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](mailto:tricia.schneider@sickkids.ca?subject=Clinical%20Trials%20Incubator:%20Completed%20Submission%20Form%20+%20Research%20Proposal%20for%20Consideration) by **Monday, November 17** at **12PM ET**.