**Full Submission Checklist**

**Read the CTN’s *Study Submission and Review Process Guidance* document prior to completing your submission.**

**Your submission must include the following\* in the order listed below. If any of the following are not included, you must provide justification why in the relevant section of this Application Form:**

[ ]  Completed *CTN Application Form* (provided by the CTN)

[ ]  Completed *CTN Study Proposal Form* (provided by the CTN)

[ ]  The participant Informed Consent Form

[ ]  Completed *CTN Recruitment Plan* (provided by the CTN)

[ ]  Community Engagement Plan

[ ]  Completed *CTN Budget Template* (provided by the CTN)

[ ]  A copy of the full primary grant/funder application, including the budget and budget justification submitted to the granting agency/funder, along with all appendices, as well as a copy of the approval letter and all reviewer comments.

Supporting documents (only include if applicable):

[ ]  If a clinical trial, the Health Canada “No Objection Letter” (if received) and information about drug/device procurement from the vendor/manufacturer (e.g., a letter from a

 pharmaceutical company guaranteeing provision of a study drug, placebo, and investigational

labelling for the trial and/or a letter from the drug manufacturer that outlines the purchase price of the study drug, placebo, and investigational labelling for the trial).

[ ]  Any other documentation available that may be relevant for the review of your project. Examples could include documents such as case report forms, investigator’s brochures or product monographs, and letters of support from community groups or community advisory boards.

Questions? Contact submissions@hivnet.ubc.ca or 604-806-8340 OR contact the relevant Core Lead.

\* Applications submitted late or without the required documents listed above will be not be accepted for review.

**Full Submission Application Form**

(Double click on the check boxes below to enable the “check-box” function)

|  |  |
| --- | --- |
| **Type of submission** | [ ]  Final Submission[ ]  Re-submission[ ]  Pre-final Submission (*Use only if seeking feedback from CTN Review*  *Committees prior to considering submission of a Final Proposal. Pre-*  *final proposals are not approved as CTN studies until a Final Proposal or Re-submission is reviewed and approved.*) |

|  |  |
| --- | --- |
| **Have there been changes to the study since the LOI Registration?**  | [ ]  Yes - If yes, please provide a list of changes since the LOI registration here:[ ]  No |

|  |  |
| --- | --- |
| **Estimated start date of recruitment/study start date** |  (Mon/Year) |

|  |  |
| --- | --- |
| **Estimated final date** **of participant follow-up** |  (Mon/Year)[ ]  Not applicable for this project |

|  |  |
| --- | --- |
| **Estimated date of final study/project report** |  (Mon/Year) |

|  |  |
| --- | --- |
| **Funding Source &** **CTN National Centre Service/Support Request** | [ ]  Confirmed funding source/agency/company name:  List type of grant (e.g. CIHR Project Grant):  OR List type of agency/company support (e.g. Investigator-initiated grant  in aid from a pharmaceutical company):Did you receive the full funding you requested in your application?[ ]  Yes[ ]  No - If no, why and what funding was not provided? (List or provide a brief explanation here):Refer to the *Study Submission and Review Process Guidance* document before completing the following section as it provides key details regarding the services and/or funding that the CTN may provide.Will you require services from the CTN National Centre to conduct this study? [ ]  No[ ]  Yes - Justification for this request must be provided in the *CTN Study Proposal Form*. Were funds for the services requested from your primary funder? [ ]  Yes - If yes, list which services have full or partial funding here:[ ]  No - If no, why were funds for these services not requested in your primary funding application (e.g. CIHR does not provide funds for monitoring clinical trials)? Please provide an explanation here:Will supplemental funds be requested from the CTN?[ ]  No[ ]  Yes - If yes, justification for this request must be provided in the *CTN Study Proposal Form* |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **CTN National Centre Services Requested, check all that apply.**Refer to Glossary of Terms on pages 5 and 6 in the [*Study Submission and Review Process Guidance*](https://www.hivnet.ubc.ca/wp-content/uploads/2021/08/CTN-Submission-Review-Process-18AUG2021_FINAL.pdf) documentfor full descriptions of each service and when they may be requested. |

|  |  |
| --- | --- |
| [ ]  Protocol development [ ]  CTN National Centre project management for multi-centre studies |   |
| [ ]  CTN National Centre database [ ]  CTN National Centre data management |  |
| [ ]  Health economics  |  |
| [ ]  Statistical analysis [ ]  Methodology consultation |  |
| [ ]  Monitoring (clinical trials only) |  |
| [ ]  Data Safety Monitoring Committee (DSMC) |  |
| [ ]  National Regulatory Submission (Health Canada regulated trials or  trials regulated in/by other jurisdictions – e.g., FDA regulated) [ ]  Communications/Knowledge Translation |  |
|  |
| [ ]  Other (please describe):  |  |

 |

|  |  |
| --- | --- |
| **Participant Informed Consent Form attached?**  | [ ]  Yes [ ]  Not applicable - If not applicable, please explain why informed consent is not required for your study here:  |

|  |  |
| --- | --- |
| ***CTN Recruitment Plan* (use the CTN provided Form)** | [ ]  Completed *CTN Recruitment Plan* form appended.[ ]  Not applicable - If not applicable, please explain why here:  |

|  |  |
| --- | --- |
| **Community Engagement** | Did you consult with the relevant community during study development?[ ]  Yes – attach your Community Engagement Plan[ ]  No - If no, please explain why here:  |

|  |  |
| --- | --- |
| **Completed *CTN Budget Template* (use the CTN provided template) attached?** | [ ]  Yes [ ]  No - If no, please explain why here:  |

|  |  |
| --- | --- |
| **Is a Health Canada Clinical Trial Application (CTA) required?**  | [ ]  Yes - Please identify the submitting institution/ sponsor here: [ ]  No [ ]  Pending[ ]  Not sure - regulatory advice required |

|  |  |
| --- | --- |
| **Do you have a Data Safety and Monitoring Committee (DSMC**) **for your study?**The CTN’s DSMC is available to provide review for all CTN-approved interventional studies. Note: a DSMC is legally required for all regulated clinical trials.  | [ ]  Yes - Name of DSMC:[ ]  No[ ]  Not applicable for this type of project |

|  |  |
| --- | --- |
| **Has this trial been registered with Clinicaltrials.gov?** | [ ]  Yes[ ]  No[ ]  Not applicable for this project |

|  |  |
| --- | --- |
| **Have you secured the drug/biologic/interventional treatment supply for the study?** | [ ]  Yes [ ]  No[ ]  Not applicable for this project |

|  |  |
| --- | --- |
| **Signature(s) of Applicant(s)\*** | **Date (DDMMYYYY)** |
|  |         |
|  |        |
|  |        |

 **\* If applicable to this project, by signing, the applicant hereby declares that he/she has no financial**

 **interest(s) in the marketing of any of the drugs or agents in the study.**

Complete this form and append all of the forms/documents listed on the *Full Submission Checklist* (save as PDF documents), in the order listed *on the Checklist.*  Applications not saved as PDF documents, missing required forms/documents, not provided in the required order and not submittedon or before the competition deadline will not be accepted. Submit to submissions@hivnet.ubc.ca.