# 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 s	supplied in the	application	except the	pages labe	elled "for	Administr	ative use	only" \	vill be	made
available, with you	ur 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



Canadian Institutes of Health Research

Instituts de recherche en santé du Canada

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Application	Number
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	Application Number							
			RESE	ARCH MODULE				
Research funding program(s)	CIHR	Rx&D	SME	Salary Support	CIHR	Rx&D	SME	
Operating				New Investigator				
Randomized Controlled Trials				Investigator				
Research Resource Grant				Senior Investigator				
Team Grant*				Senior Research Fellowship (Phase 2)				
Emerging Team Grant*				Clinician Scientist (Phase 2)			□ □ New	☐ Renewal
New ☐ Renewal ☐				Research Chair				
Funding Reference Number (FRN)	:							
* A letter of intent to CIHR must pre	ecede submi	ssion to the	ese progran	ns.				
Competition Date:				Proposed Start Date	(MM/YYYY	)   (Salary Pro	grams Only)	
Nominated Principal Applica	nt / Candid	late						
Surname				Given Names				
Project Title:								
Primary location where research w	ill be conduc	ted		Department		Facult	ty	
Is this a multi-center study?				☐ Yes ☐	□No			
Institution which will administer project funds (Institution Paid)								
CERTIFICATION REQUIREMS If this research will involve any of the accordance with policies on ethical	ne following,	check the esearch.	box(es). If	the grant is awarded, th	he necessa	ry certification	requirements must b	e met in
☐ Human subjects	☐ Human s	tem cells	☐ Anima	als	Biohaz	ards	☐ Environmenta	l assessment
A requirement for containment	☐ Level		□ 1	□ 2	□ 3		□ 4	
Does this application include a Rar	ndomized, Co	ontrolled Tr	rial?	Yes 🗌 No				
Period of support requested: (For C	Grants only)			☐ Years	☐ Months	3		
Language in which proposal is writ	ten			☐ English	☐ French	1		
Amount Requested from CIH	R in First F	ull Year	(For Gran	nts only)				
Operating			Equipm	nent		Total requ	ıested	
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 d of Department		Signature o	of Dean of Faculty of Institution	or Director	
Print Name:		Print N	Print Name:			Print Name:		
Date:		Date:				Date:		

Canada

lame of Nominated Principal Applicant/ Candidate and Primary location of Research  Total Gr (1st year			Total Grant Amount Requested from CIHR (1 <sup>st</sup> year)
Signatures List all applicants in the following or necessary.	der: Nominated Principal Applicant	/ Candidate, Principal Applicants	s and Co-Applicants. Print additional pages if
It is agreed that the general condition			ng of Signatures on Application Forms" as ant to this application and are hereby accepted by
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' ORGANIZATIO An authorized official from each ins	titution other than the Institution Pai	d must sign this page. Additiona	l Signature Pages will be accepted.
on Application Forms?" apply to any			as well as the statement "Meaning of Signatures accepted by the organization.
	nily name and given name of signing itle of position, and name of organiz		Signature

Canadian Institutes 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 en santé du Canada	
ACKNOWLEDGEMENT TO THE NOMINATED PRINCIPAL APPLICANT O	DR CANDIDATE
This will acknowledge receipt of your application.	Program Applied to:
Acknowledgement to be sent to: (Give name and mailing address)	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 (1st year)			
			(1 ) 50)			
Telephone No.	Fax No.	E-mail address				
Location where research will be conducted	ed					
Lay title of research (two lines only)						
Principal Applicant(s) and Co-Applicants						
Abstract (suitable for preparation of a press release)						

Name of Nominated Principal Applicant /	Total Grant Am (1 <sup>st</sup> year)	nount Requested from CIHR		
Information Page to be completed	by Nominated Principal Applic	cant / Candidate: FC	R ADMINISTR	RATIVE USE ONLY
Suggested Peer Review Committees:	(not applicable for Industry-Partner	ed or Group core appl	ications)	
1.				
2.				
Suggested External Referee(s) (A Names / Addresses / Telephone No's. / B	II Grants and Awards) E-mails		Areas of Exp	pertise
1.				
2.				
3.				
4.				
5.				
6.				
Nominations for Future CIHR Con Give name and Institution of a scientist in committee.	nmittee Member(s) (All Grants an your field you would like to see on a	ind Awards) future CIHR committee.	Include his / he	r areas of expertise and proposed
Name	Institution	Proposed Committee		Areas of Expertise
1.				
2.				
3.				

Name of Nominated Principal Applicant / Candidate	Total Grant Amount Requested from CIHR (1 <sup>st</sup> 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 se	ent. (Provide addresses)				
<b>Descriptors:</b> Provide keywords to describe the research project, addresses. No additional pages may be added.	the techniques and the methodologies to be emplo	yed, and the diseases or conditions the research				
List Callaborators /For numerous of sysi	diam conflict of interest during reviewer as	in month				
· · · · · ·	ding conflict of interest during reviewer ass					
Surname	Given Name	Institution				
1.						
2.						
_						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
Degrees / Appointment (Salary Support Pr	rograms Only):					
Degrees Held: PhD ☐	MD ☐ MD/PhD ☐ C	Other (specify)				
As of this competition deadline, for how long will th	e Principal Applicant / Candidate have held an appo					
-	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 <sup>st</sup> year)				
Information Page to be completed by Nominated Principal Applicant/ Candidate: FOR At The information on this page will not be used in the evaluation of the application.	DMINISTRATIVE USE ONLY				
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 toget <b>Before proceeding</b> , consult the "How to Apply" section(s) of the Priority Announcement(s) through the completion of the Relevance Form is required. <b>If completion of the Relevance Form is not the text boxes below</b> .	ugh which you are requesting funding, and determine if				
When completion of the Relevance Form is required, enter the relevant research area(s) and continuous three relevant research areas may be entered per application to a regular competition.	orresponding Priority Announcement titles below. Up to				
☐ Priority Announcement					
Title of Priority Announcement: (Listed in the	Relevant Research Area e "Relevant Research Areas" section of the Priority Announcements):				
1.					
2.					
3.					
Is this application a resubmission of a previously					
unsuccessful new application Yes No No					
unsuccessful renewal application Yes No No Grant Awarded?	Yes No FRN:				
If you are attempting to rejoin an ongoing group, provide name of Director:					
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	э:				
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.					
	earch on societal, cultural and environmental ences 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 <u>each</u> 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 (1st 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.

ist the names of the individual	Position Held	Institution	Support Support	Collaborator

Name of Nominated Principal Applicant / Candidate and Primary location of Research			Total Grant Amount Requested from CIHR (1st year)	
APF	PEND	IX 2 – FOR SALARY SUPPORT PROGRAMS ONLY		
For t	he pro	IENTS REQUIRED ogram to which you are applying, append the following documents: onsor's letters must be provided in an envelope, sealed at the source and preferably ir	ncluded with the application.	
New	Inves	stigators		
	1.	Three sponsors' letters		
	2.	Letter from Dean of Faculty or Director of Research		
	3.	Appendix 2(A)		
Inve	stigat	ors		
	1.	Three sponsors' letters *		
	2.	Letter from Dean of Faculty or Director of Research	Dean of Faculty or Director of Research	
	3.	Appendix 2(A) - Parts 1 and 2		
		ese letters must be from an individual outside the candidates' current department and bould be from an individual with whom the candidate has never collaborated or from an		
Seni	or Inv	restigators 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		
	three	of these letters must be from international experts in the candidates' field of research. nada.	At least two of these should be from individuals	
Clini	ician \$	Scientists (Phase 2)		
	1.	Three sponsors' letters		
	2.	Sponsor letter from research mentor***		
	3.	Letter from Dean of Faculty	<b>—</b>	
П	4	Annondix 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

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.

Name of Nominated Principal Applicant

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.

**Date** 

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