**Clinical Trial Services**

**Intake Form**

The Clinical Trial Services (CTS) intake is a mandatory process for investigator-initiated regulated clinical trials for which Sunnybrook Research Institute is the regulatory sponsor. CTS is also available for services for non-regulated trials.

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| **STUDY TITLE** |  |
| **Date of Form Completion**  | YYYY-MMM-DD |

**Please complete the information below and submit to** **CTS@sunnybrook.ca****.**

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| **CONTACT INFORMATION** |
|  | **Name** | **Sunnybrook/SRI email** | **Contact Phone** |
| Principal Investigator |  | [ ] MD [ ] PhD [ ] PharmD[ ] Other: |  |  |
| Coordinator |  |  |  |
| Other:  |  |  |  |
| **STAGE OF THE STUDY** |
| [ ]  Study development (prior to grant submission and finalization/writing of study protocol) *Please attach draft protocol (if available) and any other supporting documents* |
| [ ]  Funding awarded  *Please attach protocol or grant application/proposal* | Amount awarded: Co-applicants (if applicable): Funding Source:  |
| **PARTICIPATING CENTRES** |
| [ ]  Single centre[ ]  Multi-centre  | Multi-centre |
| Total number of sites: International sites: No [ ]  Yes [ ]  🡪 If yes, number of international sites:       |
| List centres:  *If more than 5, please attach a list.* |
| Name | City | Country |
|  |  |  |
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|  |  |  |
| **STUDY DETAILS** |
| Study Population: |
| Has the sample size been calculated? No [ ]  Yes [ ]  | 🡪 If yes, estimated sample size:  |
| Study objectives:  |
| Study duration (accrual period plus follow up phase):  |

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| **INVESTIGATIONAL PRODUCT (IP) [ ]  Not Applicable (please continue to #7)** |
| **DRUG, BIOLOGIC, OR NATURAL HEALTH PRODUCT (if more than 1, list separately)** |
|  | **Type** | **DIN or NHP/DIN-HM #** | **Manufacturer** | **How will IP be obtained?**  | **Supply Source**  | **Use in the study** |
| 1 | [ ]  Drug[ ]  Biologic[ ]  Natural Health Product | #: | Name:Country:Importation? No [ ]  Yes [ ]  | [ ]  Purchased [ ]  Donated | [ ]  Manufacturer [ ]  Wholesaler [ ]  Commercial supply [ ]  Other:  | Dose: Schedule: Route: Study indication:  |
| 2 | [ ]  Drug[ ]  Biologic[ ]  Natural Health Product | #: | Name:Country:Importation? No [ ]  Yes [ ]  | [ ]  Purchased [ ]  Donated | [ ]  Manufacturer [ ]  Wholesaler [ ]  Commercial supply [ ]  Other:  | Dose: Schedule: Route: Study indication:  |
| 3 | [ ]  Drug[ ]  Biologic[ ]  Natural Health Product | #: | Name:Country:Importation? No [ ]  Yes [ ]  | [ ]  Purchased [ ]  Donated | [ ]  Manufacturer [ ]  Wholesaler [ ]  Commercial supply [ ]  Other:  | Dose: Schedule: Route: Study indication:  |
| 4 | [ ]  Drug[ ]  Biologic[ ]  Natural Health Product | #: | Name:Country:Importation? No [ ]  Yes [ ]  | [ ]  Purchased [ ]  Donated | [ ]  Manufacturer [ ]  Wholesaler [ ]  Commercial supply [ ]  Other:  | Dose: Schedule: Route: Study indication:  |
| **PLACEBO**  |
| Supply source: |

|  |
| --- |
| **DEVICE** |
| Name: |  |
| Manufacturer:  |  |
| License (if applicable):  |  |
| Class: |  |
| Study indication:  |  |
|  |  |
| **REDCap REQUIREMENTS** [ ]  Not applicable |
| Do you require randomization? No [ ]  Yes [ ]  | 🡪 If yes, please list the stratification details: |
| Because of validation requirements for regulated trials, CTS is responsible for programming of eCRFs. Are you requesting eCRFs for your trial? No [ ]  Yes [ ]  Unsure [ ]  | 🡪 If yes or unsure, please provide us a copy of your data collection forms and/or your data dictionary. |
| Will de-identified images or large files be uploaded into REDCap?No [ ]  Yes [ ]  Unsure [ ]  | 🡪 If yes , Estimated number of files:Estimated size of each file (please specify the unit): |
| Are you requesting to link REDCap to any other NON-CLINICAL system?No [ ]  Yes [ ]  Unsure [ ] *(Please note that REDCap cannot be linked to any clinical databases)* | 🡪 If yes , please provide details on what will be linked and how you will transfer the data: |
| How many data collections forms will be required for this project?Estimated number of variables/questions and sub-questions in each form:Will you require participant-administered questionnaires/forms?No [ ]  Yes [ ]  Unsure [ ]  |
| **IMPORTANT:** Direct identifiers, including but not limited to, name, address, phone number, email addresses, MRN, OHIP, etc., ARE NOT PERMITTED to be entered into REDCap. CTS regularly reviews REDCap and will inactivate any projects that include these fields. |
| **STUDY PERSONNEL** |
| Qualified Investigator (if different from Principal Investigator):  |  |
| Sub-investigators (Sunnybrook):  |  |
| Do you have research coordinators/assistants: No [ ]  Yes [ ]  |  |
| **ADDITIONAL INFORMATION** |
| Please provide any additional information or comments that should be considered in the assessment of your study. |

**For CTS use:**

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| Completed by: | Date (yyyy-mmm-dd): |
| Comments / Notes: |