Clinical Trials Incubator Concept Submission Form

# **Administrative Details**

## Principal Investigator

|  |
| --- |
| Name: Click or tap here to enter text. |

|  |
| --- |
| Affiliated Institution: Click or tap here to enter text. |
|[ ]  Not Applicable |

|  |
| --- |
| Email Address: Click or tap here to enter text. |

## Co-Investigator(s)

Do you currently have any co-investigator(s) involved in your proposed trial?

|  |
| --- |
|[ ]  No |
|[ ]  Yes |
|  |  | Name(s) and institution(s) of your co-investigator(s): Click or tap here to enter text. |

## Trainee(s)

Do you currently have any trainee(s) that you anticipate being involved in your proposed trial?

|  |
| --- |
|[ ]  No |
|[ ]  Yes |
|  |  | Name(s) and institution(s) of your trainee(s): Click or tap here to enter text. |

## Person(s) With Lived Experience

Do you currently have any persons with lived experience (PWLE) involved?

*Note: It is a requirement of all ACCESS-supported projects that PWLE are involved from the outset of the project’s development.*

|  |
| --- |
|[ ]  No |
|[ ]  Yes |
|  |  | Name(s) of any PWLE involved: Click or tap here to enter text. |

## Collaborator(s)

Do you currently have any collaborator(s)/collaborating site(s) that you anticipate being involved in your proposed trial?

|  |
| --- |
|[ ]  No |
|[ ]  Yes |
|  |  | Name(s) and institution(s) of your collaborator(s): Click or tap here to enter text. |

## Potential Reviewer(s)

Do you have any suggestions for (a) potential reviewer(s)?

|  |
| --- |
|[ ]  No |
|[ ]  Yes |
|  |  | Name(s) and email address(es) of your suggested reviewer(s): Click or tap here to enter text. |

# **Proposed Clinical Trial Project**

## Proposed Project Details

Concept/Proposal Title

|  |
| --- |
|  Click or tap here to enter text. |

Lay Summary

*Note: Please keep this summary to 200 words or less.*

|  |
| --- |
| Click or tap here to enter text. |

Scientific Abstract

*Note: Please keep this abstract to 500 words or less.*

|  |
| --- |
| Click or tap here to enter text. |

What is the anticipated **trial** **phase** of your proposed trial?

*Select ALL that apply.*

|  |
| --- |
|[ ]  Unsure |
|[ ]  Pilot |
|[ ]  Phase I |
|[ ]  Phase II |
|[ ]  Phase III |
|[ ]  Phase IV |

What is the anticipated **allocation model** of your proposed trial?

*Select only ONE option.*

|  |
| --- |
|[ ]  Unsure |
|[ ]  Non-Randomized |
|[ ]  Randomized |
|[ ]  Other Allocation Method (specify): Click or tap here to enter text. |

What is the anticipated **intervention model** of your proposed trial?

*Select only ONE option.*

|  |
| --- |
|[ ]  Unsure |
|[ ]  Uncontrolled |
|[ ]  Parallel Arm |
|[ ]  Factorial |
|[ ]  Crossover |
|[ ]  Adaptive |
|[ ]  Other Intervention Model (specify): Click or tap here to enter text. |

List any anticipated **stratification variables** for your proposed trial (e.g., diagnosis dependent).

*Note: Please enter ‘Unsure’ if you have not yet considered this trial detail.*

|  |
| --- |
| Click or tap here to enter text. |

List the anticipated **eligibility criteria** for your proposed trial (e.g., all pediatric cancer patients, all patients between 0 – 29 years of age with ‘hard to cure’ cancers).

*Note: Please enter ‘Unsure’ if you have not yet considered this trial detail.*

|  |
| --- |
| Click or tap here to enter text. |

List the anticipated **clinical sites** for your proposed trial (e.g., single- vs. multi-centre; Canada only vs. multi-national project).

*Note: Please enter ‘Unsure’ if you have not yet considered this trial detail.*

|  |
| --- |
| Click or tap here to enter text. |

What is the anticipated **intervention** of your proposed trial?

*Select ALL that apply.*

|  |
| --- |
|[ ]  Unsure |
|[ ]  Commercially Available Drug (specify): Click or tap here to enter text. |
|[ ]  Investigational New Agent (IND) (specify): Click or tap here to enter text. |
|[ ]  Cellular/Immunotherapy (specify): Click or tap here to enter text. |
|[ ]  Radiotherapy/Targeted Radionuclide Therapy (specify): Click or tap here to enter text. |
|[ ]  Other (specify): Click or tap here to enter text.*(e.g., dietary/nutritional intervention, counseling intervention, imaging intervention)* |

What is the anticipated **comparator** of your proposed trial?

*Select ALL that apply.*

|  |
| --- |
|[ ]  Unsure |
|[ ]  Historical Data |
|[ ]  Commercially Available Drug (specify): Click or tap here to enter text. |
|[ ]  Investigational New Agent (IND) (specify): Click or tap here to enter text. |
|[ ]  Cellular/Immunotherapy (specify): Click or tap here to enter text. |
|[ ]  Radiotherapy/Targeted Radionuclide Therapy (specify): Click or tap here to enter text. |
|[ ]  Other (specify): Click or tap here to enter text. |
|[ ]  Not Applicable |

What is the anticipated **primary outcome/objective** of your proposed trial?

*Note: Please enter ‘Unsure’ if you have not yet considered this trial detail.*

|  |
| --- |
| Click or tap here to enter text. |

What is the anticipated **primary outcome measure** of your proposed trial?

*Note: Please enter ‘Unsure’ if you have not yet considered this trial detail.*

|  |
| --- |
| Click or tap here to enter text. |

What is the anticipated **follow-up duration and timeline** of your proposed trial?

*Note: Please enter ‘Unsure’ if you have not yet considered this trial detail.*

|  |
| --- |
| Click or tap here to enter text. |

What is the **estimated sample size** of your proposed trial?

*Note: Please enter ‘Unsure’ if you have not yet considered this trial detail.*

|  |
| --- |
| Click or tap here to enter text. |

## Proposed Project Status

What is the current status of the clinical trial project?

*Select only ONE option.*

|  |
| --- |
|[ ]  Unsure |
|[ ]  Early Concept *(i.e., no funding and/or industry commitment [if relevant] AND full proposal not yet developed)* |
|  | **Please submit along with this form an abbreviated research proposal (maximum three [3] pages excluding references).** ***Your submission will not be considered complete without this accompanying abbreviated research proposal.****Note: The abbreviated research proposal should include the trial rationale; aims; fit with ACCESS mandate; plans for PWLE involvement; and plans to embed equity, diversity and inclusion considerations within the trial’s design and conduct.* |
|  |  |
|[ ]  Protocol Development *(i.e., proposal developed with, at least, some funding and industry commitment [if relevant])* |
|  |  |  |
|  |  | Indicate the estimated budget for this trial: Click or tap here to enter text. |
|  |  |  |
|  |  | Has any **funding** been **received**? |
|  |  |  |[ ]  Unsure |
|  |  |  |[ ]  No |
|  |  |  |[ ]  Yes |
|  |  |  |  |  | Funder(s): | Click or tap here to enter text. |
|  |  |  |  |  | Funding Period(s): | Click or tap here to enter text. |
|  |  |  |  |  | Amount: | Click or tap here to enter text. |
|  |  |  |
|  |  | Has (have) the **intervention(s)** and **comparator(s)** been **procured** (if needed)? |
|  |  |  |[ ]  Unsure |
|  |  |  |[ ]  No |
|  |  |  |[ ]  Yes |
|  |  |  |[ ]  Not Applicable |
|  |  |  |
|  | **Please submit along with this form a research proposal (maximum five [5] pages excluding references and figures/tables).** ***Your submission will not be considered complete without this accompanying abbreviated research proposal.****Note: The research proposal should include the trial rationale; aims; statistical considerations; timeframe and feasibility; PWLE involvement; equity, diversity and inclusion considerations with respect to the trial’s design and conduct; and fit with ACCESS mandate.* |

Do you have any anticipated upcoming deadlines?

*Select only ONE option.*

|  |
| --- |
|[ ]  No |
|[ ]  Yes |
|  |  | Upcoming Deadline: Click or tap here to enter text. |
|  |  | Deadline Rationale (e.g., funding competition): Click or tap here to enter text. |
|  |  | Supporting Details (e.g., website): Click or tap here to enter text. |

What type of support do you require from the Clinical Trials Incubator (or do you believe would be of benefit)?

*Select ALL that apply.*

|  |
| --- |
|[ ]  Unsure |

***Early Concept Stage***

*Note: Please complete this section if you indicated that your proposed trial’s status is in the ‘Early Concept’ stage in the question above.*

|  |
| --- |
|[ ]  Early Methodological Elements |
|  |  |[ ]  Study Design |
|  |  |[ ]  Study Population |
|  |  |  |  |[ ]  Eligibility Criteria |  |  |
|  |  |  |  |[ ]  Other Study Population Consideration (specify): Click or tap here to enter text. |
|  |  |[ ]  Intervention(s) and/or Comparator(s) |
|  |  |[ ]  Outcome(s) and/or Outcome Measure(s) |
|  |  |[ ]  Study Assessments and Follow-Up |
|  |  |[ ]  Statistical Considerations |
|  |  |  |  |[ ]  Statistical Hypothesis |[ ]  Sample Size Determination |
|  |  |  |  |[ ]  Analysis Plan Overview |  |  |
|  |  |[ ]  Other Early Methodological Support (specify): Click or tap here to enter text. |
|  |  |
|[ ]  Trial Budget Development |
|  |  |
|[ ]  Funding Proposal Development/Finalization |
|  |  |[ ]  Proposal Preparation |
|  |  |[ ]  Proposal Budget Development |
|  |  |[ ]  Letter(s) of Support/Endorsement |
|  |  |[ ]  Other (specify): Click or tap here to enter text. |
|  |  |
|[ ]  Connection(s) with Industry |
|  |  |
|[ ]  Connection(s) with Relevant Stakeholders and Knowledge Users |
|  |  |
|[ ]  Other Support (specify): Click or tap here to enter text. |

***Protocol Development Stage***

*Note: Please complete this section if you indicated that your proposed trial’s status is in the ‘Protocol Development’ stage in the question above.*

|  |
| --- |
|[ ]  Methodological Elements |
|  |  |[ ]  Study Design |
|  |  |[ ]  Study Population |
|  |  |  |  |[ ]  Eligibility Criteria |[ ]  Sampling Process |
|  |  |  |  |[ ]  Study Setting and Recruitment |  |  |
|  |  |  |  |[ ]  Other Study Population Consideration (specify): Click or tap here to enter text. |
|  |  |[ ]  Intervention(s) and/or Comparator(s) |
|  |  |[ ]  Outcome(s) and/or Outcome Measure(s) |
|  |  |[ ]  Study Assessments and Follow-Up |
|  |  |[ ]  Minimization of Bias (e.g., Blinding, Outcomes Assessment) |
|  |  |[ ]  Statistical Considerations |
|  |  |  |  |[ ]  Statistical Hypothesis |[ ]  Sample Size Determination |
|  |  |  |  |[ ]  Analysis Plan (e.g., general statistical approach, analysis of primary and secondary endpoint(s), safety analyses, interim analysis, sub-group analyses, exploratory analyses). |
|  |  |[ ]  Other Methodological Element (specify): Click or tap here to enter text. |
|  |  |
|[ ]  Operational Elements |
|  |  |[ ]  Trial Governance |
|  |  |[ ]  Ethical and Regulatory Considerations |
|  |  |[ ]  Informed Consent and Assent Process |
|  |  |[ ]  Remote Access Considerations |
|  |  |[ ]  Safety Considerations |
|  |  |  |  |[ ]  Adverse Event Reporting |[ ]  Discontinuation of Intervention |
|  |  |  |  |[ ]  Participant Discontinuation/Withdrawal |[ ]  Protocol Deviations |
|  |  |  |  |[ ]  Safety Assessments |[ ]  Safety Oversight |
|  |  |  |  |[ ]  Unanticipated Problems |  |  |
|  |  |  |  |[ ]  Other (specify): Click or tap here to enter text. |
|  |  |[ ]  Data Collection |
|  |  |[ ]  Data Management |
|  |  |[ ]  Data Monitoring |
|  |  |[ ]  Quality Assurance and Quality Control |
|  |  |[ ]  Record Retention |
|  |  |[ ]  Future Use of Data and/or Stored Specimens |
|  |  |[ ]  Trial Discontinuation and Closure |
|  |  |[ ]  Knowledge Mobilization |
|  |  |[ ]  Other Operational Support (specify): Click or tap here to enter text. |
|  |  |
|[ ]  Trial Document Development/Finalization |
|  |  |[ ]  Trial Protocol |
|  |  |[ ]  Informed Consent and Assent Forms |
|  |  |[ ]  Case Report Forms |
|  |  |[ ]  Data Management Plan |
|  |  |[ ]  Monitoring Plan |
|  |  |[ ]  Pharmacy Manual |
|  |  |[ ]  Manual of Operating Procedures |
|  |  |[ ]  Other Trial Document (specify): Click or tap here to enter text. |
|  |  |
|[ ]  Connection with Industry (specify): Click or tap here to enter text. |
|  |  |
|[ ]  Connection(s) with Relevant Stakeholder(s) and Knowledge User(s) (specify): Click or tap here to enter text. |
|  |  |
|[ ]  Other Support (specify): Click or tap here to enter text. |

Please submit your completed form and accompanying research proposal to Tricia Schneider by **Monday, November 17** at **12PM ET**.