Stream Tip Sheet: Clinical Trial Initial Application (CTIA) and Observational Study Initial Application (OSIA)

Below are recommendations for a successful submission of a new Stream study

Study-wide Informed Consent Form Template[1]

A study-wide consent form template is submitted to the REB of Record for review as part of the initial study-wide application called the Clinical Trial Initial Application or Observational Study Initial Application. When creating the study-wide ICF template(s) for your study, you **must use the correct ICF template**. This template has been accepted by the REB council and contains language and elements required by the participating site. Any study-wide ICF template which does not follow the correct ICF template format will be returned to the applicant for revisions.

Tips for creating the Study-Wide Template:

(1) **Follow the instructions included with the study-wide ICF template** and minimize changes to the template language while making sure that the information included is correct and applicable for your study. When adding study-specific details, aim to use plain (lay) language that is easy for a non-medical person to understand.

(2) The template includes **text with yellow highlighting** which reflect instructions for participating sites to follow when creating their site-specific ICF. This text, including the highlighting, should not be altered or removed from the ICF that is uploaded into the CTIA/OSIA.

(3) **Do not include site-specific wording** within the study-wide ICF template. This includes logos, site-specific requirements (these are addressed in the site-specific applications), Investigator names, etc.

(4) The following language **must** be included in the **confidentiality section**.

Authorized representatives of the following organizations may look at your original (identifiable) medical/clinical study records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- This institution and affiliated sites, to oversee the ethical conduct of research at this location

(5) The **confidentiality section** of the study-wide consent form(s) **must** include the following statement:

"Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study."

Creating and Accessing the CTIA/OSIA

A member of the lead research team (which can include the sponsor/CRO) will create the CTIA/OSIA; this individual becomes the "Project Owner". When the CTIA/OSIA is first created, only the Project Owner has access. Other members of the lead research team need to be given a Role on the study (entering a person's name/information on the form **does not** grant them access). Don't forget to assign Roles to the Lead Applicant and any other study staff who need access to your study at the study-wide level.

More information on roles and collaboration can be found in the **Managing Study Access with Roles** user manual.

The **Streamlined Research Ethics Review System (SRERS) Administration Form** contains details about a site's research administration processes, identifies the institution representative(s) and lists collaborators who must have access to the applications in Stream. You can download a copy of the form from the CTO website: https://www.ctontario.ca/cto-programs/streamlined-research-ethics-review/participating-sites/

Tip: Once the CTIA/OSIA has been created, the Participating Site Initial Applications (PSIAs) can be created at any time. More information on how to create a PSIA can be found in the **Creating a Participating Site Initial Application** quick guide.

CTIA/OSIA Content

Smart Forms

The application forms use smart questions, which means questions will appear or disappear based on other answers within the form. Don't worry if the questions are not numbered sequentially – this just means certain questions aren't applicable to your study. Mandatory questions are marked with an asterisk (*). Questions marked with an "i" icon contain help text.

Short Study Title

The Short Study Title (also called Project Title) is entered when the new project is created, but it can be revised later by updating the short study title question in section 1.0 of the CTIA/OSIA. This short study title is displayed for the list of projects in your Work Area.

Study Number/ID

The CTIA/OSIA requests the Study ID/Number if applicable. This number refers to a code or short identifier used by the lead researcher/lead research group/sponsor to identify the study. If included, this information will appear in REB letters. This information may be the same as the Short Study Title – if you'd like this to appear in the REB letters, please include in both spots.

Institutional Representatives

The name and contact information for the Institutional Representative(s) must be entered into the CTIA/OSIA. These individuals are identified by each institution and documented on the **SRERS Administration Form.**

Document Name, Version Date and Version

When uploading documents into the application, a pop-up window will appear. The user will browse their computer to select the file. The "Document Name" will automatically appear as the file name - this should be changed to reflect the name that should appear in the REB approval letter. Entering the Version Date and/or Version is optional. Please ensure the information entered in these fields while uploading reflects the information on the document.

The information entered into the Document Name, Version Date (if applicable) and Version (if applicable) fields will appear in the REB approval letters exactly as written in the application.

Requesting Signatures and Submitting the CTIA/OSIA

Once you have completed filling out the CTIA/OSIA, you must request a signature from the Lead Applicant in the Agreement & Approval section of the form. The application will automatically submit once the required signature has been applied to the form.

More information how to sign an application can be found in the **Signing Applications in Stream** user manual.