



OCREB Online User Guide: Initial Provincial Application

(includes routing the application to the study sponsor and back)

Intended Users:

- Provincial Applicant/Provincial PI
- Study Staff assisting with the Provincial Application
- Sponsor or CRO Staff assisting with the Provincial Application

Version 1.0

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1. About OCREB Online

OCREB Online (O2) is a transparent, secure, web-based system designed to automate and streamline the preparation, submission and review processes for ethics applications submitted to OCREB by institutions in Ontario authorized to use OCREB. Ethics applications for new studies and post-approval applications such as amendments, renewals, study closures and reportable events (e.g., local SAEs, safety updates, DSMB reports, protocol deviations), are submitted via the online system by the principal investigator or by the designated study team member. Applications are prepared using “smart forms”, which dynamically show or hide questions depending on the applicability to the study. The system automatically prompts for missing information, thereby ensuring that submissions are complete before submission.

1.1. Intended Audience

This guide is intended for the Provincial Applicant or Provincial PI and the Study Staff assisting with the provincial application. It is also intended for the study sponsor or CRO staff who may assist with the completion of the provincial application.

1.2. Accessing the System

To access the live O2 system, go to <https://ocrebonline.ca>. Review the Terms and Conditions for restrictions on and authorized use of O2, and for privacy, security and confidentiality details.

1.3. Technical Details

- O2 is best viewed on Microsoft Internet Explorer (version 7 or higher).
- O2 will also work on Mozilla Firefox, Apple’s Safari (Mac), and Google Chrome.
- Sun Java will be required for downloading files from O2, which can be obtained from www.java.com/en/. If you have firewall or downloading restrictions, you may need local IT assistance to download this onto your work computers.
- O2 uses pop-ups and multiple windows. You will need to allow pop-ups for the O2 website so that these windows are not blocked.
- The display of system-generated date fields is dependent upon the settings on the computer that you are accessing the system with as well as the browser you are using. Please refer to the “Getting Started” user manual to adjust date settings.

1.4. O2 Support

- During business hours contact O2 Support at:
Tel: 416-673-6649 or toll-free at 1-866-678-6427 Ext 6649
Email – ocrebonline@oicr.on.ca; or
- After business hours, send an email to: ocrebonline@oicr.on.ca.

2. Initial (New) Provincial Study

2.1. Pre Submission



Before you begin, prepare your submission documents (protocol, IB and/or PM, study budget, consent forms, NOL if available, other patient materials, etc). You will be directed to upload these documents at appropriate places in the application. Clearly name and organize the documents in an easily-accessible area on your computer or local network.

To start a new provincial application, select **New Provincial Study**. This is accessible from a variety of places, including the **Studies** page and **My Home** page.

John Smith | My Home | Logoff

O2 Home Studies Centres Researcher Profile Issues & Support

Page for Demo Principal Investigator

Study Staff

Page for Demo Principal Investigator

Welcome to your Personal Folder, the central resource of managing your applications. Use the following guidelines to process your applications:

- Process all submissions in your **Inbox**. Items appearing here require immediate action by you to speed your submission through the review process. Click on link to process an item. The system will automatically notify you when action is required by you.
- Monitor the progress of your submissions using the other tabs. Items on these tabs do not require any action by you.

My Action Items My Studies My Amendments My Renewals My Reportable Events

Displays all items which require action by the study team. Click on links for more information.

Filter by ID [Go] [Clear] Advanced

ID	Name	SmartForm	Date Modified	Type	Owner	State	Last State Change
Pro0000094	TM.02		2/9/2011 2:59	Initial	Pre		2/9/2011 2:59 PM

You must complete and **Save (1)** the first page of the application form before the study record is created.

When you are finished with the current page, select **Continue (2)**, to move to the next page.

Questions marked with a red asterisk (*) are mandatory. You will not be allowed to continue to the next page unless these questions have been answered. However, at any point after the study is created, you can **Exit** and come back to work on it later by selecting

Edit Application

Back Save | Print.. Continue >>

1.1 Study Identification

This is the first step in your Human Research Ethics Application. You will automatically be guided to the appropriate questions or sections needed to complete your submission. Guidance notes will be in italics. Red asterisks (*) indicate mandatory questions. Submission of the application will be blocked unless all mandatory questions are answered.

1.0 * Is this a multi-centre cancer clinical trial?: (OCREB's mandate is multi-centre cancer clinical trials i.e., a trial conducted at more than one centre in Ontario using OCREB) Yes Clear

If NO, please contact the OCREB office.

2.0 * Protocol number (i.e., sponsor protocol number - enter EXACTLY as written on the protocol e.g., BR.29 not BR29):

Study acronym or other unique identifier or nickname:

OCREB number (please contact the OCREB office at 416-673-6649 if you do not have an OCREB number):

3.0 * Full Study Title (enter exactly as written in protocol):

4.0 * Provincial Applicant/Investigator:
Test Principal Investigator 2

5.0 Study Co-ordinator or Assistant (this person will have access to and can edit this application and will receive all notifications for this study):

Once you have created your study, menu options will appear, and the top right-hand corner of the screen will now display a unique identifier assigned to your application. Menu options:

1. **Save** – saves your work and keeps you on the same page;
2. **Exit** – takes you out of the application to the study workspace;
3. **Hide/Show Errors** – will display a list of mandatory questions that have not been answered;
4. **Jump To** – is a drop down list that allows you to “jump” directly to other sections of the form;
5. **Back** or **Continue** – will take you to the previous page or to the next page of the application.

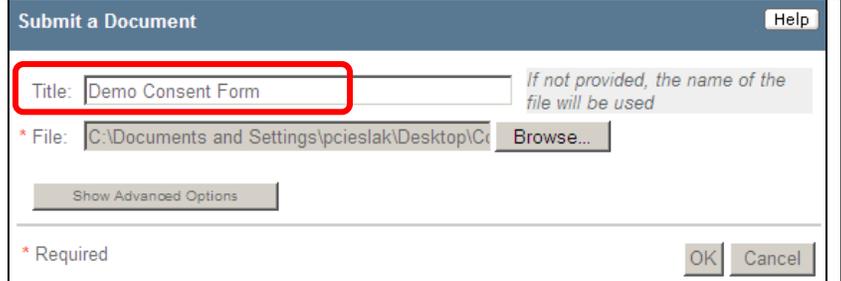
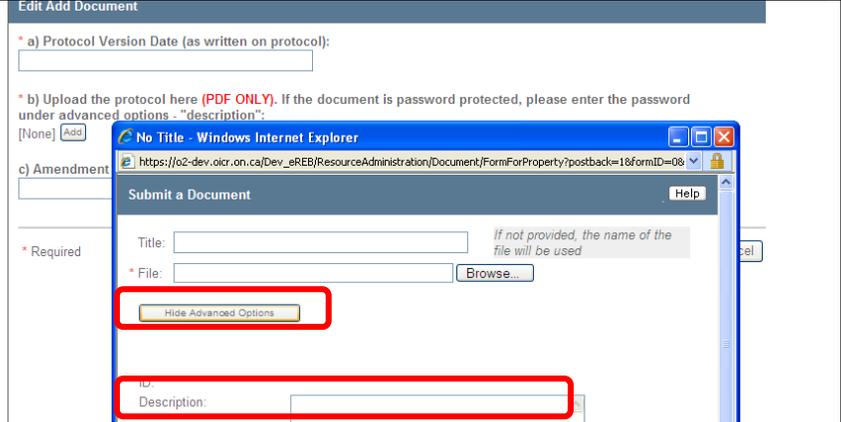


Under **Study Locations & Other Reviews**, select the PI at every centre that plans to participate in the study (obtain this information from the study sponsor). **You must add your own centre as a study location in order to be able to submit your centre application.**

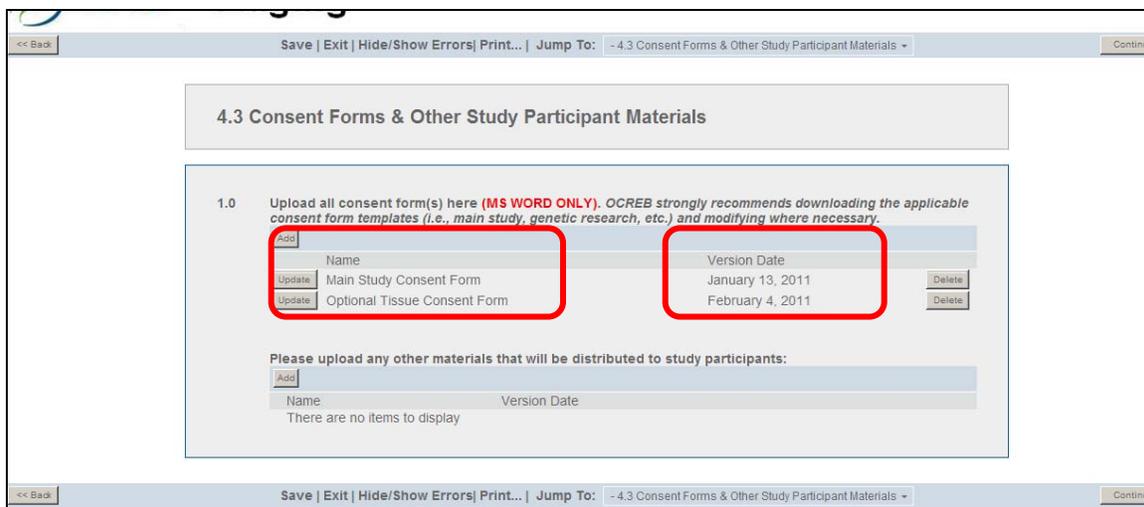
If you start typing the last name, first name or organization in the fields in any application form that asks you to **Select** a person, choices with similar names will appear for you to select from. You also may **Select** and choose from a full drop-down list.

Select the main study coordinator who will receive all notifications related to the provincial study. Add any other Study Staff members requiring access to the provincial study, including the ability to submit amendments, renewals or reportable events.

2.1.1. Uploading Documents

<p>At various points in the application, you will be prompted to upload relevant documents. Uploading a document is a two-step process. Selecting Add will open up an Edit/Add Document window. Enter the version date of the document if applicable, and select Add again to upload.</p>	
<p>This will open up another window. Enter the title of the document and select Browse to locate the document on your computer. Select OK to upload the document to the application. Select OK and Add Another to upload other documents, or select OK until you return to the application form.</p>	
<p>If the document is password protected, you must select Show Advanced Options and enter the password in the Description field.</p>	

You should now see the uploaded document(s) and the version date(s). Select **Update** to correct the version date. If you have uploaded the wrong document, **Delete** the document and then repeat the **Add** procedure to upload the correct document. If you do not enter a document name in the **Title** field, the "Name" will default to the filename you gave to the original document. This means that if you have already clearly named your documents, you can skip entering the **Title** field in the upload procedure.





The application forms are “SmartForms”, which are designed to show or hide questions as they apply to your study. Using the **Jump To** menu to navigate from page to page as you work through the application instead of **Continue** will override this feature. However, using the **Jump To** menu is a very good way to come back to a page that you were previously working on, or to bypass a mandatory question that you are not ready to answer. It is strongly recommended that you use the **Continue** button to move to the next page when you are filling in the application to avoid missing any mandatory questions and to trigger the SmartForm feature.



Because the system auto generates a different Pro number for the initial provincial study and each initial centre application, until this is fixed, a single OCREB number will be assigned to the overall project. The format will be the first two numbers of the current year followed by a 3-digit number (e.g., 11-001).

Until this process is automated, when you are ready to submit your application, please contact the OCREB office (416-673-6649) for your OCREB number. Enter the assigned OCREB number in the relevant question on the first page of the application.

2.1.2. Study Workspace

When you **Finish** or **Exit** the application, you exit to a Study Workspace. Workspaces are where you conduct your work or activities. Workspaces are created for each type of submission and contain activity buttons that allow you to create, view or work on submissions (e.g., new provincial application; post provincial approval activities such as amendments, centre applications, reportable events, etc).

1. **State** displays where your application is in the review process. Monitor the progress by checking the current state, which changes as the application moves through the review process;
2. **Edit Application** takes you back to the application to make edits any time prior to submission;
3. **View Smartform Progress** displays questions in the application as complete or incomplete;
4. **My Activities** – displays the activities that you can execute in this state (e.g., “Pre Submission”). Activities will change as the state changes with the various steps of the review process;
 - “Send for Sponsor Review” routes the application to the sponsor contact to allow them to assist in completing the application;
 - “Submit Study” is only available to the PI for initial provincial and initial centre applications;
 - “Withdraw” – removes the study from REB review anytime after it has been submitted;
 - “Edit the Email List” to add others who should receive notices;
 - “Edit Guest List” to give others (e.g., study monitors) view only access to the study;
 - “Send Email to PI” sends an email from the system to the PI’s regular email address;
 - “Send Email to REB Staff” sends an email to the selected person in the REB office.
5. **Project Properties** tab – displays information about the study. This information auto populates from the application form and upon completion of other system activities;
 - Centres** tab – shows a list of potential centres participating in the study
6. **History** tab – displays an ongoing list of study activities (*some of the REB activities will not be displayed to study staff for confidentiality reasons*);
7. **Attachments** tab – in one location, provides a listing of and access to all documents that were uploaded to the application.

The screenshot shows the OCREB Study Workspace for study SPSR.001. The interface includes a navigation menu at the top with options like 'O2 Home', 'Studies', 'Centres', 'Researcher Profile', and 'Issues & Support'. The sidebar on the left contains activity buttons: 'Pre Submission', 'Edit Application', 'Printer Version', 'View SmartForm Progress', and 'My Activities' (which includes 'Send For Sponsor Review', 'Withdraw', 'Edit Email List', 'Edit Guest List', 'Send Email to REB Staff', 'Send Email to PI', and 'Edit Study Personnel'). The main content area has tabs for 'Project Information' (selected), 'Centres', 'History', and 'Attachments'. The 'Project Information' tab displays details for 'Provincial Study - Credit Valley Hospital' and 'Study: SPSR.001'. Below this, there are sections for 'History' and 'Attachments'. Red boxes in the image highlight the 'Pre Submission' button (1), the 'Edit Application', 'Printer Version', and 'View SmartForm Progress' buttons (2), the 'My Activities' section (4), the 'Project Information' tab (5), the 'History' tab (6), and the 'Attachments' tab (7).

2.1.3. Routing the Provincial Application to the Sponsor or CRO in Pre Submission

The provincial applicant or study staff can route the application to the study sponsor or to the CRO (if applicable) to assist in the completion of the initial provincial application.



The sponsor or CRO contact must be in O2 in order to be able to route the application to them. Be sure to send the person's full contact information to O2 Support to have them added to the system and set up with an account. **Be sure to check with the sponsor or CRO contact before adding them to the system or routing the application to them!**

<p>Select Send for Sponsor Review to route the application to the sponsor or CRO. The sponsor or CRO contact that will assist with the application must be entered in the appropriate section of the application. Only one CRO or sponsor contact can be selected to assist with the application. Be sure to confirm the contact with the sponsor or CRO.</p>	
<p>A “Send for Sponsor Review” window will appear. The selected sponsor or CRO contact will appear in this window.</p> <p>Enter any instructions or information for the sponsor or CRO contact in the Comments field.</p> <p>Documents typically should not be added to this notice. All study-related documents (e.g., consent form) should be uploaded directly into the application form.</p>	

Once you select **OK**, the state will change from **Pre Submission** to **Pre Submission (Sponsor Review)**. The provincial applicant/PI and study staff will have “View” access only to the application until the sponsor routes it back.

ocreb Test Study Coordinator | My Home | Logoff

O2 Home Studies Centres Researcher Profile Issues & Support

Studies > SPSR.001

Pre Submission (Sponsor Review)

View Application
Printer Version
View SmartForm Progress

My Activities
Edit Email List

Project Information Centres

Provincial Study - Credit Valley Hospital
Study:SPSR.001 (Pro00001270) OCREB #: 12-100

Acronym: Sponsor Review

Full Title: Preparing the training materials for routing the provincial application to the sponsor

Principal Investigator: Test Principal Investigator 1 Study Coordinator: Test Study Coordinator

The sponsor or CRO contact will receive a notice from ocrebonline, and the study will be sitting in his/her “My Action Items” tab.

NOTE: the study will remain in the “My Action Items” section of the provincial applicant/PI and study staff with view-only permission until the sponsor routes the application back to the provincial applicant.

ocreb John Test | My Home | Logoff

O2 Home Studies Centres Researcher Profile Issues & Support

Page for John Test

Sponsor

My Roles
Sponsor

Quick Links
Consent Forms

Page for John Test

Welcome to your **Personal Folder**, the central resource for managing your applications. Use the following guidelines to process your applications:

- Process all submissions in your **Inbox**. Items appearing here require immediate action by you to speed your submission through the review process. Click on link to process an item. The system will automatically notify you when action is required by you.

My Action Items
Displays all items which require action by you. Click on links for more information.

Filter by ID [dropdown] [Go] [Clear] [Advanced]

ID	Name	SmartForm	Date Modified	Type	Owner	State	Last State Change
Pro00001270	SPSR.001	<input checked="" type="checkbox"/>	01/03/2012 5:03 PM	Initial Submission	John Test	Pre Submission (Sponsor Review)	01/03/2012 5:03 PM

The sponsor or CRO contact must select **Edit Application** to edit the application form. Selecting **Printer Version** opens a print friendly version of the application.

When finished, the sponsor or CRO contact must select the **Submit Sponsor Review** activity to route the application back to the provincial applicant/PI.

ocreb John Test | My Home | Logoff

O2 Home Studies Centres Researcher Profile Issues & Support

Studies > SPSR.001

Pre Submission (Sponsor Review)

Edit Application
Printer Version
View SmartForm Progress

My Activities
Edit Centre PI List
Submit Sponsor Review
Send Emails to Study Contact

(Initial)

Project Information Centres

Provincial Study - Credit Valley Hospital
Study:SPSR.001 (Pro00001270) OCREB #: 12-100

Acronym: Sponsor Review

Full Title: Preparing the training materials for routing the provincial application to the sponsor

Principal Investigator: Test Principal Investigator 1 Study Coordinator: Test Study Coordinator

Funding Sources: Demo Sponsor Review Type:

History Attachments Change Log

This area shows instructions and questions and important notifications regarding this Study.

Activity	Author	Activity Date
<input checked="" type="checkbox"/> Sent For Sponsor Review	Study Coordinator, Test	01/03/2012 5:03 PM GMT-05:00
<input checked="" type="checkbox"/> Hello John. As discussed, I am routing the provincial application to you to assist in completing it. Thanks		
<input checked="" type="checkbox"/> Created Study	Study Coordinator, Test	01/03/2012 4:23 PM GMT-

A **Sponsor Review Acknowledgement** window will appear. Enter any relevant comments or notes and select **OK** to route the application back to the provincial applicant/PI and study staff.

Submit Sponsor Review

Sponsor Review Acknowledgement

When you have completed review of the application, select "OK" to send the application back to the PI/Study Coordinator for final review and submission.

Insert any notes or comments to the PI/Study Coordinator in the comment field below.

Comments:

The State will change back to **Pre Submission** and the sponsor or CRO contact now can view the application only.

ocreb John Test | My Home | Logoff

O2 Home Studies Centres Researcher Profile Issues & Support

Studies > SPSR.001

Pre Submission

- View Application
- Printer Version
- View SmartForm Progress

My Activities

- Withdraw
- Edit Centre PI List
- Send Email to Study Contact

(Initial)

Project Information Centres

Provincial Study - Credit Valley Hospital
Study:SPSR.001 (Pro00001270) OCREB #: 12-100

Acronym: Sponsor Review

Full Title: Preparing the training materials for routing the provincial application to the sponsor

Principal Investigator:	Test Principal Investigator 1	Study Coordinator:	Test Study Coordinator
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Funding Sources: Demo Sponsor **Review Type:**

History Attachments Change Log

This area shows instructions and questions and important notifications regarding this Study.

Activity	Author	Activity Date
Submitted Sponsor Review	Test, John	02/03/2012 12:30 PM GMT-05:00

Added CRO contact. This responsibility has been delegated to the CRO. The application should be routed to the CRO contact to assist in completing it.

The provincial applicant and study staff can once again edit the application.

The cycle of routing the application to and from the sponsor or CRO contact can be repeated as needed.

ocreb Test Study Coordinator | My Home | Logoff

O2 Home Studies Centres Researcher Profile Issues & Support

Studies > SPSR.001

Pre Submission

- Edit Application
- Printer Version
- View SmartForm Progress

My Activities

- Send For Sponsor Review
- Withdraw
- Edit Email List
- Edit Guest List
- Send Email to REB Staff
- Send Email to PI
- Edit Study Personnel

(Initial)

Project Information Centres

Provincial Study - Credit Valley Hospital
Study:SPSR.001 (Pro00001270) OCREB #: 12-100

Acronym: Sponsor Review

Full Title: Preparing the training materials for routing the provincial application to the sponsor

Principal Investigator:	Test Principal Investigator 1	Study Coordinator:	Test Study Coordinator
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Funding Sources: Demo Sponsor **Review Type:**

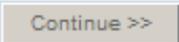
History Attachments Change Log

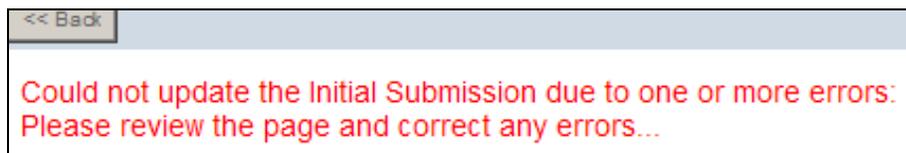
This area shows instructions and questions and important notifications regarding this Study.

Activity	Author	Activity Date
Submitted Sponsor Review	Test, John	02/03/2012 12:30 PM GMT-05:00
Sent For Sponsor	Study Coordinator, Test	01/03/2012 5:03 PM GMT-

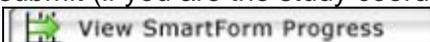
Added CRO contact. This responsibility has been delegated to the CRO. The application should be routed to the CRO contact to assist in completing it.

2.1.4. Finalizing the Provincial Application

The study will remain in **My Action Items** until it is submitted. Select  to open the application and make edits at any time prior to submission. Once you are back in the application, select  to continue section by section, or use the  menu to go to a specific section or sections. These two options can be found at the top and the bottom of the application. As you **Continue** from page to page, an error message will appear if any of the mandatory questions on that page have not been answered.



REMEMBER that using the **Jump To** menu will override the SmartForm feature that shows or hides questions as applicable to your study. For example if the collection of biological specimens is included in your study, selecting “*Biological Specimens*” in the “Research and Methods” section of the application will result in the appearance of questions relating specifically to biological specimens. If you are collecting biological specimens in your study and you don’t see the related questions, go back to ensure that you made the appropriate selections in the “Research and Methods” section.

Once the application is finished, double-check that it is complete before submitting it (if you are the PI), or before contacting the PI to submit (if you are the study coordinator). Selecting “Hide/Show Errors” from within the application, or  from the workspace will open up a **Progress** window showing whether the sections are complete or incomplete. If a section is “incomplete” it means that at least one of the mandatory questions was not answered. Select the item from the “Section” column to go directly to that section.

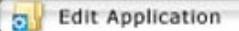


Section	Description	Progress
1.0 Study Identification, Funding & Locations	Provincial	Incomplete
2.0 Study Objectives & Design	Provincial	Incomplete
3.0 Research Methods and Procedures	Provincial	Incomplete
4.0 Study Population, Recruitment and Consent	Provincial	Incomplete
5.0 Risks and Benefits Assessment	Provincial	Incomplete
6.0 Data Privacy, Confidentiality & Security	Provincial	Incomplete
7.0 Data & Safety Monitoring Plan	Provincial	Incomplete
8.0 Budgets, Costs & Contracts	Provincial	Incomplete

Once you have determined that the application is complete, if you are the study coordinator you can inform the PI from within the study workspace by pressing the  activity button, or you can send an email outside the O2 system using your institutions email system (e.g., Outlook), or you can simply call the PI or tell the PI in person that the study is ready for him/her to submit.

NOTE: emails sent from the study workspace will contain study identifiers and the sender’s name as well as a direct link to the study workspace after login; however, the emails will be “From” ocrebonline and not the person sending the email.

2.2. Submission (PI Only)

Only the PI has the authority to submit an initial provincial application. The PI must log in and locate the study in **My Action Items** on his/her home page and select the study “Name” to open up the provincial study workspace. If an email was sent from the workspace, the PI can use the link to be taken directly to the study workspace after login. Review the application by viewing the “Printer Version” or review and edit the application by selecting . When ready, the PI selects .

If the application is incomplete, an error message will list all questions that are incomplete. Selecting the link in the **Jump To** column will take the PI directly to the application page in question. The PI will not be terribly happy if this error message pops up at this stage....

Message	Field Name	Jump To
 This is a required field; therefore, you must provide a value.	Funding Type	1.2 Funding Information
 This is a required field; therefore, you must provide a value.	Investigator Initiated Study	1.2 Funding Information
 This is a required field; therefore, you must provide a value.	Funding from USA DHHS	1.2 Funding Information
 This is a required field; therefore, you must provide a value.	Funding CRO Involved?	1.2 Funding Information
 This is a required field; therefore, you must provide a value.	Previous REB review	1.5 Study Locations and Other Reviews

If the application is complete, the Provincial Applicant/PI Agreement window will appear. Check off the box in the bottom left-hand corner before selecting **OK** to submit the study. This serves as the official Provincial Applicant/PI signature. Once submitted, the study moves out of **My Action Items** and Study Staff can no longer make any changes.

Submit Study

PROVINCIAL APPLICANT/INVESTIGATOR AGREEMENT:

- I attest that this application as submitted is in compliance with the Tri-Council Policy Statement; ICH Good Clinical Practice Consolidated Guidelines; Division 5, Canadian Food and Drug Regulations, and the applicable laws and regulations of Ontario;
- I attest that the information in the application is complete and accurate to the best of my knowledge;
- I attest that this application contains the current and complete protocol, including and sub-studies;
- I am aware the the OCREB review materials (i.e., provincial application form, correspondence between the PI and OCREB, approval letter) will be shared with all Ontario sites participating in this study;
- As provincial applicant, I acknowledge that I am responsible for reporting to OCREB any proposed modifications or amendments to the protocol, all external (non-local) SAEs, and updated Investigator Brochures or Product Monographs unless the sponsor formally agrees to do so on my behalf.
- I will submit an OCREB Application for Approval of Centre Participation for review/approval to conduct the study at my centre;
- I am aware that OCREB will provide the following study information to all Ontario oncology trial sites: OCREB project I.D.#, sponsor name, sponsor protocol #, REB review status, name of provincial applicant (i.e., submitting PI), list of participating centres.

After you click OK you will no longer be able to edit the application. You will receive email when each approval is granted or refused, and again when all the required approvals are received.

*If you are not ready to submit your application, click **Cancel**.*

I agree with the above statement: *

OK **Cancel**



The principal investigator must login to officially sign-off on the initial provincial application. This activity cannot be delegated; doing so is equivalent to forging a signature.

2.3. Contingencies

Once your study has been submitted and assigned to an REB Coordinator (REBC). The REBC will review the application, set contingencies as required, and either assign it to a meeting, assign it to an expedited reviewer or send the application back to you to edit, as applicable. If the application is sent back to the Study Staff, you and the PI will receive an email notice with a link to the study. The study also will be located under the **My Action Items** tab, which means it now requires action by you. At this point, it is opened up to you again to edit.

A contingency is an item that was not included at the time of initial submission, but must be submitted before approval can be issued. The Health Canada authorization (e.g., NOL, ITA, NHP), the study budget and the Clinical Trial Registration number are all possible contingencies for provincial initial applications. To view any contingencies, from the Study workspace select the **Attachments** tab and scroll down to **Attached Documents - Other**. Note that the *Date Completed* column is blank indicating that these items must be received by OCREB before approval can be issued.

Attached Documents - Other

Contingencies:

Type	Description	Date Completed	Date Created
View	Health Canada - NOL, ITA, NHP		1/26/2011
View	Clinical Trial Registration		1/26/2011
View	Study Budget		1/26/2011

Supporting Documents:

Name	Version	Modified	Description
There are no items to display			

OCREB Recommended Consent Form Changes:

Name	Version	Modified	Description
There are no items to display			

PI Response:

Name	Version	Modified	Description
There are no items to display			

To submit any outstanding “contingency” items, upload them to the application if they are available at the time of preparing the revised application with your PI response. Alternatively, if the application is no longer open to you to edit, you can attach the documents and send them by email to the REB Coordinator “Owner” of your study. The email can be sent from within the study workspace in O2 or by regular email. If the items are sent by email, the REB Coordinator will upload them to the contingency area and change the contingency to “completed”. This now will allow the approval to be issued. Because the REB office cannot modify your application, you can find any contingency documents received separately from your application under the **Attachments** tab.

2.4. Tracking the Progress of the Application

A unique feature of the OCREB Online system is that you can track the progress of your application through the entire ethics review process. If you look at the top left-hand side of the Study workspace, highlighted in yellow is the current **“State”** your application is in. For example, before you submit the study, the state of your application is called **“Pre-Submission”**. After you submit the study it will change to **“REB Administrative Review”**, and to **“REB Staff Review”** once assigned to an REB Coordinator.

Upon submission, the **State** changes from ...



You can track the progress of all of your applications by viewing the **State** column on **My Home** page:

ID	Name	SmartForm	Date Modified	Owner	State	Application Type	Review Type	PI	Expiration Date
Pro00000080	SST.01 (TRAIN)	<input checked="" type="checkbox"/>	05/02/2011 4:51 PM	REB Coordinator 2, Test	Assigned To REB Meeting	Provincial	Full Board Review	Smith	

or the **State** column on the **Studies** page....

Demo Principal Investigator 1 | My Home | Logoff

OCREB

Studies

Centres

Researcher Profile

Issues

Other Submission Types

- ▶ Amendments
- ▶ Renewals
- ▶ Reportable Events

Create Provincial

Studies

View all studies by In Progress, Approved, and Closed groupings. Use the 'My Home' link in the top right-hand corner of your screen to see the list of submissions related to you.

Provincial - In Progress
Provincial - Approved
Provincial - Closed
Provincial - All Studies

ID	Name	SmartForm	Date Modified	State	Review Type	Provincial PI	Expiration Date
Pro00000008	DEMO_2c	<input checked="" type="checkbox"/>	27/01/2011 2:41 PM	Approved	Full Board Review	Principal Investigator 2	27/01/2012
Pro00000016	DEMO_3c	<input checked="" type="checkbox"/>	28/01/2011 2:56 PM	Approved	Full Board Review	Principal Investigator 3	28/01/2012
Pro00000022	DEMO_4c	<input checked="" type="checkbox"/>	31/01/2011 10:12 AM	Approved	Full Board Review	Principal Investigator 4	31/01/2012
Pro00000033	DEMO_5c	<input checked="" type="checkbox"/>	31/01/2011 3:24 PM	Approved	Full Board Review	Principal Investigator 5	31/01/2012
Pro00000057	DEMO_19	<input checked="" type="checkbox"/>	01/02/2011 1:45 PM	Approved	Expedited	Principal Investigator 19	31/01/2012
Pro00000003	DEMO_1c	<input checked="" type="checkbox"/>	03/02/2011 9:30 AM	Approved	Full Board Review	Principal Investigator 1	27/01/2012
Pro00000001	DEMO_1a	<input checked="" type="checkbox"/>	03/02/2011 2:38 PM	Pre Submission		Principal Investigator 1	
Pro00000002	DEMO_1b	<input checked="" type="checkbox"/>	03/02/2011 2:39 PM	PI Response Pending	Full Board Review	Principal Investigator 1	27/01/2012
Pro00000006	DEMO_2a	<input checked="" type="checkbox"/>	03/02/2011 2:40 PM	Pre Submission		Principal Investigator 2	

2.5. PI Response Pending

Once the initial application has undergone REB review (typically at a full Board meeting), the REB will issue a review letter with any questions, requests for clarifications, recommendations, or concerns. Once the review letter is issued, the state automatically changes to **PI Response Pending**, and the application is once again open to the Provincial Applicant and study staff for editing.

2.5.1. Accessing the OCREB Review Letter

When the REB review letter is issued, the PI and main Study Coordinator both will receive an automatic email notice with a direct link to the study workspace. The study also shows up in the **My Action Items** tab from My Home page along with any other items requiring action by the study coordinator and PI. Select the study from the “Name” column to open the study workspace. The application is now open to the study staff to edit in response to the OCREB review letter. Find the review letter under the **Letters** tab, and select [View Correspondence Letter](#) to open the letter. To download a copy, right click on [View Correspondence Letter](#).

The screenshot shows the OCREB web application interface. At the top, there is a navigation bar with 'OCREB', 'Studies', 'Centres', 'Researcher Profile', and 'Issues'. Below this, the breadcrumb 'Studies > DEMO_1b' is shown. The main content area is titled 'Project Information' and displays details for 'Provincial Study - Demo Centre 1 DEMO_1b (Pro00000002)'. Key information includes the description, principal investigator (Demo Principal Investigator 1), study coordinator (Demo Study Coordinator 1), OCREB coordinator (Test REB Coordinator 1), review type (Full Board Review), and meeting date & time (11/02/2011 - 11:00am). A 'Letters' tab is highlighted in the navigation bar. Below the tabs, there is a section for 'Last Issued Letter' with a 'View' link. At the bottom, a table titled 'Review Letters' shows one entry: 'Sent Letter to PI' by 'REB Chair, Test' on '27/01/2011 1:50 PM GMT-05:00'. A 'View Correspondence Letter' link is highlighted in the table.

2.5.2. Accessing the OCREB Recommended Changes to the Consent Form(s)

The REB recommended consent changes will be displayed in the consent forms. Download copies to your computer to make the changes as agreed with the PI and sponsor. Change the version date and delete the initially submitted consents and upload the revised consents to the application.

OCREB Recommended Consent Form Changes:

Name

[Main Consent - OCREB Recommended Changes](#)

[Tissue Consent - OCREB Recommended Changes](#)

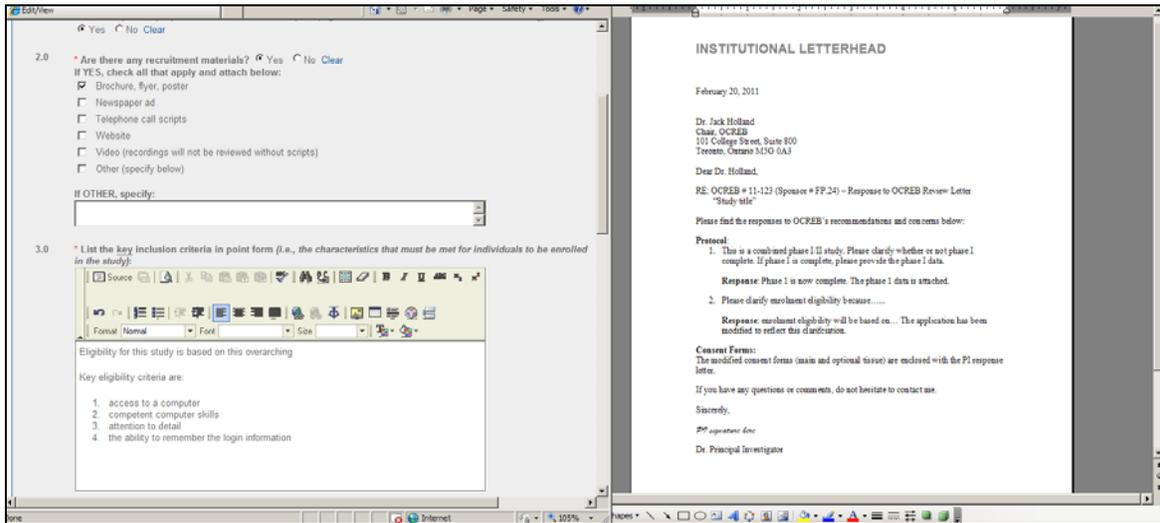
The review letter will contain a link to the consent forms containing the REB recommended changes.

The consent forms with the REB recommended changes also can be accessed from the **Study** workspace. Select the **Attachments** tab and scroll down to **Attached Documents – Other**.

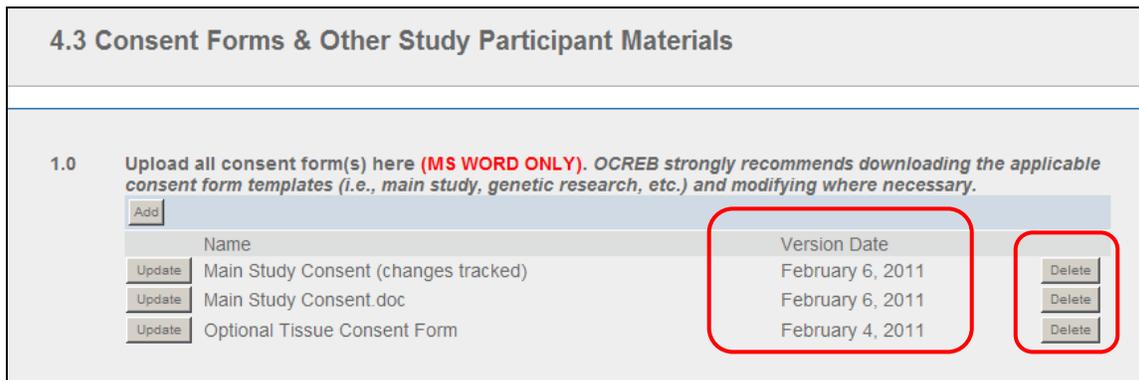
The screenshot shows the 'Attached Documents - Other' section. It contains a table of 'Supporting Documents' with columns for Name, Version, Modified, and Description. The table is currently empty, with the text 'There are no items to display' below it. A red box highlights the 'OCREB Recommended Consent Form Changes' entry in the table.

2.5.3. Preparing the PI Response

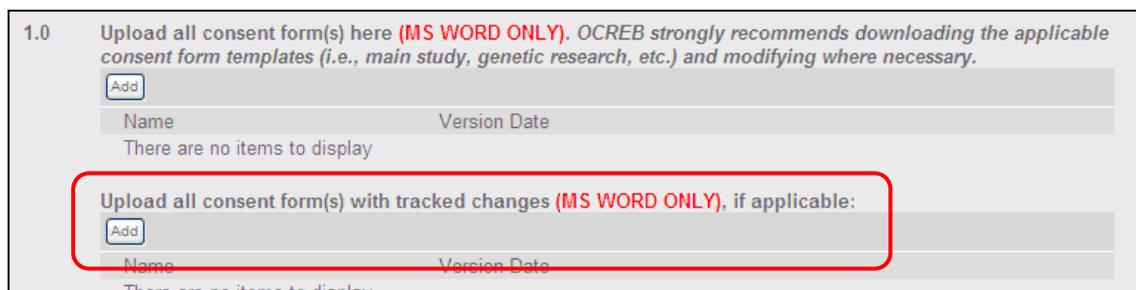
To prepare the PI response, create a letter **on your local letterhead**. Remember to copy and paste the REB questions from the review letter into the response letter so that the questions and responses are in one location. In addition to responding with a letter, the relevant changes must be made directly in the application form, which is a living document that should reflect the most current study information. To edit the application, right click on **Edit Application**, and open the application for editing in a new window. Resize and position your PI response letter window beside the application windows so you can view them side-by-side as you modify the application and your response. **The PI must sign the PI response letter.**



Editing the application includes uploading revised versions of documents (i.e., consent forms). **Delete** the initially submitted document (e.g., consents) and upload the clean version (i.e., with changes incorporated) of the revised consents to the application.

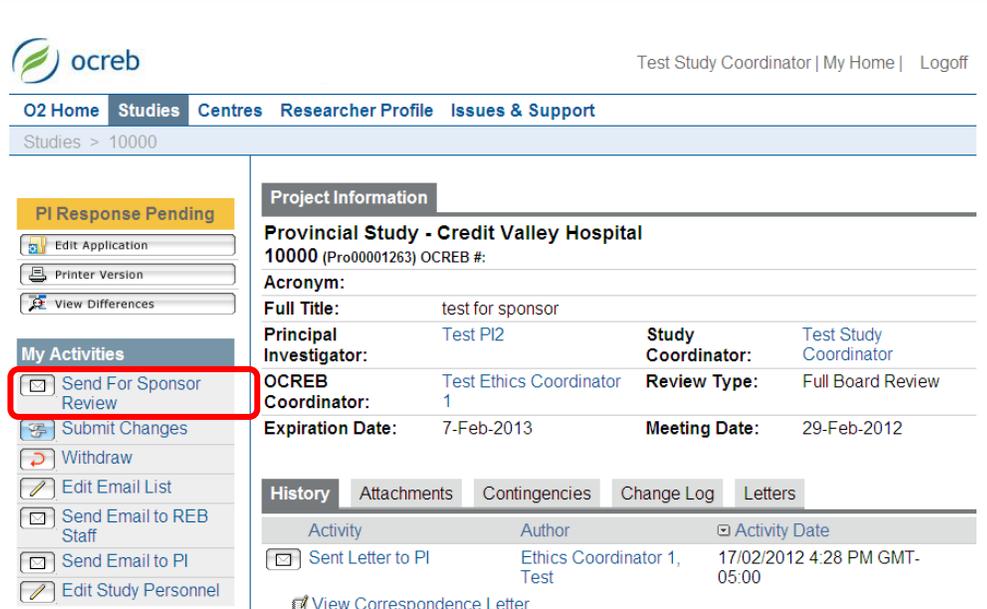
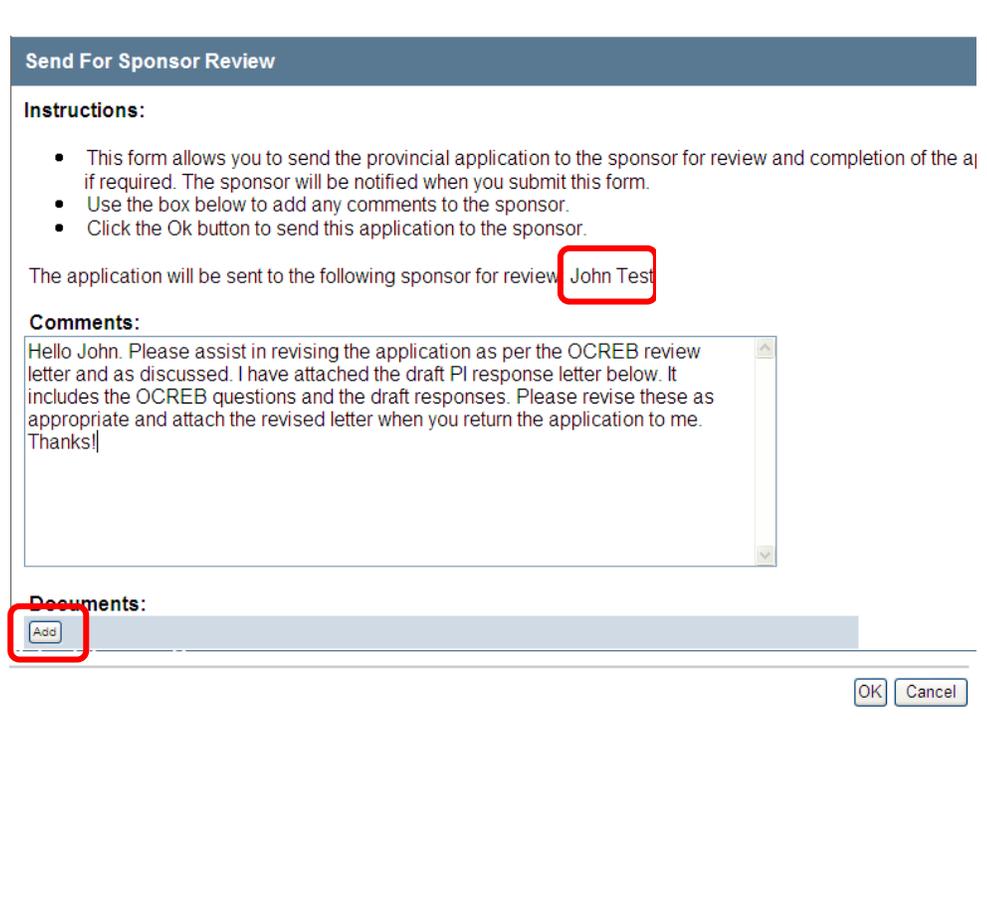


Include the **tracked change versions of the consent form(s)** to show the changes by uploading them (**Add**) to the tracked change consent form area of the application.



2.5.4. Routing the Provincial Application to the Sponsor or CRO – PI Response

The provincial applicant or study staff can route the application to the study sponsor or to the CRO (if applicable) to assist in preparing the PI response.

<p>Select Send for Sponsor Review to route the application to the sponsor or CRO contact to assist in preparing the PI response (i.e., application edits and responses to questions). Be sure to confirm the contact with the sponsor or CRO.</p> <p>A “Send for Sponsor Review” window will appear showing the sponsor or CRO contact.</p>	 <p>The screenshot shows the OCREB web interface. At the top, there is a navigation bar with 'O2 Home', 'Studies', 'Centres', 'Researcher Profile', and 'Issues & Support'. Below this, there is a 'Studies > 10000' breadcrumb. A sidebar on the left contains a 'PI Response Pending' section with buttons for 'Edit Application', 'Printer Version', and 'View Differences'. Below that is a 'My Activities' section with a list of actions: 'Send For Sponsor Review' (highlighted with a red box), 'Submit Changes', 'Withdraw', 'Edit Email List', 'Send Email to REB Staff', 'Send Email to PI', and 'Edit Study Personnel'. The main content area shows 'Project Information' for 'Provincial Study - Credit Valley Hospital 10000'. It lists details such as 'Full Title', 'Acronym', 'Principal Investigator', 'OCREB Coordinator', 'Expiration Date', 'Study Coordinator', 'Review Type', and 'Meeting Date'. A 'History' table shows a 'Sent Letter to PI' activity by 'Ethics Coordinator 1, Test' on '17/02/2012 4:28 PM GMT-05:00'. A 'View Correspondence Letter' link is at the bottom.</p>
<p>Enter any notes to the sponsor or CRO in the Comments field.</p> <p>Select Add then Browse to find and add the draft PI response letter if the sponsor or CRO will assist with the responses.</p> <p>Remember to copy and paste the REB questions from the review letter into the response letter so that the questions and responses are in one location.</p> <p>Select OK to send the application to the sponsor or CRO. The state will change from PI Response Pending to PI Response Pending (Sponsor Review).</p> <p>The provincial applicant/PI and study staff will have “View” access only to the application until the sponsor routes it back.</p>	 <p>The screenshot shows the 'Send For Sponsor Review' form. It has a title bar 'Send For Sponsor Review'. Under 'Instructions', there are three bullet points: 'This form allows you to send the provincial application to the sponsor for review and completion of the application if required. The sponsor will be notified when you submit this form.', 'Use the box below to add any comments to the sponsor.', and 'Click the Ok button to send this application to the sponsor.' Below the instructions, it says 'The application will be sent to the following sponsor for review' followed by a text box containing 'John Test' (highlighted with a red box). The 'Comments' section has a text area with the text: 'Hello John. Please assist in revising the application as per the OCREB review letter and as discussed. I have attached the draft PI response letter below. It includes the OCREB questions and the draft responses. Please revise these as appropriate and attach the revised letter when you return the application to me. Thanks!'. The 'Documents' section has an 'Add' button (highlighted with a red box) and a 'Cancel' button at the bottom right.</p>

The sponsor or CRO contact selects **Edit Application** to revise the application form, including adding and removing documents (e.g., consent forms).

Select **Submit Sponsor Review** to route the application back to the provincial applicant/PI.

The screenshot shows the OCREB web interface. At the top, there are navigation tabs: O2 Home, Studies, Centres, Researcher Profile, and Issues & Support. Below this, a breadcrumb trail reads 'Studies > 10000'. On the left side, there is a 'PI Response Pending (Sponsor Review)' section with three buttons: 'Edit Application' (highlighted with a red box), 'Printer Version', and 'View Differences'. Below that is a 'My Activities' section with buttons for 'Withdraw', 'Edit Centre PI List', 'Submit Sponsor Review' (highlighted with a red box), and 'Send Email to Study Contact'. At the bottom of this section, it says '(Assigned To Committee Meeting)'. On the right side, the 'Project Information' section is visible, showing details for 'Provincial Study - Credit Valley Hospital 10000'. It includes fields for Acronym, Full Title, Principal Investigator, OCREB Coordinator, Expiration Date, Study Coordinator, Review Type, and Meeting Date. Below this is a 'History' table with columns for Activity, Author, and Activity Date. The first entry is 'Sent For Sponsor Review' by 'Study Coordinator, Test' on '05/03/2012 12:05 PM GMT-05:00'.

A **Sponsor Review Acknowledgement** window will appear.

If the sponsor or CRO has edited the PI response letter, it should be uploaded in this window. Select **Add** then **Browse** to find and upload the draft PI response letter. The PI must sign the review letter.

Select **OK** to route the application back to the provincial applicant/PI and study staff.

The screenshot shows the 'Submit Sponsor Review' window. At the top, it says 'Submit Sponsor Review'. Below that is the 'Sponsor Review Acknowledgement' section, which contains text: 'When you have completed review of the application, select "OK" to send the application back to the PI/Study Coordinator for final review and submission. Insert any notes or comments to the PI/Study Coordinator in the comment field below.' There is a 'Comments' text area with the following text: 'The appropriate edits have been made to the application form. The revised consents have also been uploaded. Please have the PI review the application for accuracy. The revised draft PI Response Letter is attached below. Please have the PI review the letter, make any changes and sign it. Remember, a signed *.pdf copy of the letter must be attached at the time the PI response is submitted to OCREB. Thanks!'. Below the comments is a 'Documents:' section with an 'Add' button highlighted by a red box. At the bottom right, there are 'OK' and 'Cancel' buttons.

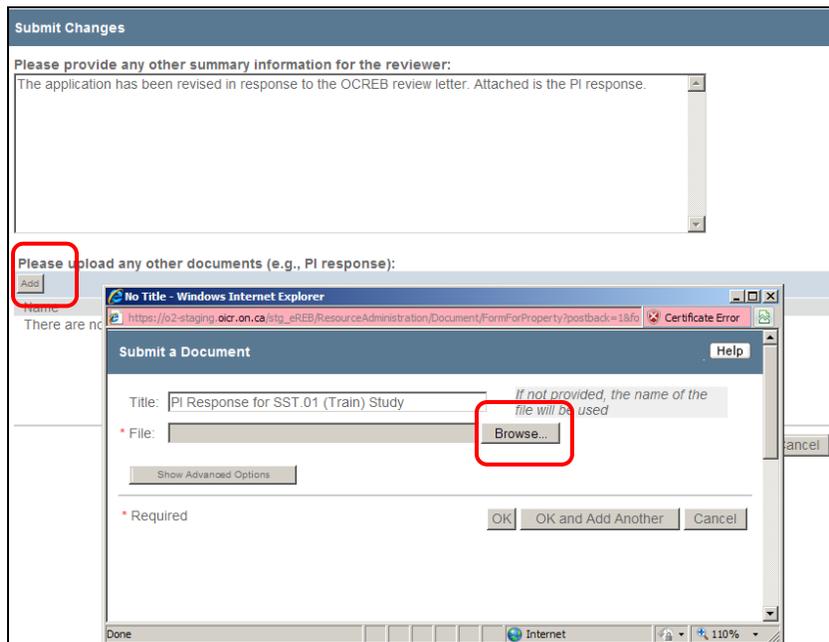
The State will change back to **PI Response Pending** and the provincial applicant and study staff can once again edit the application. The sponsor and CRO now will have view access only.

The cycle of routing the application to and from the sponsor or CRO contact can be repeated as needed.

The screenshot shows the OCREB web interface in the 'PI Response Pending' state. The navigation and breadcrumb trail are the same as in the previous screenshot. The 'PI Response Pending' section now has three buttons: 'View Application', 'Printer Version', and 'View Differences'. The 'My Activities' section is the same. The 'Project Information' section is also the same. The 'History' table now has a new entry: 'Submitted Sponsor Review' by 'Sponsor, Test' on '05/03/2012 12:47 PM GMT-05:00'. Below the history table, there is a note: 'The appropriate edits have been made to the application form. The revised consents'.

2.5.5. Submitting the PI Response

Now that the PI response letter has been reviewed **and signed by the PI**, the modifications have been made to the application form, and the revised consent form(s) with the new version date(s) have been uploaded directly into the application, you are ready to select **Submit Changes**, which sends the updated application to OCREB. Enter any comments or information to OCREB in the summary field in the pop-up window, select **Add** to upload the PI response letter and then select **OK**. The status of the study will change to **“REB Staff Modifications Review”**, and Study Staff can no longer make changes to the application.



The REB Coordinator will guide the PI response/revised application and consent forms through the final review process, ensuring that the REB recommendations are adequately addressed. An approval letter will be issued once all of the REB requirements are met, at which time the study will move to the **“Approved”** state.

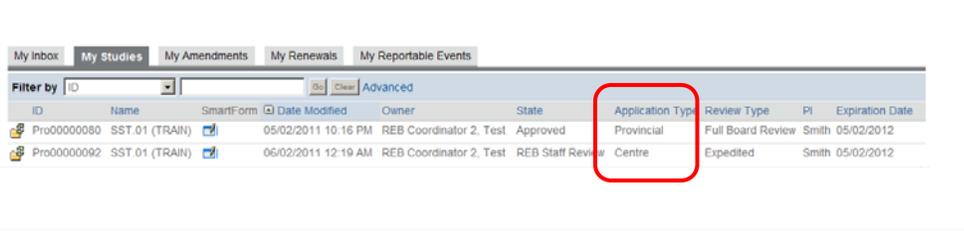
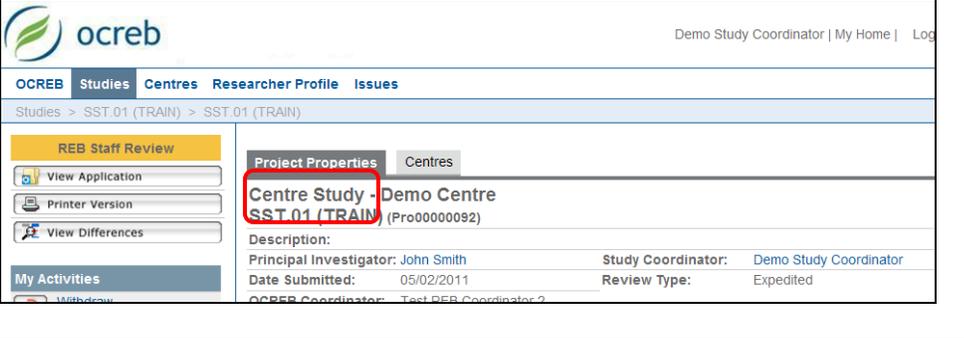
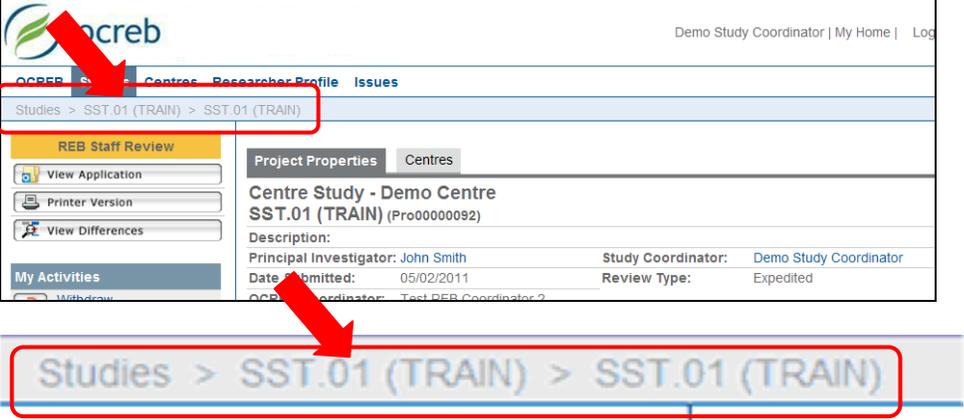
Access the approval letter by selecting the **Letters** tab of the study workspace and selecting **View Correspondence Letter** under the *Activity* column under **Study: Approved**. You can also access the letter under the **History** tab; however, over the life of the study, this area is likely to become very long and busy.



2.5.6. Centre Application or Provincial Application – Where am I?

The Provincial and the Centre Studies will have the same name, which might seem confusing at first. Think of the Provincial Study as the parent, and the study name as the parent's last name. Each Centre Study becomes a child with the same last name. There are many different ways to tell if you are in or accessing the provincial application/study or the centre application/study:

NOTE: “Name” in this system is the sponsor protocol number.

<p>The provincial applicant will see the same study listed more than once in lists of studies. The “Application Type” column will show which one is Provincial and which ones are Centre.</p>	
<p>When accessing a Provincial Study, “Provincial Study” will be displayed in the Provincial Study workspace under the “Project Properties” tab. To access the list of participating centres, select the “Centres” tab.</p>	
<p>When accessing a Centre Study, “Centre Study” will be displayed in the Centre Study workspace under the “Project Properties” tab.</p>	
<p>If you see the study name twice in the crumb trail, you are in the Centre Study workspace.</p> <p>Go up one level to the Provincial Study workspace by taking the crumb trail back to the “parent” from the Centre Study workspace.</p>	



The Provincial Applicant will see all of the Centre Studies/Applications associated with that Provincial Study. In other words, as the parent, you get to see the actions of all of your children....