

CTO Stream Tip Sheet: Participating Site Initial Application (PSIA)

Here are a few recommendations to help submit your Participating Site Initial Application

Site-Specific Informed Consent Form (ICF)

Use the Study-wide approved ICF template(s) to create your site-specific consent form(s). Revisions should only include the following:

- Local administrative details (e.g., letterhead, local PI contact etc.)
- Replacing placeholders on the Study-wide template with site-specific details
- Addition of any institutional requirements listed on the Documented Institutional Ethics Requirements (DIER) Form for your site (if applicable) You can download a copy of the DIER Form (if your site has one) from the CTO website: <https://www.ctontario.ca/cto-programs/streamlined-research-ethics-review/participating-sites/>

Other tips:

- (1) Specific ICF wording (if required by the institution) is listed in the site's DIER Form. Please ensure that all applicable wording is included in the site-specific ICF. If you are assisting another site with their application, you can download or request a copy of their DIER Form from the CTO website (or we'll let you know if there is no DIER for that site).
- (2) The confidentiality section of the Study-wide approved ICF describes individuals/organizations that may have access to original medical and study records. This section will include the following statement which should not be removed or altered:
 - This institution and affiliated sites, to oversee the conduct of research at this locationSome institutions have specific requirements about how their site is named in this section; this will be reflected in that site's DIER form.
- (3) The contacts section of the ICF should include the contact information for the **REB of Record** for questions about participant rights or ethical issues. This information is often included in the approved Study-wide ICF template; if not, you can request the contact information from the REB of Record through Correspondence. Some institutions have specific requirements about who should be listed in this section; this will be reflected in that site's DIER form.

The Streamlined Research Ethics Review System (SRERS) Administration form contains details about a site's research administration processes, identifies the institution representative(s) and other collaborators who must have access to the applications in Stream. Make sure you have the current **SRERS Administration Form** and, the **Documented Institutional Ethics Requirements (DIER) Form** (if applicable) before you begin working on the Participating Site Initial Application. Forms are available on the [Templates & Forms](#) page of the CTO website.

Creating Participating Site Initial Applications (PSIA)

We encourage research teams to create the PSIA for each participating site as soon as possible. These forms can be created any time after the new project has been created. Creating these site-specific forms early ensures that each team can start working on their application as soon as possible and may support local research administration/institutional authorization processes.

More information on how to create a PSIA can be found in the [Creating a Participating Site Initial Applications](#) Quick Guide.

Accessing the PSIA

Members of the research team must be given access to the PSIA by someone who already has access (such as the Project Owner, member of the Study-wide study team or the sponsor). This is done by assigning that new user a Role (entering a person's name/information in the form does not grant them access). Don't forget to assign Roles to the PI, Co-I and any other study staff who need access to your study.

Users with site-level roles will be able to see all Study-wide, study-wide materials (like the protocol and Study-wide ICF template) and work on forms for their own site.

TIP: Before you begin working on your PSIA, **check the site name** tagged to the application. Do this by clicking on the "Site" tab below the Project Tree which will display the site name that appears on your REB approval letters. You can change the name of your site by clicking "Change Site" if required.

More information on roles and collaboration can be found in the [Adding New Study Team Members Using Roles](#) Quick Guide or the [Roles and Sharing](#) User Manual.

PSIA Content

Institutional Requirements

Some institutions have policies that impact research ethics review and must be addressed within the PSIA. These will be documented on the DIER form. If applicable, please ensure that these requirements are reflected within the PSIA form.

Institutional Representatives

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

Department Head/Departmental Approver

The name and contact information for the department head/departmental approver for the Principal Investigator (PI) must be entered into the PSIA. At most institutions, the PI should not sign off as the

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department head/departmental approver for their own application. If you're not sure who this individual is, check with the PI or the Institutional Representative for that site.

Requesting Signatures and Submitting the PSIA

Once you have completed filling out the PSIA, you must request signatures from the PI and other required signatories in the Agreement & Approval section of the form. The signatories must match the individuals entered in section 1 of the application. Signature requests can be sent to multiple individuals in parallel, and each individual will receive an email notification to alert them of the signature request. By default, the application will automatically submit once the last signature has been applied to the form.

More information how to sign an application can be found in the [Signing Applications](#) Quick Guide.

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