;
- process/product development or commercialization;
- enhanced competitive advantage for external funding;

- expansion of high-quality ethics review to other health research communities within BC; and
- enhancement of BC's ability to participate and lead in national and international research agendas.

Section E – Financial Planning

The purpose of this section is to provide a high-level description of the major activities, processes, work products, and milestones associated with a phased implementation approach across the Initiative's life from startup/development and implementation to financial and operational viability. The Financial Plan should reflect the Initiative's degree of development at the time of initial funding.

Funding from MSFHR is to be directed to the **incremental** costs of the collaboration. It may not be used for or replace each participating organization's ethics review costs, as these are covered by the Indirect Costs of Research program, fees and other sources.

See Section F.1 for a list of [Eligible Expenses](#).

E.1 Activities and Status of Development to Date

Describe the activities of the Initiative's development to date, if any. Specifically, describe the activities currently in progress, the activities already complete, and the major issues addressed by these activities. If no part of the Initiative has yet been developed and implemented, please state that this section is not applicable to the Proposal.

E.2 Initiative Plan

Describe the major activities, processes and work products that will be undertaken to fully develop, implement, and operate the Initiative.

E.3 Initiative Schedule and Milestones

Provide a timeline/timetable of the major activities and indicate the key milestones.

E.4 Space

Identify the space requirements of the Initiative if applicable, and provide a letter of confirmation from the participating organizations that the necessary space has been secured to support the Initiative.

E.5 Human Resources Plan

Describe the human resource requirements of the Initiative and address issues such as recruiting and hiring, compensation levels, and terms of employment. Consideration should be given to changing staffing requirements over the phased implementation of the Initiative.

E.6 Agreements with Stakeholders

Provide a description of the agreements that are in place or will need to be negotiated for the development, implementation, and financial and operational viability of the Initiative. Describe the status of negotiations currently underway and the nature of the issues under negotiation. Issues that may be addressed in these agreements include:

- a space plan;

- intellectual property;
- financial transfer agreements;
- publications/authorship rights;
- consenting processes;
- commercial opportunities; and
- sharing of risks and rewards.

If appropriate, Applicants can include letters of support from key stakeholders who are critical to the development, implementation, and/or financial and operational viability of the Initiative (in appendix B to the Proposal).

E.7 Key Success Factors

Describe the key success factors required to achieve financial and operational viability. These factors may include obtaining necessary alternative sources of funding, recruiting other specialist staff, and approvals.

E.8 Upgrade Plan

At a high level, describe long-range plans to upgrade the Initiative, which may include technology, people and/or processes.

Section F - Budget Documentation

The purpose of this section is to demonstrate that the annual costs and resources required for the Initiative have been identified and budgeted, and sufficient funds have and/or will be obtained beyond initial phased MSFHR funding. Provide a clear justification for any expenditure that is allocated to MSFHR funding. The budget documentation should reflect the financial plan narrative as described in the previous Section.

F.1 Eligible and Ineligible Expenses

Eligible expenses must be shown to be associated with those incremental costs of implementing and operating the BC Ethics Harmonization Initiative across the Consortium over and above the costs of ethics review already borne by the participating organizations.

Award recipients may seek approval to fund items not included below in the list of eligible expenses, and/or items not included in the original funding Proposal, so long as those items comply with the principles above.

MSFHR reserves the right to withhold approval of expenses that do not satisfy the principles above, and to seek reimbursement for funds used for ineligible expense items.

Eligible Expenses

- Salaries and benefits for non-faculty staff located in research support offices who are supporting the incremental activities of the Initiative
- Salaries and benefits for secretarial, administrative, and technical staff supporting the Initiative

- Fees for consultants providing administrative, technical or other research support services
- Communication costs: mail, long distance telephone, fax, audiovisual, stationery, photocopying and document reproduction, network or internet access and management
- Costs relating to the dissemination of knowledge, including participation in conferences
- Costs relating to common services such as IT and database management, software licensing, software maintenance and access to specialized facilities
- Legal services required to implement inter-institutional legal agreements
- Educational materials and services related to human subject ethics review
- Travel to attend workshops and similar meetings
- Costs associated with bringing people together for the purpose of collaboration, networking, and/or knowledge exchange, including planning, co-ordination and outreach activities
- Costs associated with program governance and oversight

Ineligible Expenses

- Salaries and benefits for Initiative Co-Leaders and Management Team members
- Audiovisual costs: basic infrastructure required for producing audiovisual documents
- Publicity and representation costs
- Costs of operating the facilities: heating, ventilation, air conditioning, water, electricity, etc. for areas, furniture and equipment
- Institution's expenses for clinical care such as: laundry, uniforms, bedding, dishes and meals, etc.
- Equipment costs, including costs associated with equipment purchase, leasing, warranty, maintenance and service
- Costs of office services (except for those stated above as being eligible)
- Capital costs, including costs associated with construction, renovation or rental of offices, laboratories or other supporting facilities
- Secondary grants and awards issued by the award recipient
- Facility operating costs such as:
 - general research administration (human resources, finances, research supplies, laundry, purchasing, etc);
 - library holdings and library operations/management;
 - facilities (offices, laboratories, space rental, furniture, utilities);
 - facilities maintenance, cleaning and renovation
 - security, liability and other insurances; and
- Purchase or maintenance of network/computer servers or photocopiers.

All items not otherwise specified should be deemed non-eligible expenses.

F.2 “Uses of Cash Statement” budget template in Appendix C

Note the total expenditures for the Initiative per category per year. Demonstrate that the Initiative has sufficient cash to meet the planned expenditures. Only expenditures allocated to MSFHR funding need be noted in detail. Please refer to the eligible expenditures of the Program in Section F.1 above.

In addition, demonstrate that on-going operational costs at award end (March 31, 2015) have been considered and will be covered by Institutional in-kind/funding contributions (Columns U and V in the [Budget Template](#)).

Note: Particular attention will be paid to the Budget Justification column by the External Review Panel.

F.3 “Incremental Institutional In-Kind/Funding Contributions Statement” budget template in Appendix D

Detail the approximate value of all incremental Institutional in-kind/funding contributions that will be used towards the Initiative. Such contributions **must** be new (over and above that which is currently in place to support current activities). Refer to Section A.3 regarding requirement for attaching Letters of Support.

Note: Particular attention will be paid to the Explanatory Notes column by the External Review Panel.

Section G – Risk Analysis

The purpose of this section is to provide an analysis of significant risks to the Initiative’s development, implementation, and financial and operational viability. Risks that may be identified include:

- changes in leadership;
- withdrawal of one or more of the participating organizations;
- insufficient coverage of the Initiative within BC to justify the expenditure;
- funding shortfalls;
- schedule overruns;
- inability to secure inter-organizational agreements; and
- obsolescence of technology or inability to remain on cutting edge of technology.

G.1 Risk Identification

List the risks specific to the Initiative and rate each for the likelihood of occurrence and the severity of damage should it occur (high, medium or low). Add additional rows as needed.

Specific Risk	Probability of Occurrence (H/M/L)	Severity of Damage (H/M/L)

G.2 Risk Mitigation Strategies

For each risk identified in G.1, describe the risk mitigation strategies that will minimize its impact.

Section H – Evaluation

The purpose of Section H is to provide context for the evaluation of the Initiative if funded, at 12, 24 and 48 months after funding begins.

H.1 Baseline Evaluation Measures

Specify **current baseline** measures and data (quantitative and qualitative) against which the Initiative's performance outcome will be evaluated annually after funding. Indicators of performance outcome should be measurable, reasonable and address the objectives of the Program as articulated in the [evaluation criteria](#).

Baseline measures should include but are not limited to:

- Proportion of all ethics reviews in BC that are conducted by organizations within the Consortium
- Proportion of all ethics review applications within the Consortium that are handled through the common IT initiative
- Proportion of all multi-centre review applications within the Consortium that undergo a single primary review
- Time from application submission to primary review
- Time from application submission to final decision
- Measures regarding accessibility of qualified reviewers

H.2 Follow-up Evaluation Measures

Specify **follow-up** measures and data (quantitative and qualitative) against which the Initiative's performance outcome will be evaluated annually after funding. Indicators of performance outcome must be measurable, reasonable and address the objectives of the Program as articulated in the [evaluation criteria](#), and must relate to those specified in Section H.1.

H.3 Specification of Milestones

Provide a timeline of key **milestones** by year over the course of the award. Milestones must be unequivocal, measurable, and reasonable and address the objectives of the Program as articulated in the [evaluation criteria](#).

Milestones may include but are not limited to:

- Date of real-time implementation of IT initiative at Organization A
- Date of real-time implementation of IT initiative at Organization B, and so on
- Date of signing of reciprocity agreement by Organization A
- Date of signing of reciprocity agreement by Organization B, and so on
- Date at which all organizations in the Consortium utilize common IT initiative

- Date at which all organizations in the Consortium are covered by reciprocity agreements

Checklist for Application Submission

- Ensure that you have attached all required Résumés to the Proposal as Appendix A
- Ensure that you have attached all required Letters of Support to the Proposal as Appendix B
- Ensure that the appropriate Excel Budget document(s) are attached to your Proposal as Appendices C and D
- Review your application before you submit it to MSFHR. No changes can be made after submission.
- Submit your Application