**Letter of Intent (LOI) Checklist for Applicants**

[ ]  Read the CTN’s *Study Submission and Review Process Guidance* document prior to completing the

Form

[ ]  Applicant is a CTN Investigator

[ ]  Primary source of funding identified, disclosed on the Form and copies of approval letters and reviews

 attached

[ ]  Open to multiple sites (or justification for single centre)

**Letter of Intent (LOI) Checklist for Core Leads**

[ ]  LOI Form is complete (submitting Investigator information, study proposal abstract)

[ ]  Core Co-lead has completed the Core Approval section of the Form

## Please indicate which CTN Services\* you anticipate that you will request in a Full Application:

If you are successful at the LOI stage, please indicate which of the following services you will need from the CTN to conduct your study:

[ ]  Protocol Development (for example, input from statistician/methodologist/data manager/

 Health Canada regulatory expert/project management when using the CTN protocol template)

[ ]  Database and/or Data Management

[ ]  Methodology

[ ]  Statistical Analysis [ ]  Automated Randomization

[ ]  Regulatory – Health Canada Clinical Trial Application (CTA) Consultation and/or Submission

[ ]  Monitoring – for Health Canada regulated trials only

[ ]  Project Management Assistance/Project Management

[ ]  Health Economics

[ ]  Data Safety Monitoring Committee (DSMC)

[ ]  Communications and Knowledge Translation

[ ]  Other (please specify):

\*Please consult the *Study Submission and Review Process Guidance*, Glossary of Terms for definitions of these services.

**Letter of Intent (LOI)** **Form**

## Core Approval – to be completed by a Core Co-lead only. The Core Co-leads will complete this section prior to submitting the completed LOI Form on behalf of the applicant.

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| --- |
| **Core Approval** |
| **Review by which Core**  | [ ]  CCM [ ]  CRC [ ]  PREV [ ]  VIT |
| **Name of Core Co-lead who reviewed this Form and approves the submission** |       |
| **Date of Core Co-lead Approval** | Day:       Month:       Year:       |

## CTN Investigator Information (Applicants to complete the following sections)

|  |  |
| --- | --- |
| **Name** |       |
| **Full Address** |       |
| **Email** |       | **Telephone** |       |
| **Assistant’s Email** |       | **Assistant’s Phone** |       |

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| **Type of study** |  [ ]  Clinical Trial: If Investigator- Initiated is it: [ ]  Grant-funded  [ ]  Industry-funded [ ]  Pilot Study [ ]  Implementation Science Project[ ]  Community-based Research [ ]  Other       | [ ]  Clinical Research Study[ ]  Cohort Study |

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| --- | --- | --- |
| **Study Information****(for Review Process)** |  [ ]  Is the project/study you are planning to submit to the CTN exactly the  same as the project approved by your primary funder?  [ ]  Yes  [ ]  No If No, please explain the changes:       |  |

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| --- | --- |
| **Funding Source****Your funding approval letter and reviews must be submitted with this Form** | [ ]  Confirmed source/agency:       - Type of Grant (e.g., Team, Project, Operating, etc.):      [ ]  Anticipated; date funds will be available:      Will you require CTN Services? [ ]  YesIf Yes, were funds for these services requested from your primary funder? Please indicate which services have full or partial funding?     [ ]  NoWill supplemental funds be requested from the CTN?[ ]  YesIf Yes, why are the funds necessary for the study?     [ ]  No |

|  |  |
| --- | --- |
| **Community Consultation** | Did you consult with the relevant community during study development?[ ]  Yes[ ]  NoIf Yes, what is the nature of community engagement?        If No, provide an explanation why:       |

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| --- | --- |
| **Recruitment Plan** | Have you developed a recruitment plan for your project?[ ]  Yes[ ]  NoA recruitment plan will be required for your Full Submission. |

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| --- | --- |
| **Project Title** |       |

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| --- | --- |
| **Background** |       |

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| --- | --- |
| **Objective(s)** |       |

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| --- | --- |
| **Methods** | [ ]  Randomized Controlled Trial[ ]  Cohort[ ]  Case-Control[ ]  Implementation Science[ ]  Community Based Research[ ]  Other (provide a detailed explanation)       |

|  |  |
| --- | --- |
| **Anticipated Results** |       |

|  |  |
| --- | --- |
| **Significance/Impact** |       |