**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.

|  |  |
| --- | --- |
| **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** |  |

|  |  |  |
| --- | --- | --- |
| **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 |

|  |  |  |
| --- | --- | --- |
| **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: |  |

|  |  |
| --- | --- |
| **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?  Yes  If Yes, were funds for these services requested from your primary funder? Please indicate which services have full or partial funding?    No  Will supplemental funds be requested from the CTN?  Yes  If Yes, why are the funds necessary for the study?    No |

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

|  |  |
| --- | --- |
| **Recruitment Plan** | Have you developed a recruitment plan for your project?  Yes  No  A recruitment plan will be required for your Full Submission. |

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

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

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

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

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

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