Sunnybrook Specific Guidance Document – CTSI

Section	GUIDANCE	Sunnybrook Specific Instructions
	General Instructions: **All applicable fields should be completed prior to submitting this form to the appropriate Directorate.** This includes **complete dates (YYYY-MM-DD format) for Section 35 and Section 47**. In addition, the sponsor may also utilize their cover page to provide additional and relevant information related to specific sections of the form when submitting it to the relevant Directorate, if applicable. **For Pharmaceutical Drugs:** **The preferred format for receiving the CTSI form is electronically in Word, WordPerfect or unlocked PDF format via the clinical_trials_site@hc-sc.gc.ca email address.** Please note that passwords should be provided for encrypted/password protected files. However, completed forms may also be submitted via mail, courier or facsimile at the address or fax number for the Office of Clinical Trials as indicated on the first page of this document. **For Biologics and Radiopharmaceuticals:** Forms may be submitted via mail, courier, or facsimile at the address or fax number indicated on the first page of this document for the Biologics and Genetic Therapies Directorate.	
PART 1 – CLINICAL TRIAL PROTOCOL INFORMATION		
Type of Submission	Clinical Trial Site Information submitted to the relevant Directorate in support of a: • CTA (Clinical Trial Application) • CTA-A (Clinical Trial Application Amendment). Therefore, please check the appropriate box that reflects the type of submission. Note: A CTSI form must be submitted prior to initiation of a trial or implementation of an amendment at a site. This information may be submitted at the time of filing the CTA or CTA-A (if all information is available) or prior to commencement of the trial or amendment at a site. In the event that an amendment must be implemented prior to the approval due to safety reasons, the commencement date of the amendment should reflect the date the amendment was implemented at the site. To avoid any confusions during the data entry, a supplemental document should also be attached to the CTSI form justifying the situation. Please refer to the section C.05.008(4) of the Food and Drug Regulations for additional information." The word 'safety' can also be inserted in brackets next to the	

	date [eg: January 15th, 2008 (safety)]	
Reason(s) for Change	In situations where a revised form is submitted, please select all the relevant options. For the change of address, please specify if this was for the site, qualified investigator and/or research ethics board. For a change to the Qualified Investigator (QI), please specify the previous QI.	For Amendments: Select "other" and specify "amendment"
1	Specify the clinical trial protocol title.	Full title as per the protocol.
2	Specify the clinical trial protocol number.	This field must correspond to HC-SC 3011 Field 82 and QIU Field 2.
3	**For CTAs:** Specify the original/parent clinical trial control number, if assigned. Typically this is a 6-digit number. **For CTA-As:** Specify both the original/parent clinical trial control number, and the control number for the amendment (if assigned).	As indicated on the No Objection Letter (NOL) received from Health Canada
4	Specify the Health Canada Central Registry (CR) File Number, if assigned. Typically this is an alpha-numeric sequence that starts with "9427" and ends with the letter "C".	As indicated on the No Objection Letter (NOL) received from Health Canada

PART 2 – DRUG PRODUCT / SPONSOR INFORMATION		
	General Instructions: **Drug Product/Sponsor Information:** The information to be provided in Part 2 pertains to the sponsor in whose name the CTA is filed with Health Canada and must be consistent with the information provided in Part 1 of the HC/SC 3011 form (see: http://www.hc-sc.gc.ca/dhp-mps/prodpharma/applic-demande/form/hc3011_sc3011-eng.php), which also includes the information related to the drug product. **For CTAs and CTA-As**, sponsor is defined in Division 5, Part C of the *Food and Drug Regulations* as the individual, corporate body, institution or organization that conducts a clinical trial.	
Block A	**Drug Product Information**	
5	The **brand name** or proprietary name is the name assigned by the sponsor to distinguish the drug (product) and under which the drug is to be sold/advertised. This name should be consistent with the name provided in Part I, Section 8 of the HC/SC 3011 form. If the brand name has not yet been determined, the proper or common name of the drug or the research code may be used.	This field must correspond to HC-SC 3011 Field 8 and QIU Field 3.

6	The **proper name** for a product is the name assigned to the drug in Section C.01.002 of the *Food and Drug Regulations*, or in boldface type in other Sections of the *Regulations* or the name of the drug in its finished form identified in the title of a monograph or in any of the official publications listed in Schedule B to the *Food and Drugs Act*. Example: Ferrous Sulphate Tablets Immune Globulin Intravenous (human) The **common name** is the name by which a single ingredient drug is commonly known/designated in scientific or technical journals **other than** the publications referred to in Schedule B to the *Food and Drugs Act*. The common name includes the pharmaceutical form when used in relation to the finished drug product. If there is no proper name and the drug is comprised of a single medicinal ingredient, enter the common name. If there is no proper name and the drug is comprised of more than one medicinal ingredient, leave Section 6 blank. The proper/common name should be the same name that is indicated in Part 1, Section 9 of the HC/SC 3011 form.	This field must correspond to HC-SC 3011 Field 9 and QIU Field 4.
Block B	**Sponsor Information**	
7	Indicate the **full** name of the sponsor company in whose name the subject CTA or CTA-A is being filed.	This field must correspond to HC-SC 3011 Field 11 and QIU Field 5.
8-12	Provide the **full** mailing address of the sponsor identified in Section 7. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (8), the city/town (9), the province/state (10), the country (11) and the postal or zip code (12). Include the PO Box number (8) if a post office box is used.	
13-18	Provide the name of the principal contact person for the sponsor located at the address (8-12) for the sponsor, as identified in Section 7. This also includes the information needed to contact this individual, i.e., telephone and fax numbers (14-15), position/title (17), e-mail address (18) if applicable, and language preference (16). **Note in most cases this is either the regulatory affairs officer responsible for the CTA, but can also be the subject area expert (e.g. a qualified investigator/sponsor initiated trial).**	For Investigator-Initiated clinical trials at Sunnybrook, list the following: **Ms. Keitha McMurray** **Phone:** 416-480-6100, ext. 88120 **Fax:** 416-480-5385 **Language preferred:** English **Title:** Executive Director, Research Integrity and Clinical Research Operations **E-mail:** keitha.mcmurray@sunnybrook.ca *The CTSI is the only regulatory document that lists Keitha McMurray as the Contact for Sponsor, as this is for Inspection purposes.

Block C	**Contact for THIS clinical trial**	
19-29	Please complete this section ONLY when this contact is NOT the same as the Contact Person for the Sponsor (e.g. a third party acting on behalf of the Sponsor). Provide the full name of the contact (19), and company/organization name (21) to which the CTA or CTA-A contact belongs to (i.e., is a staff member of company "X"). If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (22), the city/town (23), the province/state (24), the country (25) and the postal or zip code (26). Include the PO Box number (22) if a post office box is used. Provide the e-mail address (20) and language preference (29).	The "contact for THIS clinical trial" should be the qualified investigator or the coordinator. This field must correspond to QIU Fields 11-20.
PART 3 – CLINICAL TRIAL SITE INFORMATION		
Block A	**Clinical Trial Site**	
30	Provide the name of the Clinical Trial Site in the format indicated on the form. This information should also provide the name of the group or unit, and subsequent affiliations, if applicable (e.g. Eye Clinic, University Hospital, and University of XYZ). A Clinical Trial Site is the address where significant trial related activities are actually conducted (e.g. administration of the investigational drug). **Note:** If the site is a private practice, use the Physician's name, or the name of the practice, corporation or partnership.	Sunnybrook Research Institute This field must correspond to QIU Field 21.
31-34	Provide the **full** mailing address of the clinical trial site identified in Section 30. If a street address is used, provide the suite/unit number (if applicable) in addition to the street name and street number (31), the city/town (32), the province/territory (33), and the postal code (34). Include the PO Box number (31) if a post office box is used.	The address where significant trial related activities are actually conducted. Include group/unit.
35	For the purposes of the Clinical Trial Site Information form the **date of commencement of the trial** is defined as the date when the **clinical trial site *is ready to enrol subjects***. For an Amendment, this would be the date when a site *is ready to implement the proposed changes*. **In either case, the commencement date is a date after which the sponsor has both the Health Canada authorization from the appropriate Directorate (date on the No Objection Letter (NOL)) AND approval from the relevant Research Ethics Board(s) (box 47 of the CTSI form).** In other words, the commencement date would be the date where the sponsor implements the protocol, which includes the screening period that occurs prior to the check-in date. Therefore, the check-in date would not be considered as the commencement date.	

	In situations where a clinical trial site becomes active after the sponsor submits an Amendment, the sponsor should specify this in Part 1 of the CTSI form. For example, when filing the CTA the sponsor originally has 4 sites, but following an Amendment, the sponsor wishes to add an additional site 5 to the trial. Furthermore, multiple sites may be identified by duplicating Part 3 as many times as necessary to capture all site addresses. These pages listing multiple clinical trial sites are attached to Parts 1 and 2, and the complete document should be paginated, e.g. 1 of 5, 2 of 5 etc. In the event that an amendment must be implemented prior to the approval due to safety reasons, the commencement date of the amendment should reflect the date the amendment was implemented at the site. To avoid any confusion during the data entry, a supplemental document should also be attached to the CTSI form justifying the situation. Please refer to the section C.05.008(4) of the Food and Drug Regulations for additional information." The word 'safety' can also be inserted in brackets next to the date [eg: January 15th, 2008 (safety)]	
Block B	**Qualified Investigator Contact Information**	
36	*Division 5* of Part C of the *Food* and *Drug Regulations* defines Qualified Investigator as: The person responsible to the sponsor for the conduct of the clinical trial at the clinical trial site, who is entitled to provide health care under the laws of the province where the clinical trial site is located and who is: (a) in the case of a clinical trials respecting a drug to be used for dental purposes only, a physician or dentist and a member in good standing of a professional medical or dental association; and (b) in any other case a physician and a member in good standing of a professional medical association. Provide the name of the Qualified Investigator conducting the clinical trial (36). Include their First and Surname as well as the Medical Designations. i.e. **John Doe, MD, FRCPC, etc**.	This field must correspond to QIU Field 26.
37	This is the title used pertaining to the clinical trial person conducting the trial.	This field must correspond to QIU Field 27 and be reflective of their role at Sunnybrook Health Sciences Centre/Sunnybrook Research Institute.
38	Indicate language preference of the person conducting the clinical trial.	This field must correspond to QIU Field 28.
39-42	Provide the **full** mailing address of the Qualified Investigator identified in Section 36. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (39), the city/town (40), the province/territory (41), and the postal code (42). Include the PO Box number (39) if a post office box is used. Provide language preference (38). **Note:** The address of the Qualified Investigator may be different than the address of the clinical trial site as identified in Sections 31-34.	These fields must correspond to QIU Fields 29-32.

43-45	Provide the information requested to contact the Qualified Investigator, i.e., telephone and fax numbers (44-45), and e-mail address (43) if applicable.	These fields must correspond to QIU Fields 33-35.
Block C	**Research Ethics Board**	
46	Provide the name of the Research Ethics Board (REB) providing approval of the protocol and informed consent forms for this clinical trial. Provide the affiliation, if applicable (e.g. University of "XYZ" or "New Province Health Sciences" Research Ethics Review Board etc.).	
47	See Notes pertaining to section 35 above. Please note that CTSI forms are only required for CTA and subsequent amendments (i.e. CTA-As). Changes to the ICF following the approval of a CTA that do not warrant a protocol amendment therefore do not require a CTSI Form. In situations where the approval for a protocol and ICF are given on separate days, the latter date should be considered the approval date. A clinical trial cannot commence until both the protocol and ICF have been approved.	Put **date of your final REB approval** (not the Provisional Study Approval date)
48-51	Provide the **full** mailing address of the Research Ethics Board contact identified in Section 52. If a street address is used, provide the suite/unit number (if applicable) in addition to the street and street number (48), the city/town (49), the province/state and country (50), and the postal or zip code (51). Include the PO Box number (48) if a post office box is used.	Street Number: 2075 Street Name: Bayview Avenue Suite: C8 19 City: Toronto Province: ON Postal Code: M4N 3M5
52-57	Provide the name of the Contact (52) for the Research Ethics Board (REB) as listed in Section 46. Provide the Salutation, First Name and Surname and the telephone number (53), facsimile number (54), Title (56) and Email address (57) for this contact.	Salutation: Dr. First Name: Brian Surname: Murray Telephone: 416-480-6100 x88144 Fax: 416-480-5385 Title: Chair, Research Ethics Board Email Address: brian.murray@sunnybrook.ca