Stream Application Forms

Stream is a web-based ethics application system for multi-site research in Ontario and/or Canada.

In this guide you will find:

- Descriptions of the application forms found within Stream and information on when to use them
- Information on who is responsible for submitting the various types of forms
- Other helpful tips and reminders

Need Help?

- Click here for general information and an overview of the Streamlined Research Ethics Review System.
- Access Stream User Manuals, Quick Guides and Tip Sheets for instructions on everything from navigating Stream and creating application forms to finding REB approval letters and managing access to projects.
- Visit our Templates & Forms page to download the Informed Consent/Assent form templates and Word versions of the Stream application forms.
- Looking for REB submission deadlines and meeting dates? Each Qualified REB posts this information on their local website.
- Connect with the Stream Helpdesk by submitting a ticket at https://support.ctontario.ca/.

(STUDY-WIDE) APPLICATION FORMS		
The Lead Applicant / Lead Applicant team is responsible for submitting these forms. *Note: A Sponsor/CRO may choose to assist the Lead Applicant team in completing these forms, but they <u>cannot</u> sign-off or be listed as the Lead Applicant in the forms.*		
Form Type	**When to use it**	**Additional Notes and Tips**
Clinical Trial Initial Application (CTIA) / Observational Study Initial Application (OSIA)	Use this form to submit a new multi-site research project for ethics review through Stream	➢ Study-wide approved documents are approved for use at all sites who join through Stream. All sites have access to view the CTIA/OSIA and download the study-wide documents and the REB approval letters. ➢ Non-consent, participant materials approved at the study-wide level can be used by sites approved in Stream. This includes materials such as diaries, recruitment posters, wallet cards etc. ➢ Sites can make administrative changes to these study-wide approved documents. Administrative changes include the addition of site logos/letterhead, insertion of local PI and study team contact information. No additional REB submission is required when administrative changes are being made to these study-wide approved documents.
Study-Wide Amendment Form (SWAM)	Use this form when you need to submit an amendment or when you need to report changes in study-wide information or study documents to the REB of Record (REB). Examples: ☐ Changes to the protocol (including changes to sample size) ☐ Changes to biological specimen collection/use ☐ Changes to the consent/assent form(s, debriefing material(s) or other consent/assent materials ☐ Changes to informed consent/assent/debriefing process ☐ Changes to recruitment plan and/or materials ☐ Changes to other participant materials (such as study instruments/questionnaires, participant diaries, wallet cards, etc.)	➢ When a Study-Wide Amendment Form is approved or acknowledged by the REB, the approval/acknowledgement applies to <u>all</u> sites participating in the study through Stream. There is no need for individual sites to submit anything further to the REB EXCEPT when: a) the study-wide amendment involves a change to the study-wide consent template(s). See the reminder below. **OR** b) if the site needs to opt out the changes because they are not implementing the Study-Wide Amendment as approved by the REB. ➢ The lead study team can submit a single amendment form for multiple changes at once. For example, if you have a new Product Monograph to submit and wish to report a change in the Lead

Form Type	When to use it	Additional Notes and Tips
Study-Wide Amendment Form (SWAM) *continued*	☐ Updated/new Investigator Brochure (IB), Product Monograph (PM), or Instructions for Use (IFU) ☐ Translation of approved materials ☐ Change to the data collected and/or how it is accessed, collected, used, or stored ☐ Changes in study funding, participant remuneration, provision or access to product(s)/device(s), and/or financial pressure(s)/incentive(s) ☐ Change/updates relating to the communication of results ☐ Change in US regulatory information ☐ New information about rejection/disapproval of the study by another REB ☐ Change to study information (e.g., study title, study acronym/nickname/short name, sponsor's study ID) ☐ Change to current Lead Applicant ☐ Change to CONTACT DETAILS ONLY for the Lead Applicant ☐ Change to the Lead Administrative Contact, study sponsor, or CRO ☐ Other	Administrative Contact, you can report them both the same amendment form. ➢ Each site will receive a notification when the study-wide amendment is submitted and when it gets approved or acknowledged by the REB. These notifications are sent to study staff who have full access roles for the project in Stream. ➢ Each site has access to the study-wide amendment and is responsible for reviewing and implementing any changes, new documents etc., that are approved by the REB. ***REMINDERS*** **If the SWAM involves a change to the study-wide consent/assent template(s), each site must:** 1. Download the newly approved study-wide consent/assent form(s) from the approved SWAM. 2. Apply your site-specific changes (site letterhead, local PI info etc., inserting your Documented Institutional Ethics Requirements (DIER), if applicable. 3. Submit your revised consent/assent document(s) to the REB using the Participating Site Amendment (PSAM) for REB approval. (Note: Step 3 is not applicable to studies reviewed by OCREB).
Study-Wide Reportable Event (SWRE)	Use this form when you need to notify the REB of a study-wide reportable event. **Examples:** ☐ DSMB/C report ☐ Interim Analysis Results ☐ Unanticipated Problem ☐ Safety Notice/Update (e.g., Action Letter) ☐ Periodic External (non-local) AE/SUSAR Summary Report ☐ Single External (non-local) Adverse Event ☐ Other reportable event not described in these examples	➢ All sites will receive a notification whenever the LA submits a RE form and when the SRE form has been approved or acknowledged by the REB. ➢ Each site has access to the SWRE and is responsible for reviewing the form, documents and REB letters
Study-wide Continuing Review (SWCR)	Submit this form to maintain ongoing study-wide ethics approval for the study.	➢ The SWCR form must be submitted by the deadline for the full-board REB meeting that occurs prior to the ethics expiry date.

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Study-wide Continuing Review (SWCR) *continued*	***IMPORTANT *** **If the SWCR is not approved by the REB prior to the study expiry date, ethics approval with lapse for the entire study and all sites.**	Check the REB of Record's website for submission deadlines and meeting dates. ➢ Each site (including the LA's own site) must also submit their own Participating Site Continuing Review form in order maintain ethics approval for their site.
Study-Wide Closure (SWCL)	Submit this form to close out the ethics file in Stream when the study is complete and study-wide ethics approval is no longer required.	➢ Before the LA can submit the SWC form, all sites in Stream must have submitted their individual Participating Site Study Closure (PSCL) forms. Only after each site file has been closed in Stream can the SWCL form be submitted to close out the study in Stream. **Transferring the LA Role** In some instances, the LA may have completed the study at their own site and submitted their PSCR (i.e., closed their REB file) before the other sites have completed the study. When this happens, the LA may wish to transfer the LA responsibility to another site PI so they can take over the responsibilities for maintaining ongoing ethics approval in Stream. The LA will need to identify a PI from one of the other sites who can take on the role. The change in Lead Applicant can be reported by submitting a Study-Wide Amendment Form. The LA will also need to ensure study staff are assigned/re-assigned the correct Role to ensure appropriate access.

(SITE-SPECIFIC) APPLICATION FORMS		
The individual site PI/site PI's research team is responsible for submitting these forms. *Note: A Lead Applicant or Sponsor/CRO may choose to assist the sites in completing these forms, but they cannot sign-off or be listed as the Participating Site Principal Investigator in the application forms.*		
Form Type	**When to use it**	**Additional Notes and Tips**
Participating Site Initial Application (PSIA)	Use this form to join a study which has received study-wide ethics approval through Stream.	➢ The PSIA form is used to obtain ethics approval to conduct a study at the site. Each site joining through Stream must submit an PSIA form (including the Lead Applicant site). Note: The LA must submit a PSIA for their own site if they wish to obtain ethics approval to conduct the research at their own site. **Reminders:** ➢ Study-wide approved (non-consent) participant materials are approved for use by all sites who join through Stream. This includes diaries, recruitment posters, wallet cards etc. ➢ Sites can make administrative changes to these study-wide approved documents and use them without re-submitting them for REB approval. Administrative changes include the addition of site logos/letterhead, insertion of local PI and study team contact information.
Participating Site Amendment (PSAM)	Use this form when you need to submit an amendment or when you need to report changes in **local** (site-specific) information or study conduct to the REB. **Examples:** ☐ Site-specific change(s) to the consent/assent form(s) used at this site ☐ Change(s) in the informed consent/assent/debriefing process at this site ☐ Site-specific translation of approved material(s) ☐ Site-specific change(s) in recruitment methods and/or recruitment material(s) (e.g., telephone, web or email scripts, flyers, brochures, etc.) used at this site	**Reminders:** ➢ Sites do not have to seek REB approval to use study-wide approved, non-consent, participant materials when only administrative changes are being made to these documents. ➢ When a new/revised study-wide consent template is approved (i.e., through a Study-Wide Amendment), sites will use the PSAM form to obtain REB approval for their new site-specific consent form. **Note: Not applicable to studies reviewed by OCREB. Please consult the OCREB website for specific information on if/when a site consent form should be submitted for OCREB approval).**

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	☐ Change(s) to other site-specific material(s) that will be given to study participants (including surveys/questionnaires/scripts, diaries and wallet cards) ☐ Change(s) to how personal information or personal health information is being accessed, collected, used, stored or transferred at this site ☐ Change(s) in the conflict of interest information previously provided to the REB for any of the investigators, study staff or members of their immediate families ☐ Change(s) in participant remuneration and/or communication of study results ☐ Change(s) in site -specific study conduct (including location of visits/procedures, standard of care, and protocol implementation) ☐ Change in Principal Investigator ☐ Change(s) to CONTACT DETAILS ONLY details for the Principal Investigator ☐ Change to name and/or contact details for the Participating Site Administrative Contact ☐ Other changes	➢ Sites must ensure they are using the most recent approved study-wide materials as indicated on the relevant study-wide approval letters.
Participating Site Initial Reportable Event (PSRE)	Use this form when you need to notify the REB of a local (site-specific) reportable event. **Examples:** ☐ Local (internal) serious adverse event (SAE) ☐ Unanticipated Problem at the site ☐ Protocol deviation/violation ☐ Privacy breach ☐ Audit/Inspection report ☐ Study participant compliant ☐ Other reportable events not	
Participating Site Continuing Review (PSCR)	Submit this form to maintain ongoing ethics approval for your site.	➢ The PSCR form must be submitted by the deadline for the full-board REB meeting which occurs prior to the ethics expiry date. Check the REB of Record's website for submission deadlines and meeting dates.

Form Type	When to use it	Additional Notes and Tips
Participating Site Closure (PSCL)	Submit this form to close out the ethics file in Stream when you have completed the study and no longer need ethics approval at your local site.	