**\*Study Title**

One of the complexities in conducting a pediatric multi-centre clinical trial is the contracts/agreement process. It has been identified that having clear organization and consideration of all of the components of a clinical trial addressed up front would greatly facilitate a streamline the approval process and improve timelines. The intention of this study terms of reference checklist is to serve as a resource to ensure that appropriate contracts/agreements and parties are considered at the start of project development and that relevant stakeholders in this process all have a common understanding of the scope of the trial. Below is a description of the proposed multi-centre clinical trial.

**Brief Description of the Study: (1-2 paragraphs max)**

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| --- |
|  |

**Investigators and Site Location**

|  |  |
| --- | --- |
| **Sponsor Investigator** |  |
| **Contact Information** |  |
| **Site Location** |  |

|  |  |
| --- | --- |
| **Sub-Site Principal Investigator** |  |
| **Contact Information** |  |
| **Site Location** |  |

**\*For investigator initiated multi-centre studies, the sponsor investigator listed above should be the principal investigator from the lead site.**

**Funding:**

* How is the study being funded?
* Please describe the flow of funds (from lead site to sub-sites, from lead site to other sites/service providers as sub-grants)

**Data management during the study**

* How will data from multiple sites be managed? What systems will you use for data collection? Will data be collected centrally in a single database or will several databases/systems be deployed?
* Who is performing the data management (data validation/ monitoring) – for example, study sites, lead site, a central data coordinating centre?

**Safety monitoring during the study:**

* Is there a Data Safety Monitoring Board (DSMB)? If yes, please describe.
* Who is performing the study/site monitoring and quality assurance?

**Data transfer/sharing after the study:**

* Where will the study data be analyzed?
* Where will the data be transferred to after the study is complete?
* Will anonymized study data be shared with the sub-sites after analysis?
* Will anonymized study data be made available for potential secondary use after analysis/publication?
* Does your ICF contemplate data transfer/data sharing?

**Biological samples:** Are biological samples (e.g. blood, urine, endothelial cells, and fibroblast lines) being collected for this study? If yes:

* Which site will manage the biological samples?
* Please describe if biological samples will be de-identified and how they will be shared (if they are shared)
* How will costs associated with sample analysis be managed?
* Are biological samples mentioned in your ICF?

**Drug and placebo:** Are there drug/placebo involved in the study? If yes:

* Where is the study drug/placebo coming from?
* Where is the study drug/placebo going to?

**Publication:**

* What are the publication guidelines?
* Are there any stipulations or specifics around publication and review timelines?

**Intellectual Property:**

* Will there be IP or patent considerations?
* If yes, please specify.

**Other:**

* Will any of the sub-sites be located outside of Canada? (If yes, additional insurance and other requirements may be applicable)