Rick Hansen Institute
Institut Rick Hansen

A world without paralysis after spinal cord injury.

REQUEST FOR APPLICATIONS | PROGRAM GUIDELINES

RICK HANSEN INSTITUTE PRECLINICAL SCI RESEARCH TOWARDS CURES

February 2014

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Contents

RHI'S VISION

A world without paralysis after spinal cord injury.

RHI'S MISSION

To lead collaboration across the global SCI community, by providing resources, infrastructure and knowledge; and to identify, develop, validate and accelerate the translation of evidence and best practices to reduce the incidence and severity of paralysis after SCI, improve health care outcomes, reduce long-term costs, and improve the quality of life for those living with SCI.

1. Introduction

1.1 RICK HANSEN INSTITUTE

The Rick Hansen Institute (RHI) is a Canadian-based not-for-profit organization committed to accelerating the translation of discoveries and best practices into improved treatments for people with spinal cord injuries. It does this by leading the collaboration of researchers, health care professionals and service providers across Canada and internationally. RHI has matched leadership and research collaboration with government funding to facilitate one of the largest interdisciplinary spinal cord injury research programs in the world. For more information, please visit: www.rickhanseninstitute.org.

Vision A world without paralysis after SCI.

Mission RHI's mission is to lead collaboration across the global SCI community by providing resources, infrastructure and knowledge; and to identify, develop, validate and accelerate the translation of evidence into best practices.

1.2 OBJECTIVES

RHI has identified four objectives towards meeting the needs of people with SCI:

1. Reduce the incidence and severity of paralysis after SCI,

2. Improve health care outcomes in the treatment of people with SCI,

3. Reduce long-term costs of care of people with SCI, and

4. Improve the quality of life for those living with SCI.

1.3 PROGRAMS

In order to execute its mission RHI has established the following four core programs: **Cure**, **Care**, and **Consumer** and **Commercialization**. The program descriptions are below:

CURE

Focuses on the generation of knowledge and the establishment of treatments that will ultimately result in a cure for paralysis after SCI.

CARE

Focuses on identifying and filling gaps in knowledge regarding the clinical management of SCI as well as to promote best practices in SCI care delivery based on existing evidence for Canadians who are newly injured or those living with an existing SCI.

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CONSUMER ENGAGEMENT

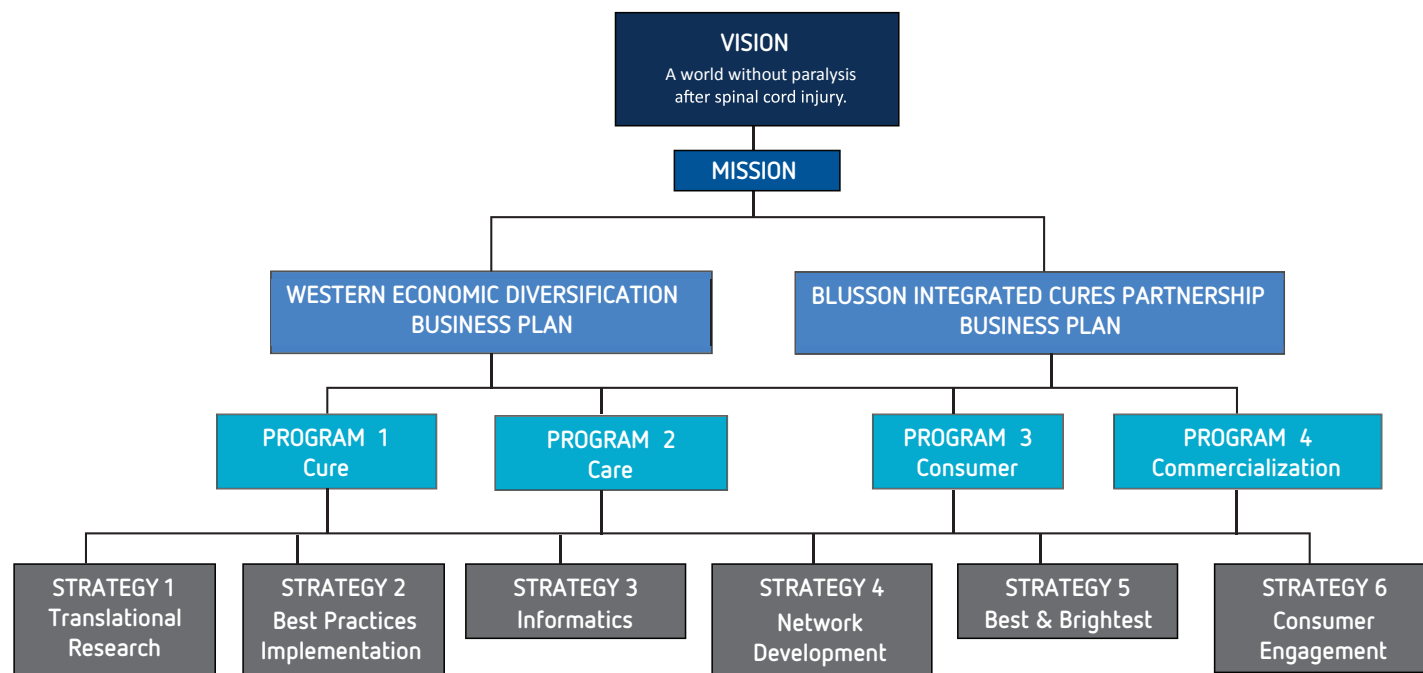Focuses on involving more individuals with SCI in research.

COMMERCIALIZATION

Focuses on facilitating increased investment into the development of innovative pre-commercial therapeutics, therapeutics, medical devices and diagnostics with application to SCI.

1.4 STRATEGIES

RHI has identified the following six strategies to support its objectives and programs:

1. Support and undertake Translational Research (TR) Studies;

2. Support and undertake Best Practices Implementation (BPI) Projects;

3. Engage in further Network Development in Canada and abroad;

4. Develop and accelerate the use of Informatics related to TR and BPI - based on the RHI Global Research Platform (RHI GRP);

5. Support the next generations of SCI specialists, the Best and Brightest; and

6. Foster Consumer Engagement.

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2. Request for Applications

In order to meet its objectives, RHI is launching a new funding opportunity to support modest and focused preclinical research projects that directly address the relevant areas of focus described in the objectives of the **RHI Cure Program:**

- Studies that increase the understanding of biology and physiology of acute and chronic SCI.

- Late-stage preclinical studies evaluating the efficacy and therapeutic agents that have already shown promise in proof-of-concept studies.

- Late-stage preclinical studies investigating the use of cellular therapies in treating acute and chronic SCI.

- Late-stage preclinical studies utilizing standardized rehabilitation and activity-based plasticity strategies.

Examples of the types of projects RHI intends to fund through this opportunity include, but are not necessarily limited to:

- Preclinical studies of combinatorial strategies that utilize as a measure of outcome a biomarker that could be utilized in human clinical trials.
  - Combinatorial strategies include any combination of neuroprotective, neuroregeneative or rehabilitation intervention.

- Establishment of biomarkers in preclinical models that can be used clinically in humans.

- Preclinical study of interventions that are currently being used in acute human SCI or other human non-SCI conditions.

- Preclinical replication study of a therapy assessing robustness of therapeutic efficacy and/or supporting its translation to human clinical trials.
  - Replication may include a different species, injury model or injury mechanism.

The objectives of this category of funding include:

- To further understanding of the biology and physiology of SCI.

- To develop promising therapies for neuro-restoration (neuroregeneration, neuroprotection, and neurorecovery) in acute and chronic SCI.

- To develop measures that can facilitate the human translation of novel therapeutics.

  RHI will provide five projects up to $100,000 CDN over approximately one year to projects approved for funding; however, matching funds are to be provided on a 1:1 co-funding basis from non-RHI sources for a total project value of up to $200,000 CDN. In order to promote international and industry collaborations the sources of co-funding must either be from outside of Canada and/or a Canadian firm or corporation. Please refer to Section 2.3 for more details regarding co-funding.

It is expected that RHI will receive more applications than it will be able to provide funding to; therefore, only the most competitive applications will receive funding.

RHI expects a return on its investment. Therefore, terms of the funding will be negotiated between RHI and successful applicants on a case-by-case basis.

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2.1 ELIGIBILITY

RHI funding can only be spent by investigators based at Canadian research-based institutions and companies; however, co-funding need not flow directly to investigators in Canada.

2.2 ELIGIBLE PROJECT COSTS

Eligible project costs are incremental costs for items that directly support the objectives of the approved project, such as salaries, equipment, fee-for-service contracts, reasonable operating costs and costs related to intellectual property evaluation. Administrative costs directly related to the conduct of the project are eligible; however, the administrative costs must not exceed 5% of the non-administrative costs of the project.

Overhead costs will not be paid by RHI.

2.3 CO-FUNDING

Co-Funding refers to eligible project costs not borne by RHI. Projects selected for funding must match RHI's funds on a 1:1 co-funding basis. Although RHI funds may only be spent in Canada, co-funding need not flow directly to investigators in Canada.

At least 50% of the co-funding (up to $50,000CDN) must be committed, with supporting documentation, upon submission of the application. RHI will only disburse funds to projects selected for funding once 100% of the co-funding is secured; however, RHI is willing to work with projects selected for funding to secure any remaining co-funding.

Supporting documentation for co-funding includes written confirmation from the co-funding source, including detail of the amount of funding and date of funding.

2.3.1 Eligible Co-Funding

Possible sources of co-funding include non-Canadian:

- Granting agencies

- Institutional funds, trust funds or foundations

- Firms and corporations

- Voluntary or charitable organizations

- Individuals

- Venture capital or other investment funds

RHI will accept co-funding from Canadian firms and corporations.

RHI will only accept funding that was applied for since October 31, 2012.

In-kind contributions will be considered as co-funding on a case-by-case basis. Supporting documentation and clear rationale for the in-kind value is required.

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3. Submission & Review Process

All applications must be submitted in PDF format via email to:

> **Rick Hansen Institute**
>
> **Attn:** Preclinical SCI Research Towards Cures
>
> **Email:** funding@rickhanseninstitute.org

Applications to this RHI funding opportunity are due on April 30, 2014 by 11:59pm Pacific Time. **Applications submitted after this time will not be accepted.**

Details on application formatting, preparation and review are found in the Appendices to this document.

3.1 KEY DATES & TIMELINE

The following is the anticipated timeline for this funding opportunity:

Funding opportunity announcement	February 11, 2014
Application deadline	April 30, 2014
Application review process	May – July, 2014
Notice of funding	July, 2014
First disbursement of funds	September, 2014

Any significant changes to the anticipated timeline will be communicated to applicants.

4. Administration Following Notice of Funding

The plan for disbursement of approved funds will be determined based on the specific needs of the project and constraints on when RHI may disburse funds based on agreements with its funding partners. The disbursement schedule may include a retainer from the approved budget until a final report is submitted by the project. The first disbursement will occur once the funding agreement between the funding recipient and RHI is executed and other conditions for the release of funds are met.

5. Contact Information

If you have any questions about this opportunity please contact one of the following:

PHALGUN JOSHI, PHD
Managing Director, Program Operations & Support
t: 604-827-1673
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Appendices

I. Application Preparation Instructions

i. FORMATTING YOUR APPLICATION

Format your application as follows:

- Calibri 11 point font
- 1.0 margin
- 1.5 line spacing
- Header: Insert Project Title and Applicant's Full Name in each page
- Footer: Insert version control (use submission date) and page number in each page
- Budget: Unless otherwise instructed, use RHI template
- Detailed CVs formatted for other institutions (e.g., CIHR) may be used provided the CV contains the requisite information (e.g., publication history, funding history)
- PDF (other formats, e.g., .doc and .docx, will not be accepted)

ii. PREPARING YOUR PROPOSAL

- **PART 1: TITLE & ABSTRACT (150 words maximum)**
  - Use plain language. This information will be used in documents prepared for the general public as for RHI's funders.

- **PART 2: PROJECT BACKGROUND (1 page maximum)**
  - Review the literature and describe the current state of knowledge.
  - Explain key assumptions, risks and mitigation strategies. Discuss how the scope, timeline and budget may be affected.

- **PART 3: RELEVANCY (1.5 pages maximum)**
  - Impact of outcomes on stakeholders
    - Provide a list of all stakeholders (e.g., health care providers, administrators, policymakers, people with SCI) affected by the project.
    - Discuss the anticipated impact of the project outcomes on stakeholders.
  - Appropriate engagement of stakeholders
    - Briefly describe completed and planned engagement with stakeholders (e.g., surveys, workshops, correspondence and consultation) including all stakeholder consultations planned as part of the project.
  - Likelihood for knowledge uptake by target audience
    - Discuss likelihood of knowledge uptake by target audience. Provide supporting evidence, if available.
  - Innovation and originality
    - Discuss the innovation and originality of the proposed project.

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- o Ethical considerations
    - Discuss any potential ethical issues that may arise and how they will be addressed during the execution of the project.

- **PART 4: SCIENTIFIC**
    - o Significance of issues(s) from clinical and scientific/technical aspects & Validity and relevance of evidence provided for project rationale **(1 page maximum)**
        - Describe the current clinical, scientific and/or technical issue(s) that the project addresses. Provide a rationale of how the project will address the issues(s) through its design and/or through the resulting outputs.
        - Discuss the solid and relevant clinical and scientific evidence on which the project rationale is based.
    - o Project design **(3 pages maximum)**
        - Provide a detailed description including, but not limited to, methodology, activities, target population and size, controls, specialized resource needs, geographical extent, evaluation methodology, outline of statistical analysis plan, outputs as appropriate to the project and resources (personnel, infrastructure, equipment as applicable) required and currently available.
    - o Strategy for knowledge translation (KT) and best practice implementation (BPI) **(1 page maximum)**
        - Describe your KT and BPI strategy, which should including the following
            - Target audience
            - How KT will be integrated into the project
            - How knowledge uptake will be measured
            - What resources will be dedicated to KT activities
            - Description of content requiring dissemination and the expected forum of translation
            - Evidence, if any, to support assumptions/strategy
    - o Expected results and performance measurement **(0.5 page maximum)**
        - Project Results (Outputs and Outcomes)
            - List the outputs, immediate outcomes and long-term outcomes of the project.
            - Outputs are the direct products or services of the project and are usually within the control of the project team (e.g., publications, conference presentations).
            - Outcomes are external consequences attributed, in part, to the project. Outcomes are not within the control of the project team; instead they are within the area of the project's influence.
                - o Immediate outcomes occur shortly after the outputs are produced and are directly attributable to those outputs. An example of an immediate outcome of a conference presentation might be increased awareness among conference delegates of the content of the presentation.
                - o Long-term outcomes are higher-level outcomes expected to logically occur once one or more immediate outcomes have been achieved. Long-term outcomes represent the raison d'être of the project. They should represent the link between the immediate

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outcomes and RHI's objectives. An example of a long-term outcome resulting from increased awareness might be an improvement in evidence-based decision-making in clinical practice environments.

- Outputs and outcomes should be SMART: specific, measurable, achievable, relevant and time-bound.

- Performance Measurement

  - Identify at least one performance indicator for each output and each immediate outcome.

  - Performance indicators describe how you will measure or assess whether a result has been achieved; they are quantitative or qualitative variables that reliably measure achievement or reflect the changes connected to a project. For example, if you wanted to measure increased awareness on a certain topic, you might distribute a questionnaire asking the following question: "What is your level of awareness about X?" The indicator might be the percentage of respondents who self-report a high level of awareness on topic X. Carrying out the survey at baseline and again after project implementation could provide an indication of the changing level of awareness over time (towards with your project may have contributed).

  - Performance indicators should be valid, reliable, affordable, available and relevant:

    - Valid: The indicators measure what they intend to measure.

    - Reliable: The data collected is the same if collected repeatedly under the same conditions at the same point in time.

    - Affordable: Cost-effective data collection and analysis methods can be developed.

    - Available: Data for the indicators are readily and consistently available to track changes in the indicator.

    - Relevant: The indicator clearly links back to the project's outcomes.

- Likelihood of success of achieving outcomes **(0.5 pages maximum)**

  - Discuss the likelihood of the success of achieving the expected outcomes.

  - **Note:** This is often determined by the study design and the availability of sufficient study participants as well as investigational products, logistics, etc.

- Linkage to/utilization of RHI strengths **(0.5 pages maximum)**

  - RHI has a number of strengths that enable it to attain its objectives effectively including: access to a national network of sites that encompass the health care continuum; national access to SCI subjects for studies; a versatile information management system (RHI Global Research Platform); project management resources; and, partnerships with granting agencies and accreditation bodies.

  - Discuss how the proposed project utilizes one or more of RHI strengths.

- Sustainability of implementation of project outcomes **(0.5 pages maximum)**

  - Provide an estimate and assessment of the following costs: 1) knowledge update, or/and 2) implementation of project outcomes. Briefly address the economic benefit of implementing the proposed project and outcomes in Canada and internationally.

- Budget **(1 page maximum)**

  - Using the template provided, provide a detailed one year budget showing:

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- Total project budget by RHI's fiscal year (i.e., Apr 01-Mar 31)
- Total budgetary request to RHI by fiscal year
- Project costs to be borne by RHI
- Project costs to be borne by sources co-funding
  - Indicate which costs are to be borne by secured sources of co-funding and identify those sources
  - Indicate which costs are to be borne by sources of co-funding that will be secured at a later date.

- Leveraging opportunities **(0.5 pages maximum)**
  - Discuss actual and planned leveraging opportunities and impact to project scope, timeline and budget

- Work plan & likelihood of meeting proposed timelines **(1 page maximum)**
  - Provide a detailed work plan showing key milestones, deliverables and decision points for project continuation (i.e., go/no go).
  - Discuss foreseeable delays and mitigation strategies. Discuss impact to scope, timeline and budget.

- Qualifications and experience of team **(1 page maximum)**
  - On one page, list all project team members, their roles and responsibilities and the percentage of their time allocated to this project (including in-kind labour). Include roles that have been identified, but not filled. If there are unfilled positions, include the recruitment plan in your work plan. RHI encourages, wherever possible, the inclusion of people with SCI in the project team.
  - Attach recent CVs for all key team members that include their detailed publication history and funding history. CVs formatted for other institutions, such as CIHR, are acceptable.

- PART 5: OTHER INFORMATION & SUPPORTING DOCUMENTATION
  - Include supporting documentation for any secured co-funding.
  - You may include other information you feel may assist in the review of your application (e.g., copies of relevant approvals, publications and/or presentations, and/or award notices and/or detailed reviewer comments if the application has been submitted to another agency for funding).

- PART 6: CONFLICT OF INTEREST STATEMENT
  - Review **RHI's Conflict of Interest Policy** and attach a completed **Conflict of Interest Statement** to your application.

- PART 7: SUGGESTION FOR POTENTIAL REVIEWERS
  - You may suggest potential reviewers as well as non-reviewers. Declare any perceived or real conflicts of interest at this time. This information will be kept confidential.

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II. Application Review

All applications are reviewed for relevance to RHI objectives (Business Case Review), potential of uptake and impact on stakeholders (Relevancy Review) and methodology/interpretation (Scientific Review). The Business Case Review is undertaken by RHI's Program Operations and Support Team to ensure that the project is consistent with RHI's Strategic and Business Objectives. The Relevancy Review is undertaken by subject matter experts and at least one person with SCI (consumer). The Scientific Review is undertaken by subject matter experts.

III. Instructions for Reviewers

i. GUIDELINES FOR BUSINESS CASE REVIEW

Unless otherwise instructed, RHI's Program Operations and Support Team (composed of the Managing Director and the leads of Clinical Research Operations, Informatics and Data Management Service Groups at RHI) will undertake the Business Case Review of the application using the **Scoring Matrix** as applicable.

ii. GUIDELINES FOR RELEVANCY REVIEW

Unless otherwise instructed, those conducting the Relevancy Review of the application will undertake the review using the **Scoring Matrix** and the criteria listed below.

iii. GUIDELINES FOR SCIENTIFIC REVIEW

Unless otherwise instructed, those conducting the Scientific Review of the application will undertake the review using the **Scoring Matrix** and the criteria listed below.

iv. RELEVANCY REVIEW CRITERIA

- IMPACT OF OUTCOMES ON STAKEHOLDERS
  - o Assess whether the application addresses the impact of the project outcomes on stakeholders relevant to the project. Stakeholders can include people with SCI, clinicians, carers and/or policymakers.

- APPROPRIATE ENGAGEMENT OF STAKEHOLDERS
  - o Assess whether stakeholder engagement has occurred and its appropriateness to the project. Stakeholder engagement can include surveys, focus groups or direct participation in project teams.

- LIKELIHOOD FOR KNOWLEDGE UPTAKE BY TARGET AUDIENCE
  - o Assess the likelihood of knowledge uptake by the target audience and any supporting evidence provided. Appropriate stakeholder engagement can often provide an indication of likelihood of uptake.

- INNOVATION AND ORIGINALITY
  - o Assess whether the design involves a novel technology/methodology or approach not previously utilized in SCI research.

- ETHICAL CONSIDERATIONS
  - o Assess whether all potential ethical issues and potential implications thereof have been identified and addressed.

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v. SCIENTIFIC REVIEW CRITERIA

- **SIGNIFICANCE OF ISSUE(S) FROM CLINICAL AND SCIENTIFIC/TECHNICAL ASPECTS**
  - Assess clinical and scientific/technical of 1) issues being addressed, and 2) how the project addresses the issues. Review in the context of whether stakeholders have identified the issue as being of relevance to the ultimate benefit to people with SCI.

- **VALIDITY AND RELEVANCE OF EVIDENCE PROVIDED FOR PROJECT RATIONALE**
  - Assess whether the project rationale is supported by the evidence provided.

- **PROJECT DESIGN**
  - Assess the project design including the methodology, activities, target population and size, specialized resource needs, geographical extent, evaluation methodology, outline of statistical analysis plan, outputs as appropriate to the project and resources (personnel, infrastructure, equipment as applicable) required and currently available.
  - Assess key assumptions, risks envisioned with the study and the appropriateness of mitigation strategies.
  - Verify a sample of the references provided to support the project design.

- **STRATEGY FOR KNOWLEDGE TRANSLATION (KT) AND BEST PRACTICES IMPLEMENTATION (BPI)**
  - Review the strategy and the evidence to support its use in the project. Assess if the strategies are integrated into the project and if the resources assigned are adequate to support its execution.

- **EXPECTED RESULTS AND PERFORMANCE MEASUREMENT**
  - Outputs are the direct products or services of the project and are usually within the control of the project team (e.g., publications, conference presentations).
  - Outcomes are external consequences attributed, in part, to the project. Outcomes are not within the control of the project team; instead they are within the area of the project's influence.
    - Immediate outcomes occur shortly after the outputs are produced and are directly attributable to those outputs. An example of an immediate outcome of a conference presentation might be increased awareness among conference delegates of the content of the presentation.
    - Long-term outcomes are higher-level outcomes expected to logically occur once one or more immediate outcomes have been achieved. Long-term outcomes represent the raison d'être of the project. They should represent the link between the immediate outcomes and RHI's objectives. An example of a long-term outcome resulting from increased awareness might be an improvement in evidence-based decision-making in clinical practice environments.
  - Outputs and outcomes should be SMART: specific, measurable, achievable, relevant and time-bound.
  - Performance indicators describe how results are measured or assessed to determine if the objectives of the project have been achieved; they are quantitative or qualitative variables that reliably measure achievement or reflect the changes connected to a project.
  - Assess whether the outputs and outcomes are SMART and aligned to the milestones and deliverables listed in the work plan. Assess whether the achievement of long-term outcomes will contribute towards one or more of RHI's objectives.

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- **LIKELIHOOD OF SUCCESS OF ACHIEVING OUTCOMES**
  - Assess the likelihood of knowledge uptake by target audience and whether this is based on appropriate evidence.

- **LINKAGE TO/UTILIZATION OF RHI STRENGTHS**
  - RHI has a number of strengths that enable it to attain its objectives effectively including: access to a national network of sites that encompass the health care continuum; national access to SCI subjects for studies; a versatile information management system (RHI Global Research Platform); project management resources; and, partnerships with granting agencies and accreditation bodies.
  - Assess whether the project utilizes one or more of RHI's strengths.

- **SUSTAINABILITY OF IMPLEMENTATION OF PROJECT OUTCOMES**
  - Assess whether the cost of knowledge uptake and the economic benefit of implementing the proposed project and outcomes in Canada and internationally is sustainable. Note: It is recognized that such analyses may not be available in the existing literature, however applicants are still required to address.

- **VALIDITY OF BUDGET (INCLUDING COST EFFECTIVENESS)**
  - Assess whether the budget accurately reflects the project scope and timeline. Assess the cost effectiveness of the study (i.e., does the cost of the project justify the expected outcomes for the affected stakeholders).

- **LEVERAGING OPPORTUNITIES**
  - Assess the secured and proposed leveraging opportunities as outline in the application and their impact on the project scope, timeline and budget.

- **WORK PLAN & LIKELIHOOD OF MEETING PROPOSED TIMELINES**
  - Review key milestones and corresponding timelines and assess whether there is a reasonable probability of successfully meeting them. Note: Sufficient time should be allocated for activities such as ethics body reviews, patient recruitment, integrated KT activities, data analysis, etc.

- **QUALIFICATIONS AND EXPERIENCE OF TEAM**
  - Review qualifications and experience of the Project Lead and all team members. Assess whether the team is capable of undertaking the project successfully. Review past records for successful completion of similar projects.

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