

Provincial Initial Application (PIA) Tip Sheet

Here are a few recommendations to help with successful submission of a new study-wide application

Provincial Informed Consent Form Template¹

A study-wide consent form template is submitted to the REB of Record for review as part of the Provincial Initial Application (PIA). When creating the Provincial ICF template(s) for your study, you **must** use the appropriate [CTO ICF template](#). This template has been accepted by the CTO Qualified REBs and contains language and elements required by the CTO participating institutions. Any Provincial ICF which does not follow the CTO ICF template format will be returned to the applicant for revision.

Tips for creating the Provincial Template:

- (1) **Follow the instructions included with the CTO 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 PIA.
- (3) **Do not include site-specific wording** within the Provincial 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 provincial 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.”

¹ Not applicable to studies submitted to and reviewed by the Ontario Cancer Research Ethics Board. Studies reviewed by OCREB will continue to use the OCREB ICF template available through the OCREB website.



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Creating and Accessing the Provincial Initial Application (PIA)

A member of the Provincial team (which can include the sponsor/CRO) will create the PIA; this individual becomes the “Project Owner”. When the PIA is first created, only the Project Owner has access. Other members of the provincial 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 Provincial Applicant, Provincial Co-Applicant (if applicable), and any other study staff who need access to your study at the Provincial level.

More information on roles and collaboration can be found in the [Collaboration Features – Roles and Sharing](#) 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 CTO 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 PIA has been created, the Centre Initial Applications can be created at any time. More information on how to create a CIA can be found in the [Creating Centre Initial Applications](#) Quick Guide.

PIA 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 is entered when the Provincial Initial Application is created, but this can be revised later by updating this question within the PIA. This information appears in the Work Area for users who have access to the study.

Study Number/ID

The PIA requests the Study ID/Number if applicable. This number refers to a code or short identifier used by the lead researcher/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 Provincial Initial Application. These individuals are identified by each institution and documented on the **SRERS Administration Form**.

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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 PIA

Once you have completed filling out the PIA, you must request signature from the Provincial Applicant and Co-Applicant (if applicable) in the Agreement & Approval section of the form. 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 required signature has been applied to the form.

More information how to sign an application can be found in the [Signing or Rejecting a Signature Request](#) manual.

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