

Randomized Controlled Trials (RCT) Outline Routing Slip

Complete and forward this sheet with the original copy of your outline to ensure that it is forwarded directly to the appropriate CIHR departments and staff. This sheet should not be included in the copies.

This routing slip is for CIHR's administrative use only.

Nominated Principal Applicant/Candidate	
Personal Identification Number (PIN)	
Application Number	
Competition Date	
Project Title	
Name of Strategic Initiative/RFA	
Name of Industrial Partner(s)	
Name of Partnership Program	
Name of Special Programs	
CIHR's Priority Announcements	
Title of Priority Announcement 1:	Relevant Research Area:
Title of Priority Announcement 2:	Relevant Research Area:
Title of Priority Announcement 3:	Relevant Research Area:

**APPLICANT CONSENT FORM FOR USE AND DISCLOSURE OF
PERSONAL INFORMATION PROVIDED TO CIHR FOR PEER REVIEW**

IMPORTANT: One original signed copy of the Applicant Consent Form is required at both the registration and application stages.

The Access to Information Act (ATI) gives Canadian citizens and Permanent Residents of Canada a limited right of access to information in federal government records. The Privacy Act gives Canadian citizens and permanent residents of Canada access to information about themselves and specifies the uses to which personal information can be put. The Privacy Act sets out the rules and conditions governing the collection, retention and disposal of personal information. It also provides a use and disclosure code for the protection of this information. This code stipulates the criteria under which information can be disclosed, including for what purposes and to whom it may be disclosed. All information collected by CIHR is subject to these laws.

CIHR seeks your certification that you have been informed that all the information supplied in the application will be made available to CIHR personnel responsible for managing the peer review process to review applications, to administer and monitor grants and awards, to compile statistics and to promote health research in Canada.

Information supplied in the application **except the pages labelled “for Administrative use only”** will be made available to Peer Review Committees composed of experts recruited from the academic, public and private sectors. Applications may also be transmitted to external reviewers.

CONSENT

(1) **OBSERVERS:** Information supplied in the application **except the pages labelled “for Administrative use only”** will be made available, with your consent to:

Observers of peer review committees. Observers requiring consent (not including CIHR staff responsible for the administration and evaluation of funding programs and members of the Standing Committee responsible for overseeing the peer review process) are:

- a) Funding Partner and / or Potential Funding Partner representatives who have no funding decision authority;
- b) Institute Staff who are not in conflict of interest and who have no funding decision authority.

I do do not consent to the sharing of the information specified above in section (1) with the observers described.

(2) **RELEVANCE REVIEW:** For use in determining an application’s relevance in accordance with the Institute’s / Partner’s / Branch’s mandate, or the application’s relevance to the research areas as identified within a priority announcement, the **Project Title, Project Summary and / or Relevance Form** already available to CIHR staff responsible for the administration of funding programs may also be provided to:

- Institute Staff managing research envelopes and Institute Advisory Board Members;
- Funding Partners and / or Potential Funding Partners;
- CIHR Senior Managers who manage research envelopes and sponsor Strategic Initiatives.

(3) **FUNDING DECISIONS:** For use in making funding decisions after Peer Review, the **Rating, Rank, Committee Recommendations on Budget and Term** will be made available, upon your consent to:

- Institute Staff and Institute Advisory Board Members;
- Funding Partners and /or Potential Funding Partners;
- CIHR Senior Managers who manage research envelopes and sponsor Strategic Initiatives.

I do do not consent to the sharing of the information specified above in sections (2) and (3) with the groups described.

I, the undersigned, do hereby give CONSENT to the use and disclosure of the information contained in my application for the purposes as herein described. This consent extends only to those specific areas where I have indicated this consent. I also understand that I may withdraw my consent at any time and that it will become effective upon its receipt by CIHR.

Name	Signature	Date
------	-----------	------

- 1) **Keep a copy for yourself**
- 2) **Send the original, signed form with your application**



Application Number

RESEARCH MODULE

Research funding program(s)	CIHR	Rx&D	SME	Salary Support	CIHR	Rx&D	SME		
Operating	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	New Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Randomized Controlled Trials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Research Resource Grant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Senior Investigator	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
CIHR Team Grant*	<input type="checkbox"/>			Senior Research Fellowship (Phase 2)	<input type="checkbox"/>				
Emerging Team Grant*	<input type="checkbox"/>			Clinician Scientist (Phase 2)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> New	<input type="checkbox"/> Renewal
New <input type="checkbox"/> Renewal <input type="checkbox"/>				Research Chair		<input type="checkbox"/>	<input type="checkbox"/>		

Funding Reference Number (FRN):

* A letter of intent to CIHR must precede submission to these programs.

Competition Date:

Proposed Start Date (MM/YYYY) | (Salary Programs Only)

Nominated Principal Applicant / Candidate

Surname

Given Names

Project Title:

Primary location where research will be conducted

Department

Faculty

Is this a multi-center study?

Yes

No

Institution which will administer project funds (Institution Paid)

CERTIFICATION REQUIREMENTS

If this research will involve any of the following, check the box(es). If the grant is awarded, the necessary certification requirements must be met in accordance with policies on ethical conduct of research.

Human subjects Human stem cells Animals Biohazards Environmental assessment

A requirement for containment Level 1 2 3 4

Does this application include a Randomized, Controlled Trial? Yes No

* Failure to disclose that your application contains a Randomized Controlled Trial will result in the application being withdrawn from the competition.

Period of support requested: (For Grants only)

Years

Months

Language in which proposal is written

English

French

Amount Requested from CIHR in First Full Year (For Grants only)

Operating

Equipment

Total requested

It is agreed that the general conditions governing Grants and Awards, as well as the statement "Meaning of Signatures on Application Forms" as outlined in the Canadian Institutes of Health Research Guides apply to any grant or award made pursuant to this application and are hereby accepted by the applicant(s) and the applicant(s)' employing Institution(s).

The nominating institution recommends this candidate for the salary support award and undertakes (1) to provide adequate accommodation and research facilities, (2) to provide the candidate with an appointment which allows him/her the time to pursue the proposed research (a faculty appointment for those working in a University or affiliated Institution) and freedom to publish the results of the research in the public domain.

Signature of President or Principal of Institution	Signature of Head of Department	Signature of Dean of Faculty or Director of Institution
Print Name:	Print Name:	Print Name:
Date:	Date:	Date:

Name of Nominated Principal Applicant/ Candidate and Primary location of Research	Total Grant Amount Requested from CIHR (1 st year)
---	---

Signatures

List all applicants in the following order: Nominated Principal Applicant / Candidate, Principal Applicants and Co-Applicants. Print additional pages if necessary.

It is agreed that the general conditions governing Grants and Awards, as well as the statement "Meaning of Signatures on Application Forms" as outlined in the Canadian Institutes of Health Research Guides apply to any grant or award made pursuant to this application and are hereby accepted by the applicant(s).

Name	Given Names	Role	Signature
Institution	Department	Faculty	Date
Name	Given Names	Role	Signature
Institution	Department	Faculty	Date
Name	Given Names	Role	Signature
Institution	Department	Faculty	Date
Name	Given Names	Role	Signature
Institution	Department	Faculty	Date
Name	Given Names	Role	Signature
Institution	Department	Faculty	Date
Name	Given Names	Role	Signature
Institution	Department	Faculty	Date
Name	Given Names	Role	Signature
Institution	Department	Faculty	Date

APPLICANTS' ORGANIZATIONS AND/OR SUPPORTING ORGANIZATIONS (if organization different from Page 1)

An authorized official from each institution other than the Institution Paid must sign this page. Additional Signature Pages will be accepted.

It is agreed that the general conditions governing grants and awards in the Grants and Awards Guides, as well as the statement "Meaning of Signatures on Application Forms?" apply to any grant or award made pursuant to this application and are hereby accepted by the organization.

Family name and given name of signing officer, title of position, and name of organization	Signature



Canadian Institutes
of Health Research

Instituts de recherche
en santé du Canada

ACKNOWLEDGEMENT TO THE INDUSTRIAL PARTNER (if applicable)

This will acknowledge receipt of the application of

Acknowledgement to be sent to the company contact person (Give name and mailing address)

Program Applied to:

Canadian Institutes of Health Research



Canadian Institutes
of Health Research

Instituts de recherche
en santé du Canada

ACKNOWLEDGEMENT TO THE NOMINATED PRINCIPAL APPLICANT OR CANDIDATE

This will acknowledge receipt of your application.

Acknowledgement to be sent to:
(Give name and mailing address)

Program Applied to:

Total amount requested (1st year - Grants only):

Canadian Institutes of Health Research

Please note: You are required to inform CIHR of any applications submitted, or funds received, to support this research during the review period of this application.

Name of Nominated Principal Applicant / Candidate and Primary location of Research	Total Grant Amount Requested from CIHR (1 st year)
--	--

Telephone No.	Fax No.	E-mail address
---------------	---------	----------------

Location where research will be conducted

Lay title of research (two lines only)

Principal Applicant(s) and Co-Applicants

Abstract (suitable for preparation of a press release)

Sample

Name of Nominated Principal Applicant / Candidate and Primary location of Research	Total Grant Amount Requested from CIHR (1 st year)
--	---

Information Page to be completed by Nominated Principal Applicant / Candidate: FOR ADMINISTRATIVE USE ONLY

Suggested External Referee(s) (All Grants and Awards) Names / Addresses / Telephone No's. / E-mails	Areas of Expertise
1.	
2.	
3.	
4.	
5.	
6.	

Nominations for Future CIHR Committee Member(s) (All Grants and Awards)

Give name and Institution of a scientist in your field you would like to see on a future CIHR committee. Include his / her areas of expertise and proposed committee.

Name	Institution	Proposed Committee	Areas of Expertise
1.			
2.			
3.			

Name of Nominated Principal Applicant / Candidate and Primary location of Research	Total Grant Amount Requested from CIHR (1 st year)
--	---

Information Page to be completed by Nominated Principal Applicant / Candidate: FOR ADMINISTRATIVE USE ONLY

If necessary, indicate those reviewers to whom you would prefer that the application NOT be sent. (Provide addresses)

Descriptors:

Provide keywords to describe the research project, the techniques and the methodologies to be employed, and the diseases or conditions the research addresses. No additional pages may be added.

List Collaborators. (For purposes of avoiding conflict of interest during reviewer assignment)

Surname	Given Name	Institution
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Degrees / Appointment (Salary Support Programs Only):

Degrees Held: PhD MD MD/PhD Other (specify) _____

As of this competition deadline, for how long will the Principal Applicant / Candidate have held an appointment as an independent investigator?

- Less than 24 months 24 months, but less than 60
 60 months, but less than 10 years 10 years or more

Name of Nominated Principal Applicant / Candidate and Primary location of Research	Total Grant Amount Requested from CIHR (1 st year)
--	---

Information Page to be completed by Nominated Principal Applicant/ Candidate: FOR ADMINISTRATIVE USE ONLY

The information on this page will not be used in the evaluation of the application.

- Strategic Initiative/RFA _____
- Industrial Partner(s) _____
- Partnership Program _____
- Special Program _____

Priority Announcements

Priority Announcements are listed on the CIHR web site in June and December each year together with CIHR's other current funding opportunities. **Before proceeding**, consult the "How to Apply" section(s) of the Priority Announcement(s) through which you are requesting funding, and determine if the completion of the Relevance Form is required. **If completion of the Relevance Form is not required, do not select the checkbox or complete the text boxes below.**

When completion of the Relevance Form is required, enter the relevant research area(s) and corresponding Priority Announcement titles below. Up to three relevant research areas may be entered per application to a regular competition.

- Priority Announcement

Title of Priority Announcement:

Relevant Research Area
(Listed in the "Relevant Research Areas" section of the Priority Announcements):

1.	
2.	
3.	

Is this application a resubmission of a previously

unsuccessful new application Yes No

unsuccessful renewal application Yes No

Funding Reference Number of current CIHR Grant (if applicable) _____

Areas of Research and Classification Codes

Areas of Research	Primary:
	Secondary:
Classification Codes	Primary:
	Secondary:

Suggested CIHR Institute(s)

Select a primary CIHR Institute whose research mandate is related to this application's research area(s) and objective(s). A second, third and fourth CIHR Institute should be indicated only if the substance of this grant application significantly overlaps with the research mandate of additional Institute(s).

Primary Choice:	Third Choice:
Second Choice:	Fourth Choice:

Themes

Indicate a primary theme classification. Indicate a second, third and fourth theme classification only where the substance of this grant / award application significantly overlaps more than one theme.

- Biomedical Research
- Clinical Research
- Research respecting health systems and health services
- Research on societal, cultural and environmental influences on health and the health of populations

How to prepare and format all attachments:

Attached documents may be prepared in the word processing software package of your choice, printed and included with the application form. Please follow these guidelines for formatting each page of an attachment. Failure to follow these guidelines may result in the administrative withdrawal of your application.

- At the top of each page, indicate your name, the project title, the amount requested in year 1 and the section title (e.g. Summary of Research Proposal).
- At the bottom of each page clearly indicate the page number (e.g., 9, 10, 11a, 11b etc).
- Type on one side of the paper only.
- A minimum margin of 2 cm (3/4 inch) around the page is mandatory.
- Observe page limitations, additional pages may NOT be added unless specified.
- Use only letter size (21.25 X 27.5 cm / 8.5" X 11") white paper for all attachments.
- Supporting documents should be photo reduced if the originals are larger than (21.25 X 27.5 cm / 8.5" X 11").
- No supplementary audio or video material will be accepted.
- A font size of 12 point, black ink. Six lines per inch. No condensed type or spacing.
- Photocopies must be single-sided.

Summary of research proposal - Attach one page numbered Page 9

New Investigator, Clinician Scientist candidates and grant applicants should summarize the objective(s), hypothesis and research plan. New Investigator and Clinician Scientist candidates should provide a clear concise description of their research proposal. A maximum of one page may be used. Investigator and Senior Investigator candidates should summarize their 5 year plan.

Summary of progress - Attach one page numbered Page 10 (not required for registration)

Do not include references, tables, charts, figures or photographs. For renewal applicants, summarize progress under the current grant and, if applicable, identify the term of your current MRC/CIHR grant. New applicants are encouraged to summarize previous work relevant to this application. New Investigator, Senior Research Fellowship and Clinician Scientist candidates should describe the research undertaken as a trainee, and, if applicable, as an independent investigator. In addition, these candidates should address their research relationship with previous supervisor(s). For Investigator and Senior Investigator and Industry-partnered Research Chair candidates, describe the research you have been engaged in over the last five years and the results obtained.

Response to previous reviews - Attach up to two pages numbered Page 11a and 11b (not required for registration)

If applicable, applicants may respond to previous reviewers comments if this is a resubmission of an unsuccessful application. The response should stand alone, and should not require reference to any other document because the reviewers do not have access to previous application information.

Research proposal numbered Page 12a, 12b, 12c etc (not required for registration)

General Instructions for Grant and Salary Program Applicants

The research proposal should be clear and concise. Page limits do not include references, tables, charts, figures and photographs. Legends should be succinct. Detailed descriptions of methods and discussion of results should be included in the body of the proposal. They should not be in the legends nor included as an appendix. Questionnaires and consent forms may be attached as appendices, where applicable.

In the research proposal applicants must explain:

- a. What they want to do (central hypothesis, research question, specific objectives)
- b. Why this is a reasonable thing to do (review of previous work done on the subject matter, rationale)
- c. Why this is important (new knowledge to be obtained, improvements to health which will result)
- d. How they are going to do it (work plan, timelines, analysis and interpretation of results, pitfalls, ways around the pitfalls, alternatives)
- e. Why **they** should do it (relevant prior experience and skills, collaborators for technical gaps, preliminary data showing feasibility)

Instructions for specific funding opportunities

1. Grant Programs - Provide a clear, concise description of your research proposal. A maximum of 11 pages may be attached in the case of one or two applicants. A maximum of 13 pages may be attached if there are three or more applicants. Apply for equipment/maintenance funds using the Operating Budget Module within the Operating Grants application, if applicable.

2. CIHR Randomized Controlled Trials Program - The page limit is 13 regardless of the number of applicants.

3. Clinician Scientist (Phase 2), and the Clinician Scientist (Phase 2) – Industry partnered programs - Provide a clear concise description of your research proposal. A maximum of 11 pages may be used.

4. New Investigator program - Provide a clear concise description of your research proposal. If you will not be holding peer reviewed operating funds as of the first potential start date of the award (and six months beyond), the New Investigator application must be submitted simultaneously with an operating grant application, and the same research proposal must be included in both applications. If you will be holding peer reviewed operating funds as a Principal Investigator, a description of any ongoing (one only), funded project may be included as the research proposal in the New Investigator application. A maximum of 11 pages may be attached in the case where the funded project had one or two applicants or 13 pages in the case of three or more applicants. Signatures of any co-applicants must also be included on page 2 of the New Investigator submission.

5. Investigator and Research Chair Programs - Industry Partnered Describe your program of research for the next five years. A maximum of six pages may be attached.

6. New Investigator Program of Research - attach up to one page, numbered Page 13 (for New Investigator applicants only - not required for registration) - Attach a clear, concise description of how the project described in the Research Proposal section of the application fits within the applicant's planned program of research for the next five (5) years.

Name of Nominated Principal Applicant / Candidate and Primary location of Research	Total Grant Amount Requested from CIHR (1 st year)
--	---

APPENDIX 1 – Attachments for Research Funding Programs only

1. Letters of collaboration and support.
 - a) Letters of collaboration:
Nominated principal applicants who propose research projects in which there will be a significant contribution from collaborators should include with their application a signed statement from each collaborator confirming his or her willingness to participate in the manner indicated.
 - b) Letter(s) of support:
In the case of a pending appointment, the Dean of the Faculty should send a letter indicating the date the appointment is expected to take effect. Letters of support may be appended when specific incremental cash or in-kind contributions are being provided in support of the proposed research. Letters in general support for the research, the researcher or the research team should not be appended and may be removed.
2. Questionnaires and consent forms may be attached as appendices when applicable.
3. Up to five publications from the past five years, relevant to this proposal, may be appended.

List the names of the individuals providing letters as described in Appendix 1 – Letters of collaboration and support.

Name	Position Held	Institution	Support	Collaborator
Sample				

Name of Nominated Principal Applicant / Candidate and Primary location of Research

Total Grant Amount Requested from CIHR
(1st year)

APPENDIX 2 – FOR SALARY SUPPORT PROGRAMS ONLY

ATTACHMENTS REQUIRED

For the program to which you are applying, append the following documents:

NOTE: Sponsor's letters must be provided in an envelope, sealed at the source and preferably included with the application.

New Investigators

- 1. Three sponsors' letters
- 2. Letter from Dean of Faculty or Director of Research
- 3. Appendix 2(A)

Investigators

- 1. Three sponsors' letters *
- 2. Letter from Dean of Faculty or Director of Research
- 3. Appendix 2(A) - Parts 1 and 2

* One of these letters must be from an individual outside the candidates' current department and outside the department where the award will be held. Another should be from an individual with whom the candidate has never collaborated or from an individual outside of Canada.

Senior Investigators and Industry-partnered Research Chairs

- 1. Three sponsors' letters **
- 2. Letter from Dean of Faculty or Director of Research
- 3. Appendix 2(A) - Parts 1 and 2

** All three of these letters must be from international experts in the candidates' field of research. At least two of these should be from individuals outside Canada.

Clinician Scientists (Phase 2)

- 1. Three sponsors' letters
- 2. Sponsor letter from research mentor***
- 3. Letter from Dean of Faculty
- 4. Appendix 2(A)

*** If a research mentor has been identified, he or she should provide a letter of support describing his or her knowledge of the candidate and any plans to help the candidate establish a career as an independent investigator.

List the names of individuals providing letters

Name of Nominated Principal Applicant / Candidate and Primary location of Research

Total Grant Amount Requested from CIHR
(1st year)

APPENDIX 2(A) ATTACHMENTS REQUIRED FOR SALARY SUPPORT PROGRAMS ONLY TO BE COMPLETED BY THE HEAD OF THE DEPARTMENT

Part 1. OTHER RESPONSIBILITIES OF THE CANDIDATE (Attach one page)

Indicate the nature and the extent (hours per year and percentage of time) of non-research activities in which the candidate would be required to engage as follows:

- a) **Teaching (excluding graduate student supervision)**
- b) **Clinical work**
- c) **Administrative duties**
- d) **Corporate involvement (involvement on boards or advisory committees)**

Part 2. RESEARCH INTERACTIONS (Attach one page)

On a separate page, indicate the colleagues and research programs the candidate would be associated with and the nature of this association emphasizing the potential contributions of the candidate. For Clinician Scientist (Phase 2) candidates, indicate the measures to be taken to enhance the candidate's clinical and research activities and the manner in which the candidate will fit into the ongoing research effort at the institution.

Part 3. COMMITMENT (Attach one page)

Required for New Investigators, Clinician Scientist (Phase 2) and Senior Research Fellowships (Phase 2) candidates only. CIHR expects that the nominating institution will offer successful candidates a full-time faculty, or equivalent position. Indicate clearly the research buildings and facilities available to the candidate, as well as any start up funds to be given. In addition, describe the institution's commitment to protect the candidate's research time.

Head of Department (please print name)	Signature from Head of Department	Date
--	-----------------------------------	------

Randomized Controlled Trials (RCT) Outline Checklist

Complete and forward this sheet with your outline package.

NOTE: The outline package must be assembled in the order listed below.

The original application and 8 copies should be assembled and submitted to the address indicated below. **Confirmation of receipt will include an application number and will be sent to each applicant normally 2 weeks after receipt of the outline.**

Name of Nominated Principal Applicant _____ **Date** _____

A: Contents required for Outline Package	
Research Module:	
<input type="checkbox"/> Routing Slip	Mandatory for all programs that require registration.
<input type="checkbox"/> Applicant Consent Form	Completion and signatures requires
<input type="checkbox"/> Page 1	No signatures required.
<input type="checkbox"/> Page 2	Signatures Page: Nominated Principal Applicant signature and names only of the Principal Applicants and Co-Applicants.
<input type="checkbox"/> Page 3	Acknowledgement Page.
<input type="checkbox"/> Page 5	Suggested External Referee(s).
<input type="checkbox"/> Page 6	Descriptors and List of Collaborators.
<input type="checkbox"/> Page 7	Information Page.
<input type="checkbox"/> Page 9	Summary of research proposal. (Attachment)
<input type="checkbox"/> Page 11 (a,b)	Response to previous reviews. (Attachment)
<input type="checkbox"/> Page 12 (a,b,c...m)	Research proposal. (Attachment)
<input type="checkbox"/> Operating Budget Module: (For Industry-Partnered Outlines only)	
<input type="checkbox"/> Partnership & Industry Module: (For Industry-Partnered Outlines only)	
<input type="checkbox"/> Common CV: All pages of the CV are required for the Nominated Principal Applicant, Principal Applicant and Co-Applicants. Only the Nominated Principal Applicant's signature is required.	

Courier address:

The outline must be courier stamped no later than the deadline date and sent to the following address:

Canadian Institutes of Health Research
 Randomized Controlled Trials Unit
 Room 97, 160 Elgin Street
 Address locator: 4809A
 Ottawa, ON K1A 0W9