OCREB Online User Guide: Complete Guide for Applicants

Version 1.0

For Study Staff including Study Coordinators and Principal Investigators

Table of Contents

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 applicants to OCREB, in particular, study coordinators and principal investigators (PIs). It also contains information for department approvers. The guide provides users with useful information on the overall OCREB Online system, as well as how to navigate the system and how to submit and track submissions to OCREB. The guide is structured so that if follows the most likely order of submissions: new provincial initial study application, initial centre applications, amendments, renewals, reportable events and study closures.

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 recommended).
- 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 .

1.4.   Sandbox (Practice Area)

Users can familiarize themselves with O2 in the "Sandbox" at https://o2-staging.oicr.on.ca. The Sandbox is a practice environment where users can test-drive the system without using real data. Contact the O2 Help for a user name and password for the Sandbox.

1.5.   O2 Help

- Submit issues or questions via the Issues & Support page from within the O2 system;
- Email – ocrebonline@oicr.on.ca; or
- Phone - 647-260-7945 or toll-free: 1-866-678-6427 Ext 7945.

2. Getting Started

2.1. O2 Home Page

On the O2 home page you will find the login link, as well as links to other OCREB information such as policies and procedures, templates, user guides and OCREB meeting dates and deadlines.
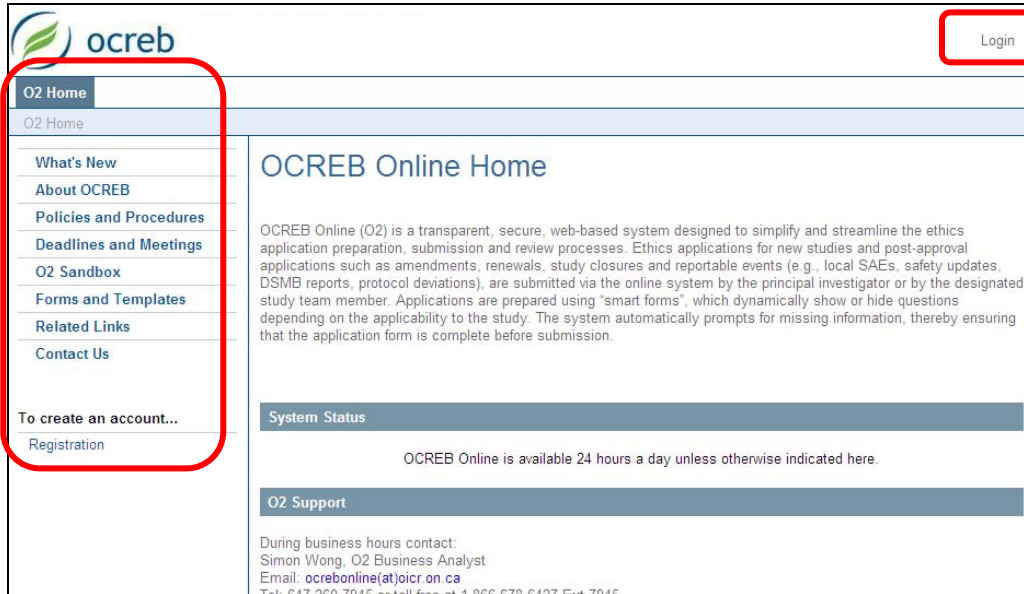
2.2. Logging In

The O2 team will create an account for each authorized O2 user and provide a user name and password. If you already have your user name and password, select the *Login* link in the top right-hand corner of the screen to go to the login screen. The first time you login, you will be prompted to change your password.
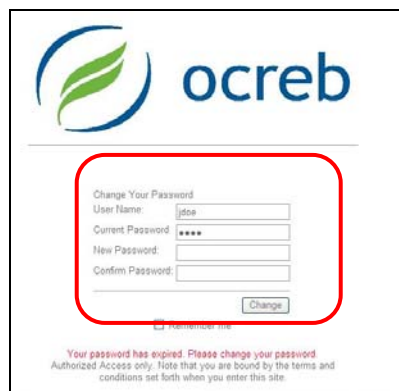
2.3. Registration
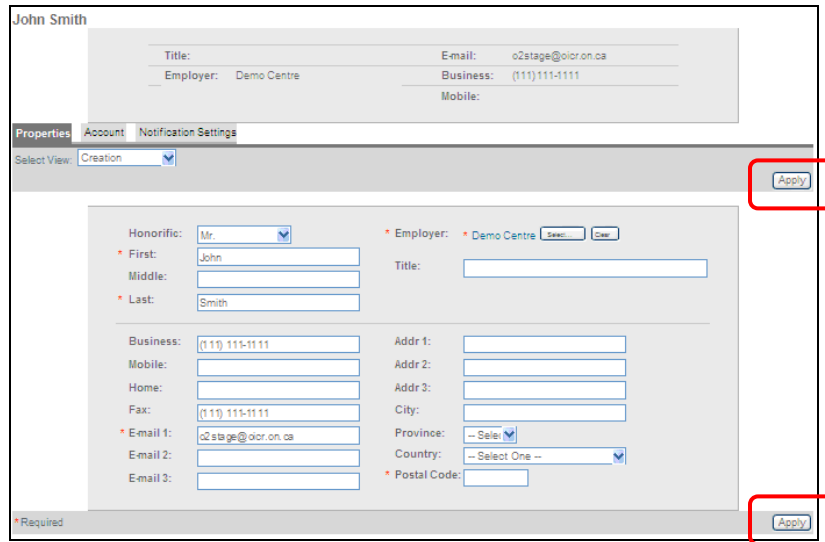
If you do not have a user name and password, you will need to register. To register, select the *Registration* link in the bottom left-hand corner of the OCREB home page, complete the registration form and select *Register* to submit. The OCREB office must have your access authorized (e.g., by your manager) before creating your account and providing you with a user name and temporary password.

2.4. User Profile – Contact and Password Information

When you login the first time, you will be directed to your **User Profile** to verify your contact information. Select *Apply* to save any changes.
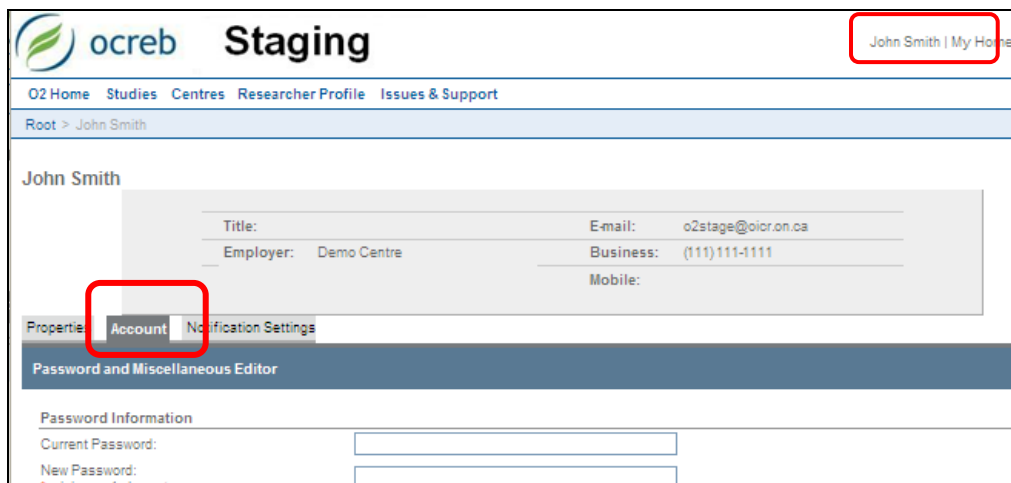
To change your password at any time, select your name from the user menu bar. This will take you to your user profile. Select the **Account** tab to access the password area.

Passwords must contain at least six (6) characters in an alphanumeric combination. Passwords must not be shared or stored in a visible and accessible location, i.e. written down. Passwords must NOT contain:

- any words that could be found in a dictionary;
- any words or references to the type of work being performed in relation to the system on which the password is being deployed;
- any identifying user information such as birthdays, spouse's birthdays, anniversaries, children's birthdays, pet names or other similar types of identifying information;
- three or more consecutive characters from your username.

	If you fail to successfully login after five (5) attempts, the system will lock you out and you will need to call O2 Help to have your password reset.

2.5.   Access Levels/Roles

Most O2 users will have only one O2 role (i.e., Study Staff). However, if you are a PI and a department approver, both roles will be added to your profile.

Although all "**Study Staff**" share the same role name, your authorized activities (e.g., view only, make changes, submit) depend on the permissions set for your specific study staff role (e.g., PI, main study coordinator, co-investigator, other study staff).

If you have more than one user role, switch between roles by selecting the appropriate role on **My Home** page. **NB. The role that you select will determine the information that is displayed on your screen and the activities you are allowed to execute.**	

2.6. Researcher Profile

The Researcher Profile link on **My Home** will take you to your researcher profile (if you are a PI) or to a list of profiles for all PIs that you are linked with (if you are a study coordinator). The Researcher Profile collects information similar to that in the *OCREB New PI Form*.

❗	**First-time O2 users**: Select *Edit Researcher Profile*, complete the fields and upload the PI's most current CV. This can be done by a study coordinator linked to a PI or by the PI. A PI can add study coordinators to his/her profile, granting them permission to update the Researcher Profile, add the PI to new ethics applications, to create an ethics application, to add or remove study coordinators from individual studies, and to submit post-approval applications (e.g., amendments) on his/her behalf.

The **Researcher Profile** link on **My Home** page links to the PI profiles.	
Select *Edit Researcher Profile* to make changes. Select *Printer Version* to view or print the full profile.	
Complete the profile fields and upload the PI's most current CV.	
Select relevant study coordinators from a pop-up list to add to this PI's profile. Press *Finish* to complete.	

3. Navigating OCREB Online

It is important to spend some time figuring out how to navigate this new system. O2 consists of a variety of pages and workspaces. The different pages help to organize and display information in a logical fashion and they act as gateways to specific study areas. Workspaces are unique areas that contain activity buttons and are where you work on your various ethics applications (e.g., on a new provincial study or on post provincial study approval activities such as amendments, centre applications, reportable events, renewals, etc).

3.1. "My Home" Page

Except for the first time you login, every subsequent login will take you to your personal home page "**My Home**". If you have more than one role in O2, this page will differ slightly for each user role. Selecting *My Home* in the upper right-hand corner of the screen will bring you back to this page if you get lost.

My Home page contains:

1. A system navigation bar with links to various pages. This navigation bar is visible from any page or workspace in the system;
2. A user tool bar/menu, with links to your profile and your home page ("**My Home**"). (*You can link to your personal profile to review or update it at any time by clicking on your name*). This user tool bar/menu is visible from any page or workspace in the system;
3. **My Roles**, which allows you to toggle between user roles by selecting the applicable user role (if you have more than one role);
4. A ⬚ New Provincial Study activity button, which will open a new Provincial application to allow you to prepare to submit a new study. This button is available from most pages and workspaces;
5. **My**… submission tabs, which display items requiring action by you ("**My Action Items**") and other tabs where you can monitor the progress of your studies and the different types of submissions related to your studies (details on page 9). **My**… submission tabs show only those studies and their related submissions that you are directly involved in;
6. **Quick Links** – for example, to OCREB templates.

My Action Items – displays items requiring action by you. When you log in, this tab will show as your default view. Once you complete your action, the submission will move out of this area to the next step in the review process.	
My Studies – displays all studies that you are preparing to submit or have submitted. Other columns show attributes such as: current state, application type (provincial versus centre), review type, PI name and expiry date, etc.	
My Amendments – displays all your amendment applications regardless of the current state (i.e., even those you are working on "pre-submission")	
My Renewals – displays a list of your renewal applications regardless of the current state.	
My Reportable Events – displays a list of all your reportable events, including the type of reportable event.	

3.1.2. Finding Your Submissions

Many views have a "*Filter*" feature to allow users to more easily find an item in a long list. For example, to find a study by sponsor protocol number, select **My Studies** tab, enter the exact protocol number in the **Filter by** "Name" field, and press *Go*. To find a PI, **Filter by** "First" or "Last" name, enter the name in the adjacent field and press *Go*. Press *Clear* to return to the full list.

If you know the O2 system-generated project ("PRO") number, filter by "**ID**" and use "%" in front of last 3 numbers of the PRO number to find the project.
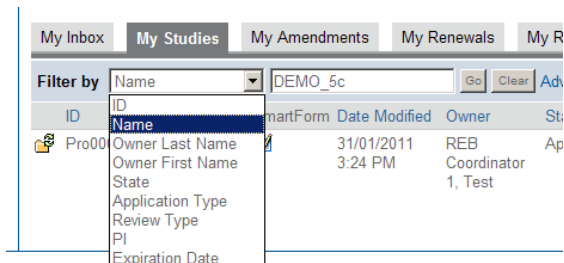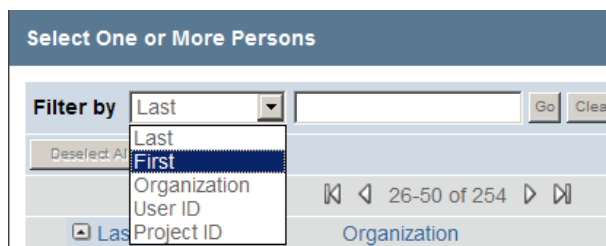
You can sort most columns in ascending or descending order. If you move your cursor over the column heading, it will change to a link if the column allows sorting. Select the column heading to sort. Select the column again to sort in the opposite direction.

 or   or   or , etc. (e.g., if you wish to display studies by the closest expiry date, sort by ascending "Expiration Date"):

If there are more items than can be displayed on one page, a bar at the bottom of the page will show the total number of items in the entire list, as well as how many items are displayed on the current page (). To go to the next page, select . Select to go to the last page.

3.2. Navigation Bar

The navigation bar is visible no matter where you are in the system, with links to:

1. **O2 Home** – takes you to the OCREB Online home page without logging you out;
2. **Studies** – links to a page listing all provincial and centre studies that you are associated with;
3. **Centres** – links to your centre profile page that includes a list of staff at your institution in the system, a list of all of the studies your centre is participating in, and other centre-specific items;
4. **Researcher Profile** - links to your researcher profile (if you are a PI), or to a list of Profiles for all PIs that you are linked with (if you are a study coordinator). See page 7 for details;
5. **Issues & Support** – links to a page where you can submit questions or issues to the OCREB Online team and access User Guides and Frequently Asked Questions (FAQs).

3.3. Studies Page

The Studies page is where you access all studies you are involved in: Provincial (top) or Centre (bottom). This includes provincial applications where you are NOT the provincial applicant, but your centre is participating or listed as potentially participating, even if you have not yet submitted your centre application. The various tabs link to Provincial and to Centre studies by their current state (i.e., *"In Progress", "Approved", "Closed"*), or to a list of "All Studies" regardless of their current state. On the left-hand side, you will see a menu of **Other Submission Types** from where you can access all post-approval provincial and centre submissions (amendments, renewals, and reportable events) related to all studies. Think of these as subfolders of the study.

3.3.1. Amendments, Renewals and Reportable Events Pages

Amendments page – displays a list of all provincial and centre amendment applications for all studies you are involved in. ***Tip: look for the crumb trail or the page title to confirm your location.***	
Reportable Events page – displays a list of all provincial and centre reportable event submissions (e.g., local SAE, protocol deviation, safety update, DSMB report) for all studies you are involved in.	

3.4. Centres Page

Selecting *Centres* in the navigation bar will take you to a link to your Centre profile. Select the link to open the profile. Only users at your centre and in the OCREB office will be able to view your Centre Profile.
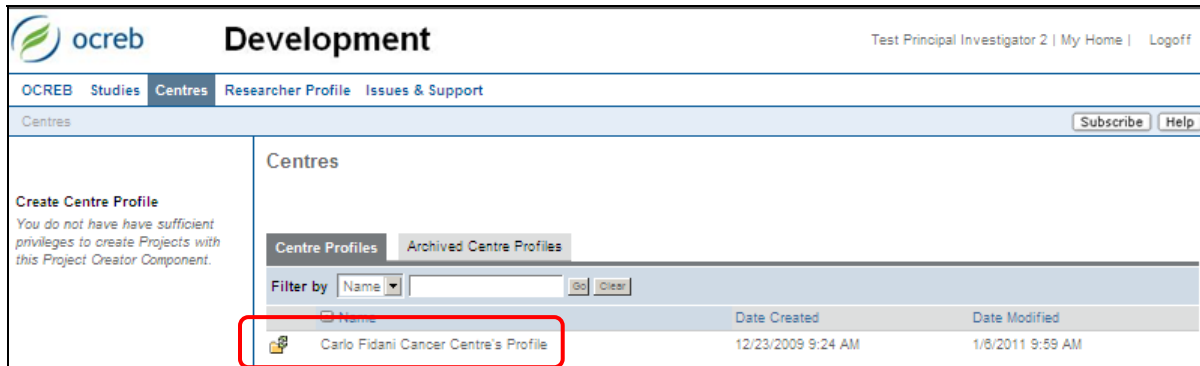
3.4.1. Centre Profile

The centre profile page allows you to view information pertaining to your centre including, a **List of Staff** at your centre who are registered in the O2 system, a place to store any relevant **Centre Policies** if you so choose, a list of OCREB **Approved Consent Form Changes**, a list of all **Studies** running at your centre, and a list of all provincial studies created by your centre (**Provincial Studies Created By**). The **History** tab will display the history of all changes made to your centre profile, the date the changes were made and by whom. Select the appropriate tab to view the relevant information.
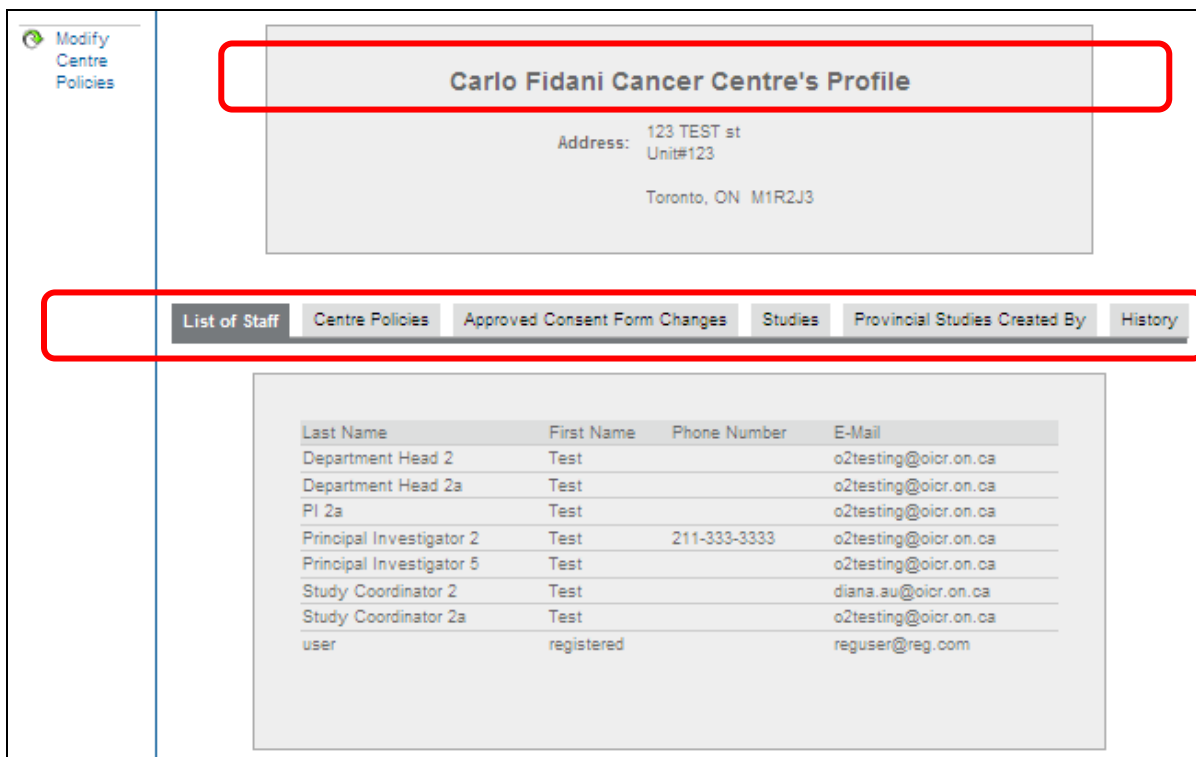
Are you ready to dive in and prepare a provincial submission?

4. Initial (New) Provincial Study

4.1. Presubmission

> **!** 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 them in an easily-accessible area somewhere 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 **Researcher Profile, Studies** page and **My Home** page.	
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 from the study workspace.	

Once you have created your study, new 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. If any mandatory questions on that page are not yet answered, you will not be able to save; however, you can *Exit*;
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.
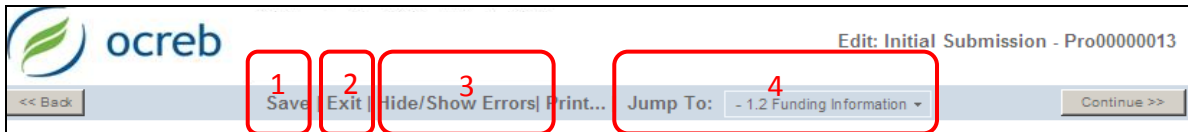
Under **Study Locations & Other Reviews**, select the centres/PIs that plan to participate in the study (obtain this information from the study sponsor). **You must add your own centre as a study location in order to be able to submit your centre application**.
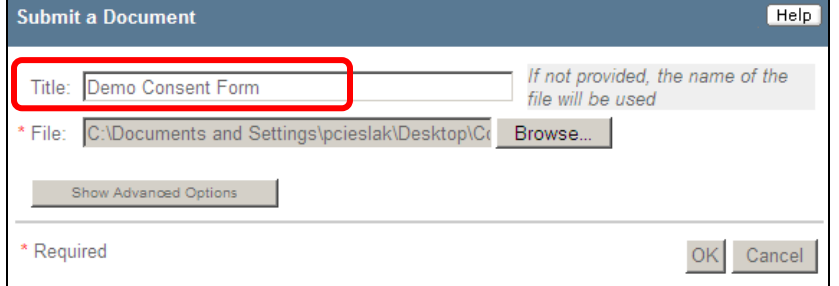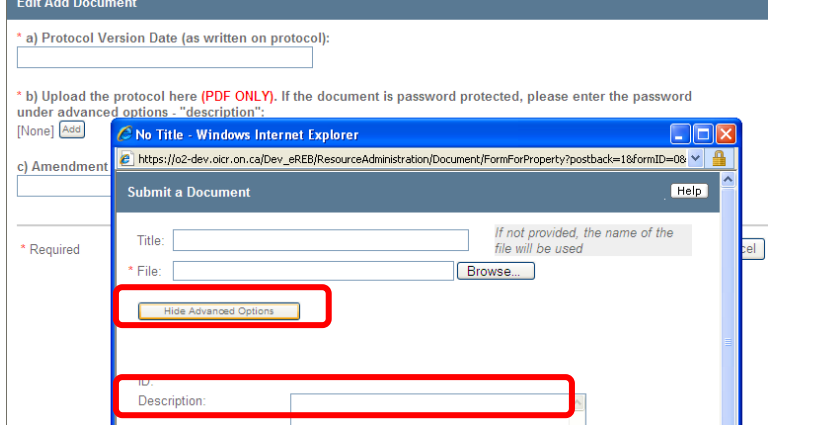
If you start typing the last name, first name or organization in the fields in any application form that ask you to *Select* a person, choices with similar names will appear for you to select from. You also may *Select* and choose from a full drop-down list.	
Select the main study coordinator who will 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. These additional staff will not receive the notifications.	

4.1.1. Uploading Documents

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 and select *Add* again to upload.	**Edit Add Document** Document: [None] Add **Version Date:** 2011-Jan-13 or January 13, 2011 * Required OK OK and Add Another Cancel
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.	**Submit a Document** Help Title: Demo Consent Form *If not provided, the name of the file will be used* * File: C:\Documents and Settings\pcieslak\Desktop\Co Browse... Show Advanced Options * Required OK Cancel
If the document is password protected, you will need to select *Show Advanced Options* and write the password in the "**Description**" field.	**Edit Add Document** * a) Protocol Version Date (as written on protocol): * b) Upload the protocol here (PDF ONLY). If the document is password protected, please enter the password under advanced options - "description": [None] Add c) Amendment No Title - Windows Internet Explorer https://o2-dev.oicr.on.ca/Dev_eREB/ResourceAdministration/Document/FormForProperty?postback=1&formID=0& **Submit a Document** Help Title: *If not provided, the name of the file will be used* * File: Browse... Hide Advanced Options ID: Description:

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, select *Delete* and then *Add* to upload the correct document. If you do not enter a document name in the **Title** field, the "File" name will default to the name 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.

<< Back   Save | Exit | Hide/Show Errors| Print... | Jump To: - 4.3 Consent Forms & Other Study Participant Materials ▾   Continu

4.3 Consent Forms & Other Study Participant Materials

1.0   Upload all consent form(s) here **(MS WORD ONLY)**. *OCREB strongly recommends downloading the applicable consent form templates (i.e., main study, genetic research, etc.) and modifying where necessary.*

Add

	Name	Version Date	
Update	Main Study Consent Form	January 13, 2011	Delete
Update	Optional Tissue Consent Form	February 4, 2011	Delete

Please upload any other materials that will be distributed to study participants:

Add

Name	Version Date
There are no items to display	

<< Back   Save | Exit | Hide/Show Errors| Print... | Jump To: - 4.3 Consent Forms & Other Study Participant Materials ▾   Continu

The application forms are designed to show or hide questions as they apply to your study ("SmartForms"). 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 your were previously working on. We strongly recommend that you use the *Continue* button to move to the next page when you are filling in the application.

Because each type of submission (e.g., initial provincial, initial centre, amendment, reportable event) is issued a different system-generated number, a standard OCREB number will be assigned to the overall project file. The format will remain the same as the current numbering system – i.e., the first two numbers of the current year followed by a 3-digit number (e.g., 11-001)

Until this process is automated, please call the OCREB office (416-673-6649) for your OCREB number before completing your application. Enter the assigned OCREB number in the application in the relevant question.

A column displaying the OCREB number will be added to every submission listing view.
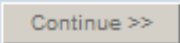
4.1.2. Study Workspace

When you *Finish* or anytime you *Exit* the application, you end up in the Study Workspace:

1. **State** – displays where your application is in the ethics review process. The state name will change as the application is routed through the review steps. You can monitor the progress of your study by looking at its current state;
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** – shows all 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;
   - "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 (in addition to the PI and main study contact) who should receive notices;
   - "Edit Guest List" to give others read 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 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.

4.1.3. Finalizing the Provincial Application

The study will remain in **My Action Items** until it is submitted. Select [Edit Application] to open the application and make edits at any time prior to submission. Once you are back in the application, select [Continue >>] to continue section by section, or use the [Jump To: - 1.1 Study Identification ▾] 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.

> << Back
>
> Could not update the Initial Submission due to one or more errors:
> Please review the page and correct any errors...
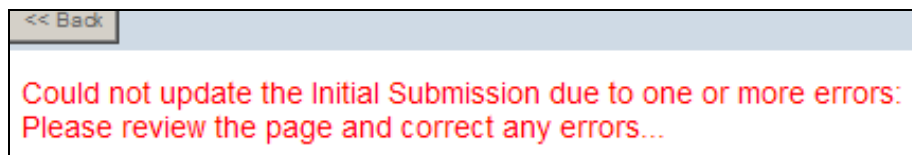
REMEMBER that using the **Jump To** menu will override the SmartForm feature that shows or hides questions as applicable to your study. For example if the collection of biological specimens is included in your study, selecting "*Biological Specimens*" in the "Research and Methods" section of the application 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 [View SmartForm Progress] 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.
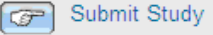
Progress		Help
Section	Description	Progress
1.0 Study Identification, Funding & Locations	Provincial	Incomplete
2.0 Study Objectives & Design	Provincial	Incomplete
3.0 Research Methods and Procedures	Provincial	Incomplete
4.0 Study Population, Recruitment and Consent	Provincial	Incomplete
5.0 Risks and 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 OCREB Online by pressing the [Send Email to PI] activity button, 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.

4.2. Submission (PI Only)

Only the PI has the authority to submit an initial provincial application. The PI must login 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. The PI can review the application by viewing the "Printer Version" or review and edit the application by selecting [Edit Application]. When ready, the PI selects [Submit Study].

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….

If 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.

!	**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.**

4.3.   Contingencies

Once your study has been submitted, the Intake Coordinator at OCREB will review your application and send it back to you to edit or assign it to an REB Coordinator, as applicable. The REB Coordinator 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 with a link to the study. The study will be located under the **My Action Items** tab, which means it now requires action by you. At this point, it is opened up for you 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.

To submit these outstanding items, upload them to the application if they are available at the time of submitting the revised application with your PI response. Alternatively, you can attach and send them in a regular email to the REB Coordinator "Owner" of your study. 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, this is where you find any contingency documents it they are received separately from your application.

4.4. Tracking the Progress of the Application

A unique feature of the OCREB Online system is that you can easily 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 ...
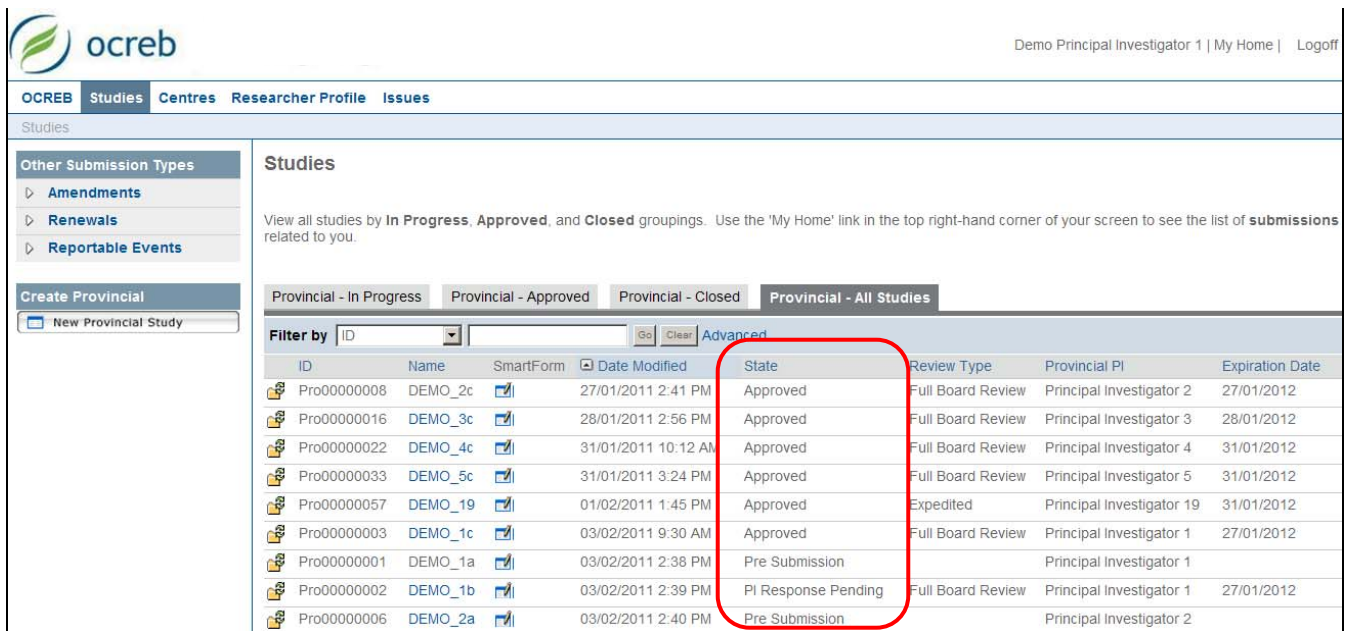
Pre Submission to REB Administrative Review .

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

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

4.5. Pending PI Response

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**.

4.5.1. Accessing the OCREB Review Letter

When the REB review letter is issued, the PI and 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 with any other items requiring action by you. 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*.

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

The REB recommended consent changes will be tracked directly in the consent forms. Download copies to your computer to review and accept or reject the changes as agreed with the PI and sponsor. Change the version date and be prepared to upload the revised consents to the edited application to submit with the PI response.	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 in the same area as Contingencies: from the **Study** workspace select the **Attachments** tab and scroll down to **Attached Documents – Other**.	

4.5.3. Preparing the PI Response

To prepare the PI response, create a response letter **on your local letterhead**. We recomment that you copy and paste the REB questions into the response letter from the REB review letter. In addition to responding to the letter, you must make the necessary changes 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 should sign the PI response letter.**
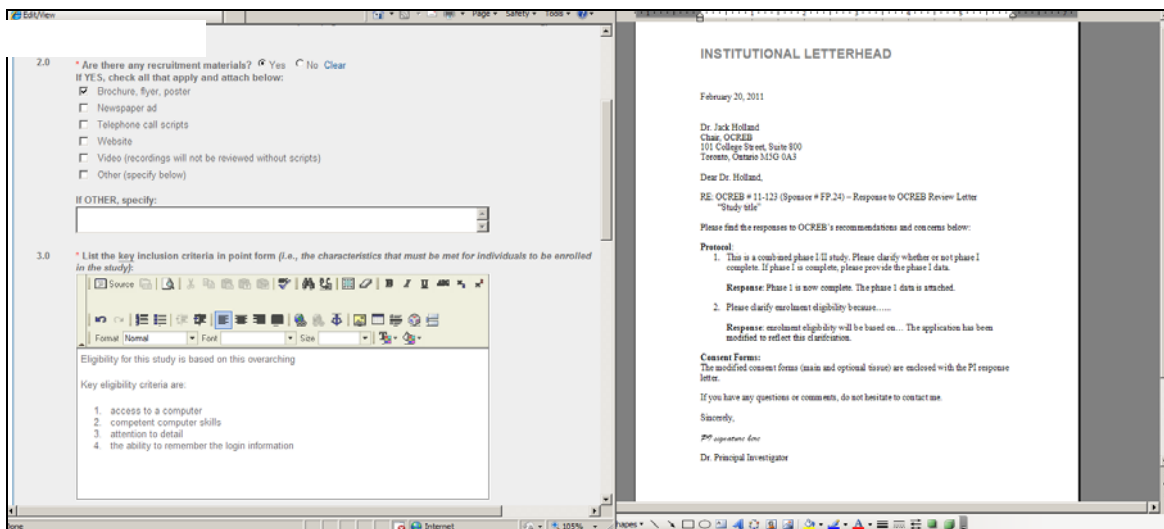
Editing the application usually includes uploading revised versions of documents (i.e., consent forms). For the clean version of each consent form (i.e., with changes incorporated), select *Delete* beside the appropriate consent form and upload the revised version.
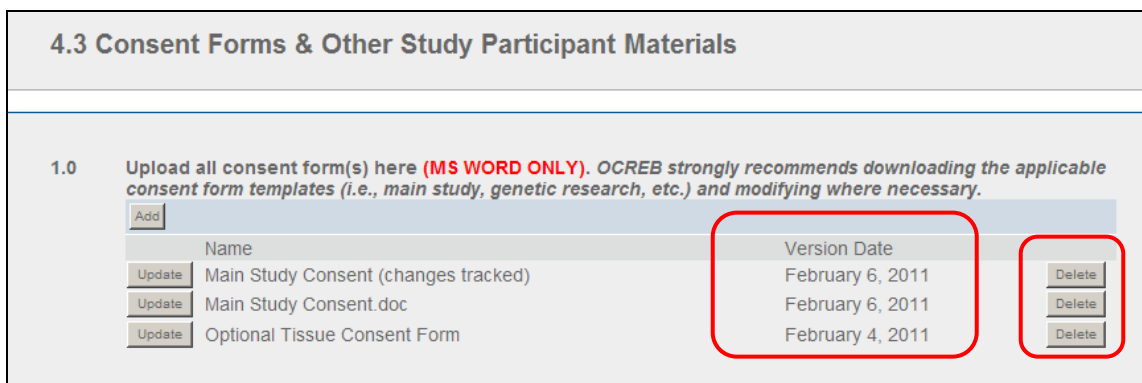
Add the **tracked change versions of the consent form(s)** by uploading them in the tracked change consent form area of the application.
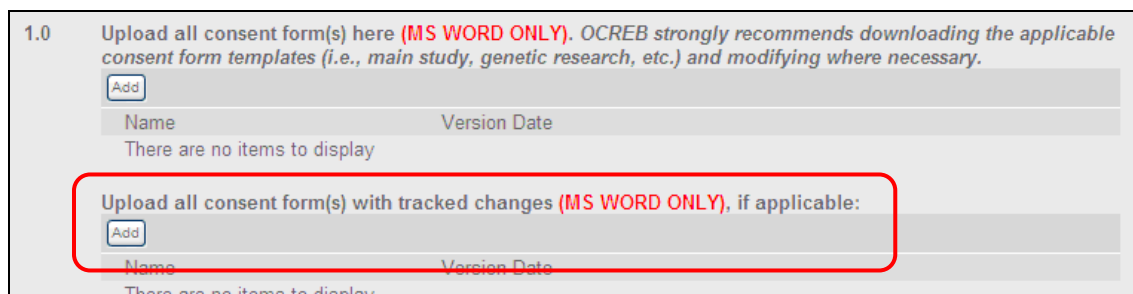
4.5.4. Submitting the PI Response

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 in the summary field in the pop-up window, select *Add* to upload the PI response letter and 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.
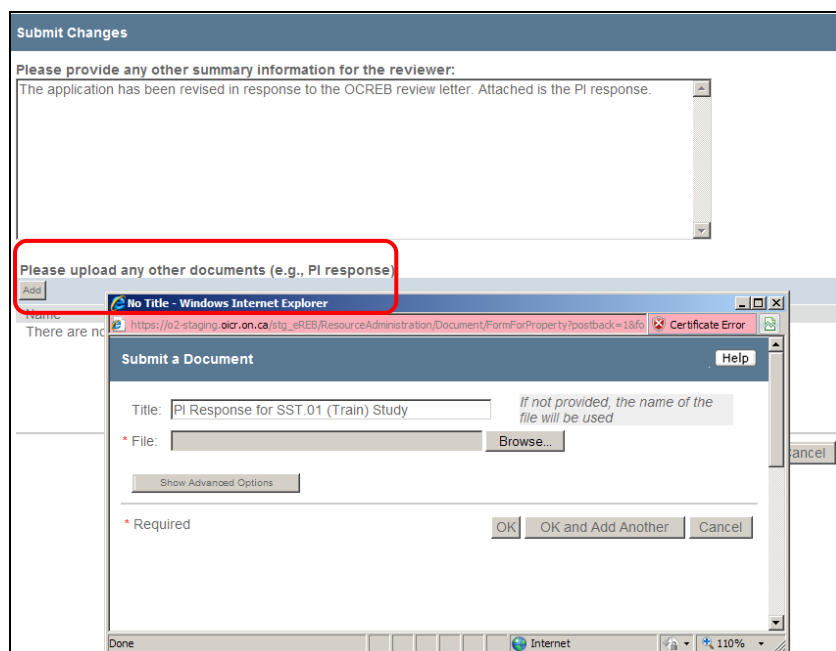
The REB Coordinator will guide the PI response/revised application and consent forms through the final review process, ensuring that the REB recommendations are adequately addressed. An approval letter will be issued once all of the REB requirements are met, at which time the study will move to the "**Approved**" 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.
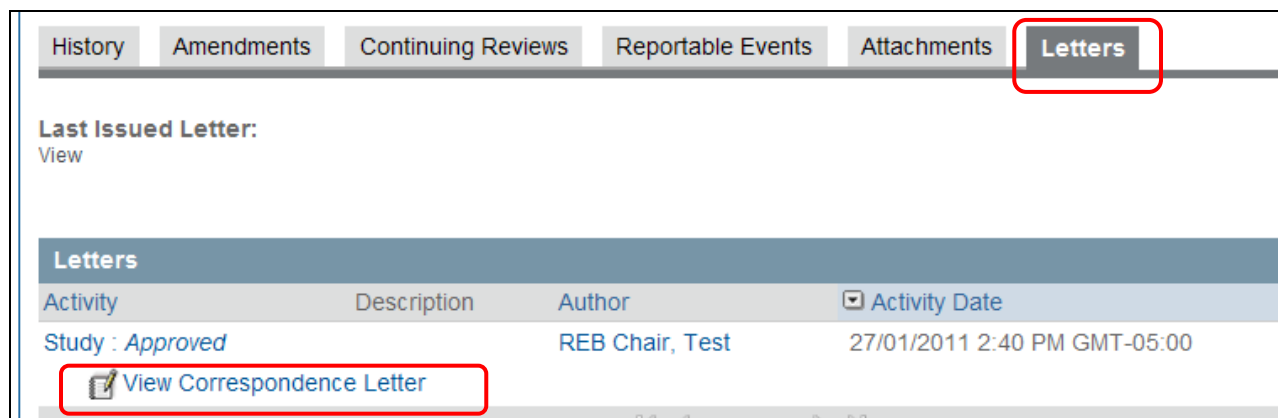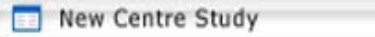
5. Post-Approval Activities

Once a study receives provincial approval, all follow-on submissions are considered post-approval activities. These include submissions of provincial amendments, reportable events and renewals, or submissions of initial centre applications, reportable events and renewals. New activity buttons will appear in the appropriate workspaces for relevant activities.
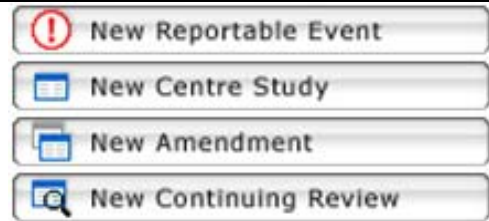
5.1. Initial Centre Application – New Centre Study

Once a provincial application is approved, all centres listed as participating are automatically notified. Select the link in the email, or **Studies** in the navigation bar to open the relevant provincial study. You can *View Application* to view and the application and access all attached documents.
In the provincial study workspace, select

to create your initial centre application.

Contact the OCREB office if you will be conducting the study and your centre was not included in the provincial application.
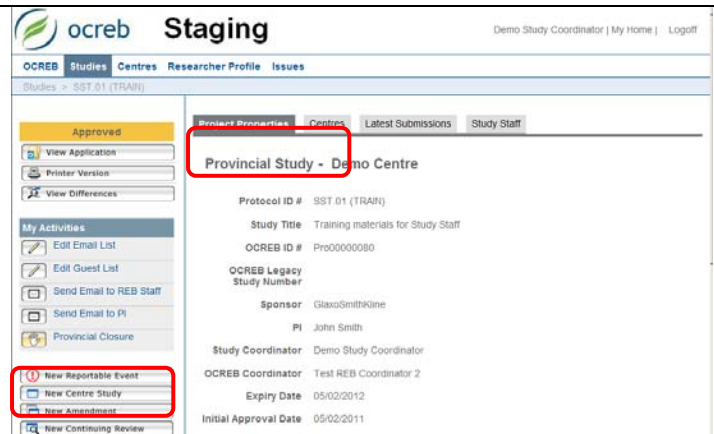
You must complete and *Save* the first page before the study record is created and a unique identifier assigned. Select *Continue* to move to the next page. Questions marked with a red asterisk (*) are mandatory. You will not be allowed to continue to the next page unless these questions have been answered.

Add any other Study Staff members requiring access to the application, including the ability to submit amendments, renewals or reportable events or those who need "read access" only. These additional staff will not receive the notifications.

For initial centre applications only, you must select a Department Approver from a drop down list. If the PI is the primary Department Approver, a delegate must be selected.

If the primary Department Approver is absent, select the delegate Approver. Ensure that Approver selected is the appropriate Approver for your study.
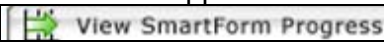
5.1.1. Consent Principles

OCREB approval of your centre application authorizes your centre to use the provincially approved documents. The provincial templates (e.g., consent forms, wallet cards) will appear in the provincial documents section of the centre application. Select *View* to open and save the document(s) locally on your computer. You can also access the documents directly from the Provincial Study workspace by selecting *View Application* and using the **Jump To** menu to go to the appropriate section(s). Make your local administrative changes to the consent (i.e., place it on institutional letterhead, add local contact information) and include any OCREB pre-approved institutional changes. Pre-approved consent changes will automatically populate from your Centre Profile into the centre application form and the approval letter. No other changes except spelling or formatting are authorized without consulting with OCREB, with the exception of the pre-approved language. The version date of the approved centre consent form will therefore remain the same as the provincially approved consent form.

You will not submit your localized consent form(s) with your centre application. However, OCREB may request a copy at any time. Copies of centre consent form(s) are required at the time of renewal.

5.1.2. Finalizing the Centre Application

Double-check that the application is complete by selecting ![View SmartForm Progress].	
This will open up a **Progress** window showing whether each section is 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 to complete it. **Note**: because the **Progress** menu is shared between the provincial and centre applications, you will see both types listed. You only need to review the progress of the centre sections when submitting a centre application.	
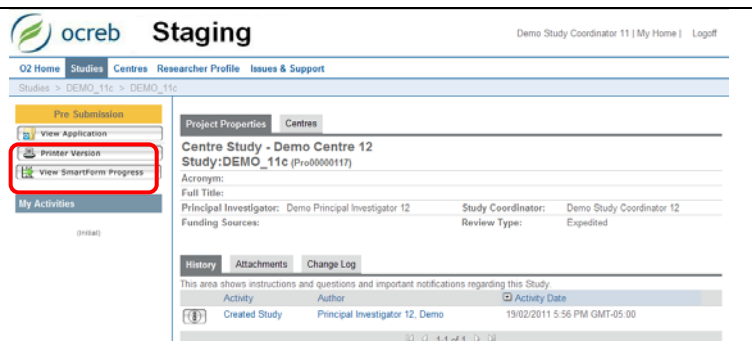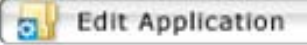
5.1.3. Submitting the Centre Application – Principal Investigator Only

Only the PI has the authority to submit an initial centre application. Review the application by viewing the "Printer Version". You may review and edit the application by selecting ![Edit Application] When you are ready, ![Submit Centre Study]	
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 user directly to the application page in question.	
If the application is complete, the Investigator Agreement window will appear. Check off the box in the bottom left-hand corner, then select *OK* to submit the study. This serves as the official PI signature. Once submitted, the study moves out of **My Action Items** and Study Staff can no longer make any changes.	
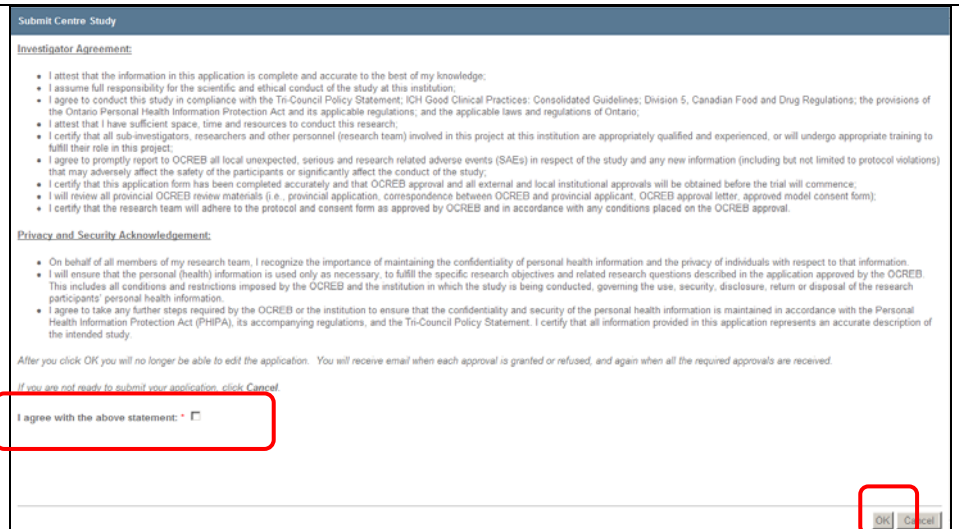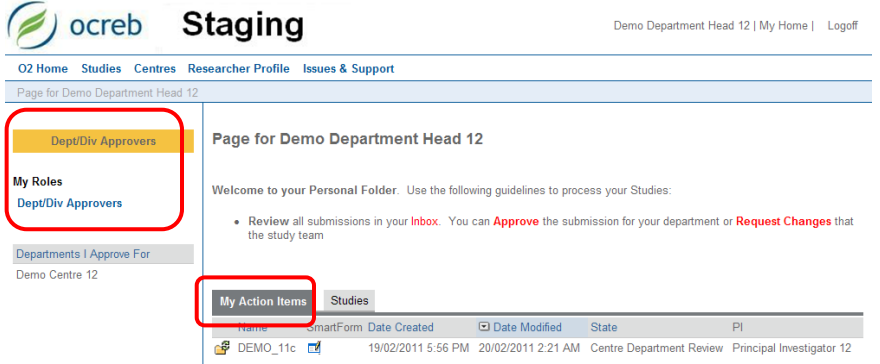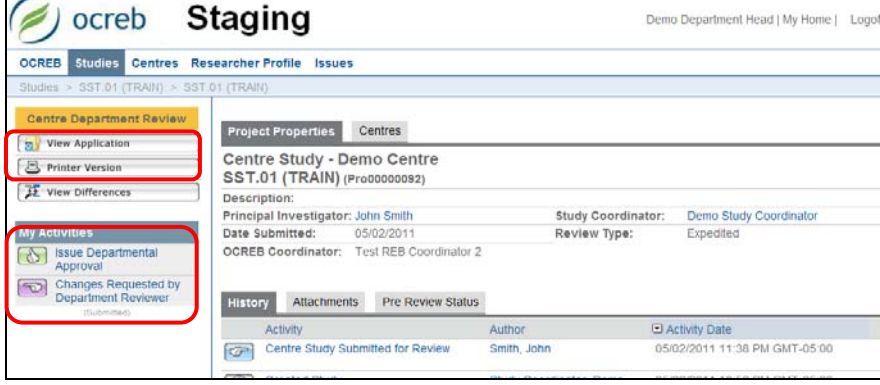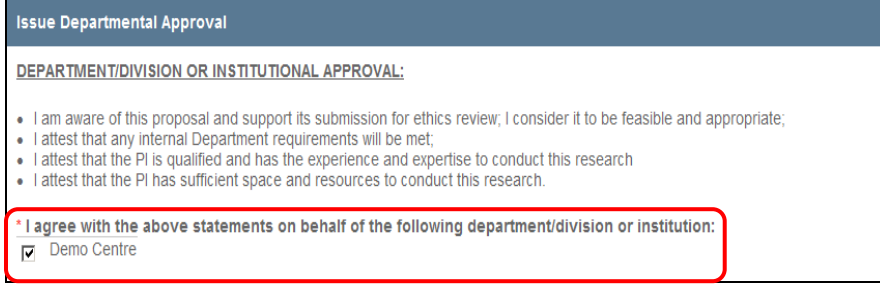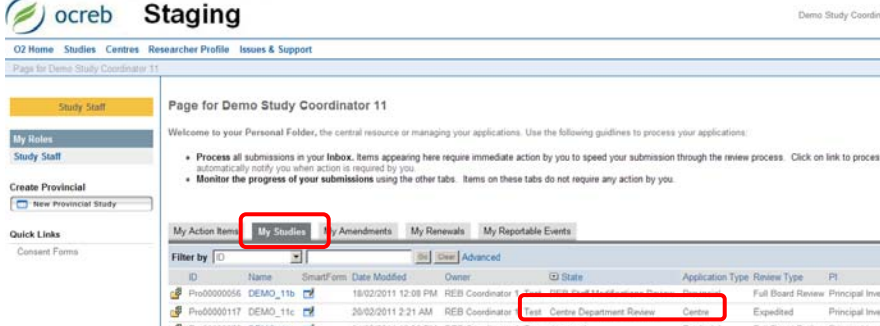
Once the PI submits the initial centre application, it is automatically routed to the selected Department Approver.

!	**The principal investigator must login to officially sign-off on the initial centre application. This activity cannot be delegated; doing so is equivalent to forging a signature**. **Regulatory inspectors/auditors (e.g., Health Canada, FDA, OHRP) may ask investigators to login to O2 to demonstrate how the PI accesses his/her REB study files.**

5.1.4. Department Approvals/Signatories

Login and locate the initial centre application/study in **My Action Items**. Ensure that you select **Dept/Div Approvers** from **My Roles** if you have more than one role in the system. **A PI cannot be Department Approver for his/her own studies.** Select the study name to open the centre study workspace.	
To review the application section-by-section, select "View Application". Select "Printer Version" to print or to review the application as a single document. To approve the application, select **Issue Departmental Approval** To return the application to the PI, select **Changes Requested by Department Reviewer**	
Check off the box in the bottom left-hand corner and then select *OK* from the bottom right to submit the study. This serves as the official Department Approver signature. Once approved, the application is automatically routed to the REB. The state changes to "**REB Staff Review".**	
The PI or Study Coordinator can monitor the progress of the application by checking the "State" column in **My Studies** tab on **My Home** page. The OCREB office will run reports to identify any submissions that have been stalled for two weeks or more. Study Staff will be asked to remind the department approver to sign off on the application.	

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

5.1.5. Contingencies

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

A contingency will always be set for the Board of Record Study Agreement because the OCREB authorized signature is always pending at the time of submission. To view the contingencies, from the **Study** workspace select the **Attachments** tab and scroll down to **Attached Documents - Other**. Note that the *Date Completed* column is blank until the REB Coordinator sets the contingency as "completed".
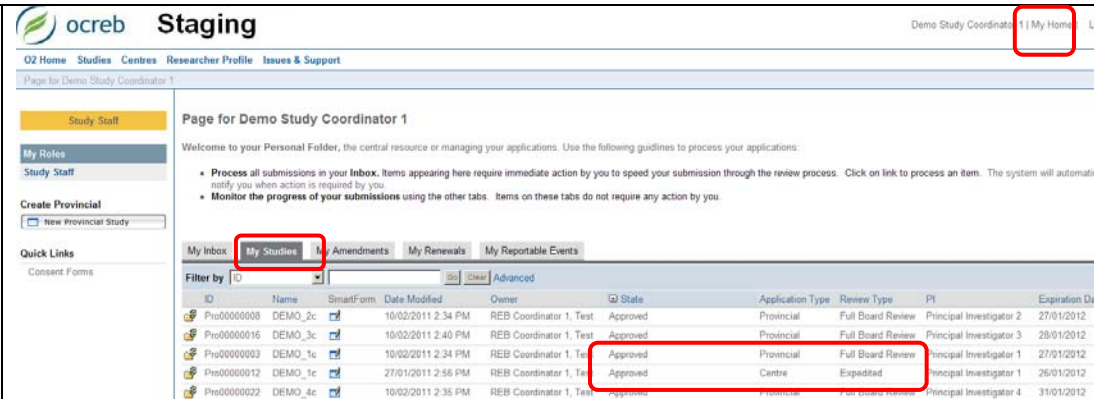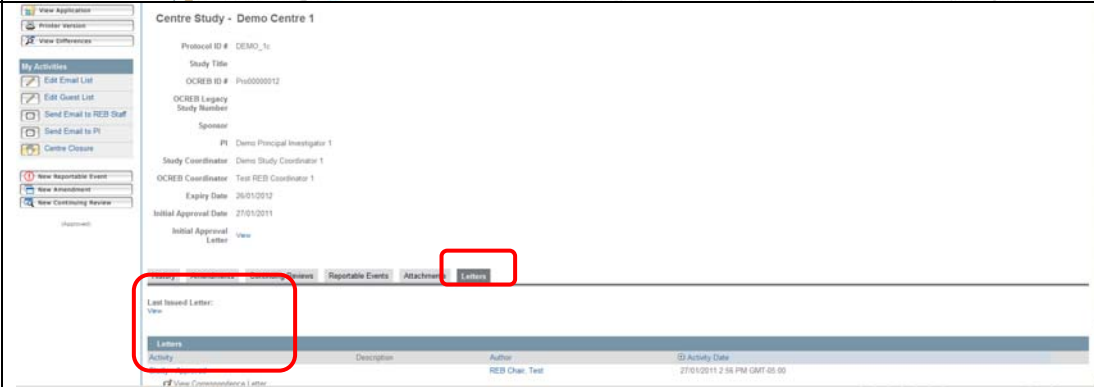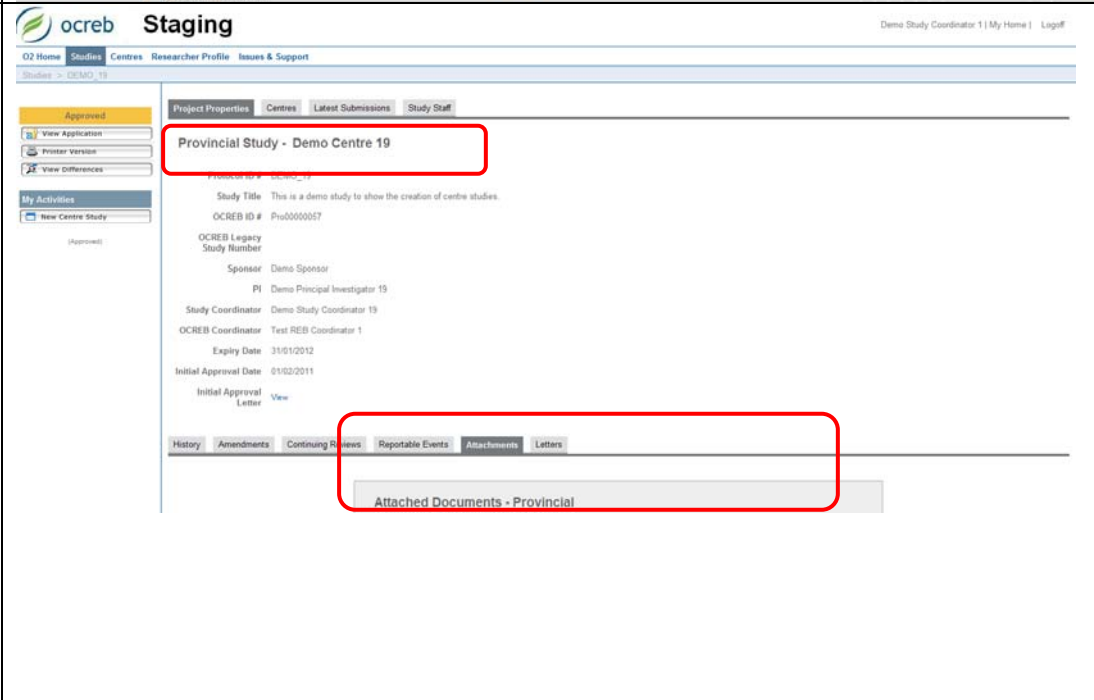
The REB office will upload the fully executed Board of Record Study Agreement (i.e., containing the signatures of all three parties to the Agreement) to the contingency area and change the contingency to "completed". This will allow approval to be issued. Because the REB office cannot modify your application, this is where you can access a copy of the fully executed Agreement should you need to download a copy. Alternatively, you can give your contracts office personnel access to the study.

> ❗ If a provincial amendment is in progress, depending on the timing (i.e., where the amendment is in the review process), your centre approval may include newly approved provincial documents that were not approved at the time you submitted your application.

5.1.6. Accessing Centre Approval Letters and Approved Documents

You will receive an email notice when your centre application is approved. The email will contain a link to the Centre Study workspace where you can access the approval letter.
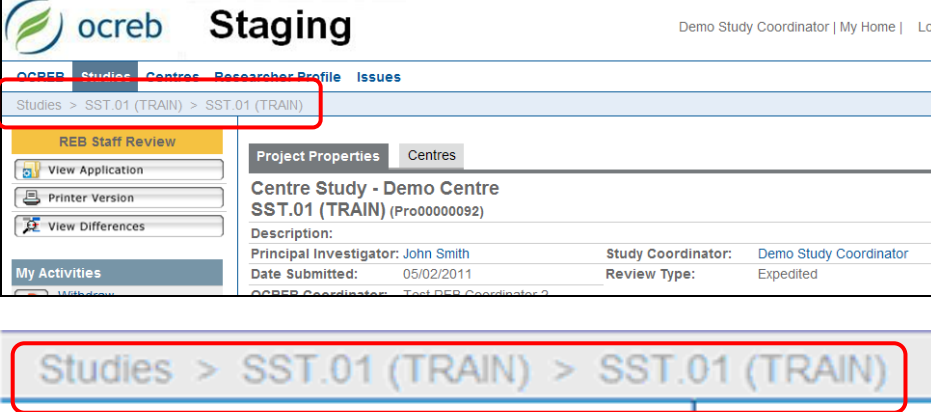
Access the approval letter by selecting **My Studies** from **My Home** page, and locating the **Approved** Centre study.	
Select the relevant study to go to the Centre Study workspace. The letter will be under the **Letters** tab.	
The provincial documents will appear in the "provincial documents" section of the centre application. Select *View* to open and save the consents, wallet cards, etc. on your computer. You can also access the documents directly from the Provincial Study workspace by selecting *View Application* and using the **Jump To** menu to go to the appropriate section(s). Make any administrative and pre-approved changes for use at your centre.	

5.1.7. 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.

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

There are many different ways to tell if you are in or accessing the provincial application/study or the centre application/study:

As a provincial applicant, you 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.	
When you link to a Provincial Study (through a "**Provincial**" tab on the "**Studies**" page), you will see "Provincial Study" in the **Provincial Study** workspace under the "**Project Properties**" tab.	
When you link to a Centre Study (through a "**Centre**" tab on the "**Studies**" page), you will see "Centre Study" in the **Centre Study** workspace under the "**Project Properties**" tab.	
If you see the study name twice in the crumb trail, you are in the **Centre Study** workspace. Go to the **Provincial Study** workspace by taking the crumb trail back to the "parent" from the **Centre Study** workspace.	

> If you are the Provincial Applicant, you 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….

5.2. Amendments

Any changes to the approved ethics application are classified as amendments. A study must be in the approved state before an amendment can be submitted. There are two types of amendments:

- **Full Amendment** – for changes to the consent form or consent procedures, a change in centre PI, protocol changes, investigator brochure updates, etc.
- **Administrative Amendment** – to correct spelling errors, for changes in contact information, for a change in provincial applicant, for translation of approved materials, and for changes in study staff except for the centre PI. Changes to centre PI must be submitted as a full amendment.

Only one request for review of an amendment is allowed at a time. This means that one Amendment must be processed completely (approved, rejected, withdrawn) before another "New Amendment" can be created. However, one amendment can include multiple changes. If a renewal application is open, you will not be able to create a new amendment.

From the **Studies** page or **My Studies** tab, open the approved Provincial Study and select New Amendment Only Study Staff of the Provincial Applicant can create and submit provincial amendments. An amendment has 3 steps:	
1. Complete a "New Amendment" form. Select *Full Amendment* or *Administrative amendment* (or both) and *Finish*. An amendment number is assigned.	
2. The Study now is considered to be modified. Edit Modified Study to update the application with the amended information. This includes uploading new versions of any updated documents. 3. Submit the amendment.	 **Amendments are submitted from the amendment workspace.**

The Study should always reflect the most current information. After a new amendment is created. You must *Edit Modified Study* to make all changes associated with the amendment in the application. The original and all subsequent approved versions of the application are accessible in the **Amendments** tab of the Study workspace.

To upload **revised** documents (e.g., protocol, consent form, IB) with your amendment (i.e., "*modified study*"), *Delete* the version in the application and *Add* to upload the revised version. A record is always retained of the previously-submitted versions.

To add **new** documents (e.g., Consent Update forms, summaries of changes to the protocol or summaries of changes to the investigator brochure, select *Add* to upload to the relevant section of the application.

If you have multiple protocol amendments with one submission, you must upload each amendment/amended protocol and protocol summary separately and clearly name each document (per the sponsor's assigned name/number/letter), and add the appropriate version date of each document in order for each document to be displayed appropriately in the approval letter.

You must manually revise the date in the "**Version Date**" each time you upload a revised document, because once the application is approved, this date field transfers directly into the approval letter as the version date of the approved document.

5.2.1. Opting Out of a Provincial Amendment

All previously-approved participating centres will receive approval of the amendment simultaneously with the approval of the provincial amendment. If the amendment does not apply to your centre, your centre can *Opt Out* of the approved amendment.

5.2.2. Centre-Specific Amendments

Amendments are almost always at the Provincial Study level only. However, there are occasions when centre-specific amendments are appropriate (e.g., change in Centre PI). From the Centre Study workspace, select [New Amendment] and proceed with your centre amendment submission.

Access amendments from the **Amendments** submission type on the Studies page, from the **Amendments** tab in the Provincial Study workspace, or from the **My Amendments** tab on **My Home** page. Once a study is amended, all subsequent amendments will be found in the amendment workspace along with the originally approved application.	

5.2.3. Amendments Involving a Change in Provincial Applicant and/or Centre PI
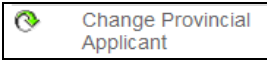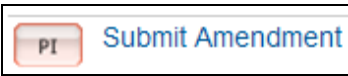
Amendments involving a change in the Provincial Applicant or in the Centre PI are slightly different.

> ⚠️ If your Centre PI is also the Provincial Applicant (PA), and you need to change both (e.g., PI has left your centre), you must change your Centre PI through a full <u>Centre Amendment</u> first. Once the Centre Amendment is approved, submit an <u>Administrative Provincial Amendment</u> to select your new centre PI as the new provincial applicant.
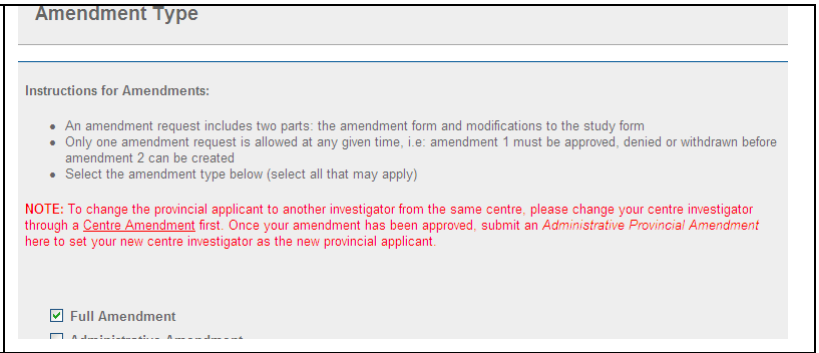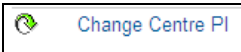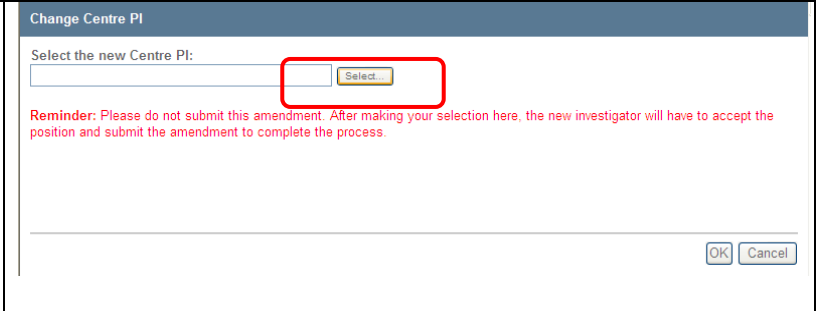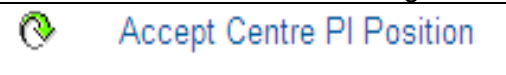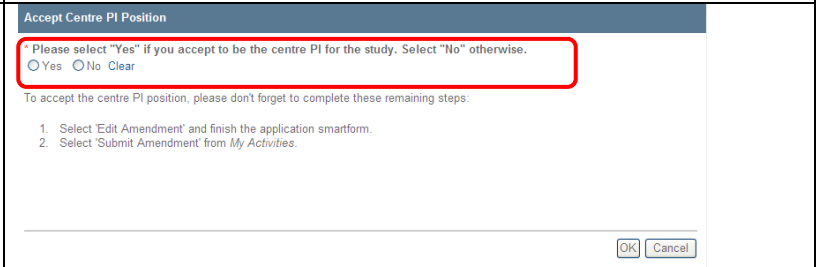
5.2.3.1. Change in Provincial Applicant (PA)

A change in Provincial Applicant (PA) is considered an administrative amendment.

1. From the Provincial Study workspace, create a Provincial *New Amendment* form. Select *Administrative Amendment* and then select "*Change in Provincial Applicant*" from the "*Type of administrative change…*" options. You will almost certainly need to select "*Study Staff Changes*" to change the Study Coordinator to the Provincial Applicant's centre as well. This step is the same as it is with any amendment.	**1.1 Administrative Amendment - General Information** 1.0 * Please select the type(s) of administrative change(s) you wish to make: ☐ Study Staff Changes ☑ Change in Provincial Applicant ☐ Adding a Centre to the Provincial Application ☐ Change in Sponsor contact information ☐ Correction of typographical or grammatical errors (specify below) ☐ Change in CRO contact information
2. Once you *Finish* the amendment form, you will exit to the Provincial Amendment workspace. You now must *Edit Modified Study* to make the changes directly in the application form to reflect the new Provincial Applicant (PA) and new Study Staff (if applicable). This step is the same as it is with any amendment.	
3. EXTRA STEP: select the [Change Provincial Applicant] activity. A "*Change in Provincial Applicant Window*" will appear with a list of PIs at all of the centres that are participating in the study. Select the new PA from the list. The new PA will receive an email notice.	
4. EXTRA STEP: The incoming PA must login and [Accept Provincial Applicant Position]	
5. DIFFERENT STEP: the incoming PA must [PI Submit Amendment] to officially accept the role.	

5.2.3.2. Change in Centre PI
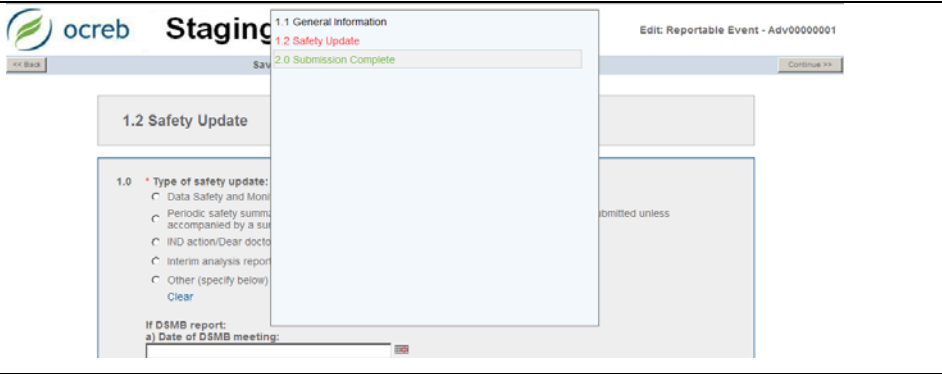
The centre amendment workspace will display an activity to "*Change the Centre PI*". The process for changing your Centre PI is similar to changing the Provincial Applicant except that a change in Centre PI is done from the Centre workspace, and it is considered a full amendment. During the review process, the REB Coordinator will need to remove the outgoing Centre PI from the provincial list of participating centre PIs and add the new Centre PI.

1. From the Centre Study workspace, create a Centre *New Amendment* form. Select "*Full Amendment*" then select "*Change in Centre PI*" from the "*Type of change…*" options. ***Don't forget to select "Administrative Amendment" as well and choose "Study Staff Changes" if the Study Coordinator will also change.***	**Amendment Type** **Instructions for Amendments:** • An amendment request includes two parts: the amendment form and modifications to the study form • Only one amendment request is allowed at any given time, i.e: amendment 1 must be approved, denied or withdrawn before amendment 2 can be created • Select the amendment type below (select all that may apply) NOTE: To change the provincial applicant to another investigator from the same centre, please change your centre investigator through a Centre Amendment first. Once your amendment has been approved, submit an *Administrative Provincial Amendment* here to set your new centre investigator as the new provincial applicant. ☑ Full Amendment ☐ Administrative Amendment
2. *Edit Modified Study* to make the change to the new PI directly in the application form. **This includes uploading a revised Board of Record Study Agreement, signed by the new Centre PI.**	ocreb **Development** — Edit: Initial Submission - MS2_Pro00000798 << Back — Save | Exit | Hide/Show Errors| Print... | Jump To: - 1.1 Study Personnel — Continue >> **1.1 Study Personnel** 1.0 Provincial PI Name: Test Principal Investigator 1 Provincial Centre Name:Credit Valley Hospital 2.0 * Centre Principal Investigator: Test Principal Investigator 2 [Select...] [Clear] 3.0 * Study Coordinator (or designated contact):
3. EXTRA STEP: select the [Change Centre PI] activity and select the new Centre PI. The PI will receive an email notice.	**Change Centre PI** Select the new Centre PI: [_____] [Select...] **Reminder:** Please do not submit this amendment. After making your selection here, the new investigator will have to accept the position and submit the amendment to complete the process. [OK] [Cancel]
4. EXTRA STEP: The incoming PI must login and [Accept Centre PI Position]	**Accept Centre PI Position** * Please select "Yes" if you accept to be the centre PI for the study. Select "No" otherwise. ○ Yes ○ No Clear To accept the centre PI position, please don't forget to complete these remaining steps: 1. Select 'Edit Amendment' and finish the application smartform. 2. Select 'Submit Amendment' from *My Activities*. [OK] [Cancel]
5. DIFFERENT STEP: the incoming PI must [PI Submit Amendment] to officially accept the role!	

> **!** When changing to a new Centre PI, the modified centre application must include be modified to reflect the change in PI. In addition, a new Board of Record Study Agreement signed by the incoming PI must be uploaded.

5.3. Reportable Events

"*Reportable Events*" is a broad term covering multiple safety-related submission types. *Reportable Events* may include local SAEs, protocol deviations and privacy breaches at the centre level, and safety updates, DSMB reports, IND Action letters, and external SAEs at the provincial level. Multiple reportable events can be submitted at one time; however, only one type can be submitted per reportable event form. The Provincial Study must be in the "**Approved**" state before provincial reportable events can be submitted. The Centre Study must be in the "**Approved**" state before centre reportable events can be submitted.

From the Provincial or Centre workspace (as applicable), submit centre or provincial reportable events by selecting (!) **New Reportable Event** A "*Reportable Event Information*" form will appear. Once it is saved, the reportable event is created and a unique number is assigned.	
Select *Continue* to complete the reportable event form. Different questions will appear depending on the type of reportable event. A reportable event workspace is created. Access reportable events from the **Reportable Events** submission type on the Studies page, from the **Reportable Events** tab in the Study workspace, or...	
...from the **My Reportable Events** tab on **My Home** page.	

> ❗ The local SAE form requests the system organ class (SOC) of the event and links to either the NCI Common Terminology Criteria for Adverse Events (CTCAE) v 3.0 or v4.0 for guidance on correctly naming the SAE. Upload a copy of the sponsors reporting form **signed by the PI** in the appropriate section of the SAE reportable event form.

5.4. Renewals

Ethics approvals are granted for one year unless otherwise indicated. Study Staff will receive email reminders when renewal deadlines are approaching (60, 30, 15 and 1 day in advance of the expiry date). Centres must submit individual centre renewal applications. In addition to their *centre* renewal application, the Provincial Applicant Study Staff must submit a *provincial* renewal application.

> ❗ If renewal applications are not received by the expiry date, ethics approval will expire, a suspension notice will be issued, and no further activities will be available in O2. Study Staff will need to contact the OCREB office for further instructions regarding requirements for initiating a re-approval for the study.

5.5. Study Closure

The "**Close Study**" activity will appear when your study is approved and there are no outstanding amendments, renewals or reportable events. All participating Centres must submit their study closure application and be closed by the REB before the Provincial Study closure application can be submitted and the study officially closed by the REB.

> **!** Once OCREB acknowledges the study closure, the study/application cannot be reopened.

6. System Notifications

The O2 system automatically generates email notifications to the Study Staff (SS) at various stages/states in the review process. Emails are automatically generated with the following activities:

- When the REB issues requests for changes or clarifications, the SS at the submitting centre are notified;
- When the initial provincial study/application is approved, SS at all centres listed as participating are notified;
- When provincial amendments are submitted, SS at all participating centres are notified;
- When formal decisions are issued (e.g., approved, expired), SS at all participating centres are notified;
- When there is a change in provincial applicant or change in Centre PI, the incoming PA or PI is notified so that he/she can login and officially accept the role.

7. Issues & Support

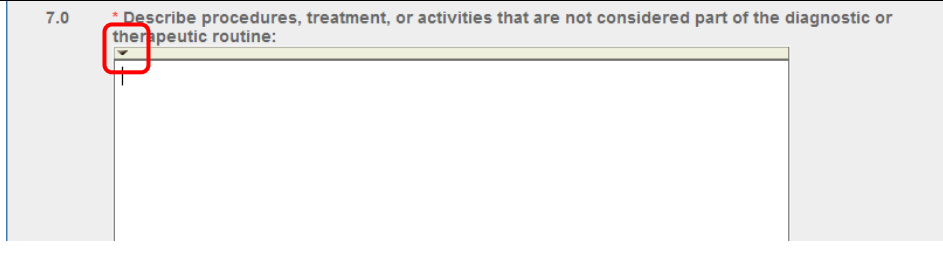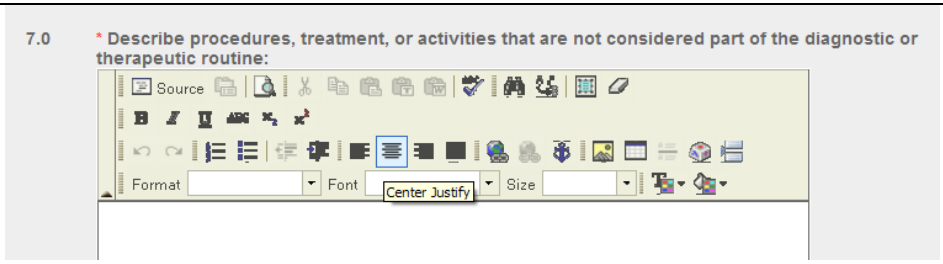|	
Select **Issues & Support** from the navigation bar and then **Ask a Question** to submit an issue. Or, check the **FAQs** tab for questions and answers submitted by other users.	
Selecting the **Ask a Question** activity will open up a new issue form. Please be as specific as possible if you are describing an issue (e.g., where you were in the system and the time, what activity you were performing or tying to perform and what happened). You can also upload screenshots or documents. Screenshots are always helpful in characterizing an issue!	

8. Application "States"

Anyone with access to O2 can monitor the progress of an application by viewing the current state of the application. The state changes as the application moves through the ethics review process. Below is a table of many, but not all, of the possible states and a description of the state.

Pre Submission	The application has been created by the Study Staff but not submitted to the REB. In this state Study Staff can continue to edit the application.
REB Administrative Review	The application has been received by the REB office, and is under review by the Intake Coordinator. Study Staff can no longer edit the application.
REB Staff Review	The REB Coordinator reviews the application and sends it back to the Study Staff for changes, or assigns it to a meeting (if full Board review required), or to a designated REB member (if it meets the criteria for expedited review) as applicable.
Changes Requested by REB Staff	The REB Coordinator identifies concerns during review of the application and sends it back to the Study Staff to edit and resubmit.
REB Staff Modifications Review	The modified application is under review by the REB Coordinator responsible for the study ("Owner").
Assigned to REB Meeting	The application has been assigned to an REB meeting and is ready for review by the REB members.
Meeting Complete Awaiting Correspondence	The REB meeting is finished and the study is awaiting the REB coordinator to draft either a review letter or an approval letter, as applicable.
Pending PI Response	If changes are required by the REB, a review letter is issued and the application is sent back to the Study Staff to respond to, edit and resubmit.
REB Chair Correspondence Review	Draft review or approval letters are under review by the Chair. The Chair can send the letters back to the REBC for changes, edit the letter, or approve the letter and issue it to the PI, which serves as the Chair's formal signature.
Designated Reviewer Modifications Review	The modified application/PI response is under review by a designated REB member.
Centre Department Review	The initial centre application has been submitted to the department head/approver for review. The department approver can approve the application, which routes it directly to the REB, or request changes, which routes it back to the PI/Study Staff.
In Expedited Review	The submission meets the criteria for expedited review (also referred to as "delegated review") and is under review by one or more REB members. Initial centre applications default to expedited review unless concerns are identified during the review.
Drafting Approval Letter	The REB reviews are complete and the REB Coordinator is drafting the final approval letter, which is routed to the Chair for final review and approval.
Approved	OCREB has approved the submission.
Acknowledged	Many types of submissions are acknowledged rather than approved (e.g., reportable events). The state changes to "Acknowledged" once REB review is complete.

9.   Tips

This section contains tips to optimize the use of O2. Please forward any suggestions.

9.1.   Formatting, Copying & Pasting

Whenever you see a down-facing arrow in an application field, it means that the field can be formatted. Click on the arrow to open the formatting tool bars.	
You can now format the text (e.g., bullets, numbers). You may wish to format the information in a Word document first, or cut and paste into this field from the protocol or consent form and then format the information directly in the application.	

9.2.   Working with Multiple Windows

It can be useful to display two windows side-by-side to see O2 and another document at the same time (e.g., O2 and this guide). Right click on links to open an item in a new window. Manually resize and position the two windows. If you have Windows 7, the two windows will snap together automatically.

To view two windows side-by-side (e.g., protocol or consent form and application), reduce the size of the windows and drag them together. 	

9.3.   Windows Computer Tips

- Holding down the "CTRL" button on your computer keyboard and scrolling with a mouse wheel allows you to change the zoom level of a page displayed on your computer screen.
- Hold "CTRL" + "F" to search within a document.
- Use "ALT" + "TAB" to switch between windows.

9.4.   Reminders:

- If you fail to successfully login after five (5) attempts, the system will lock you out and you will need to call O2 Help to have your password reset.
- The first page of an application must be created and saved before the study record is created.

- Once a reference number is generated, the form can be saved and modified at any time until it is submitted. Select "Exit" to save and exit without completing all mandatory questions on a page.
- Selecting "Back" or "Cancel" will allow you to exit from an activity before it is activated.
- You may copy and paste into application fields from external documents. A field with a down-facing arrow means that the field can be formatted. Click on the arrow to open the formatting tool bars.
- Questions marked with a red asterisk (*) are mandatory
- If you are the Provincial Applicant, you must add your own centre as a study location in order to be able to submit your centre application.
- If you are the Provincial Applicant, you will see all Centre Applications associated with that Provincial Study. In other words, as the parent, you get to see the actions of all of your children.
- A session will time out if the system is idle for 60 minutes and the user will be prompted to enter their username and password to continue.
- Using the *Jump To* menu to navigate from page to page as you work through the application instead of *Continue* will override the SmartForm feature that shows or hides questions as applicable to your study. However, using the *Jump To* menu is a very good way to come back to a page that your were previously working on. We strongly recommend that you use the *Continue* button to move to the next page when you are filling in an application.
- Pressing *Finish* does not show any errors or missing items in the application. Always *View SmartForm Progress* to check for incomplete sections before submitting.
- The Study should always reflect the most current information. Any changes to the Study/application are considered amendments.
- New Amendment forms briefly describe what has changed. After the amendment is created, you must *Edit Modified Study*" to make all of the changes associated with the amendment directly in the application, which is a living document.
- The original approved submission and all subsequent approved versions are accessible in the **Amendments** tab of the Study workspace.
- To upload **revised** documents (e.g., protocol, consent form, IB) with your amendment (i.e., "modified study"), *Delete* the version in the application and *Add* to upload the revised version. A record is always retained of the previously-submitted versions.
- You must manually type in the "Version Date" each time you upload a revised document, because once the application is approved, this date field transfers directly into the approval letter as the version date of the approved document.
- Only one request for review of an amendment is allowed at a time. This means that one amendment must be processed completely (approved, rejected, withdrawn) before another "New Amendment" can be created. However, one amendment can include multiple changes. If a renewal application is open, you will not be able to create a new amendment.
- Amendments are submitted from the amendment workspace.
- You can provide your contracts office personnel with access to the study from the centre application
- When changing to a new Centre PI, the modified centre application must be revised to reflect the change in PI. In addition, a new Board of Record Study Agreement must be signed by the incoming and uploaded in the modified application.
- A PI cannot give department approval for his/her own studies.
- You can grant and remove read access to other users using the *Edit Guest List* activity (e.g., sponsor monitors) on a study-by-study basis. However, the person must first register in O2 and be granted an O2 account before they will appear in the "guest list".
- Select *Printer Version* to view the application in its entirety or to print it. You can print to *.pdf to save a copy of the application forms locally on your computer.
- If renewal applications are not received by the expiry date, ethics approval will expire, a suspension notice will be issued, and no further activities will be available in O2.
- Once OCREB acknowledges the study closure, the study/application cannot be reopened.
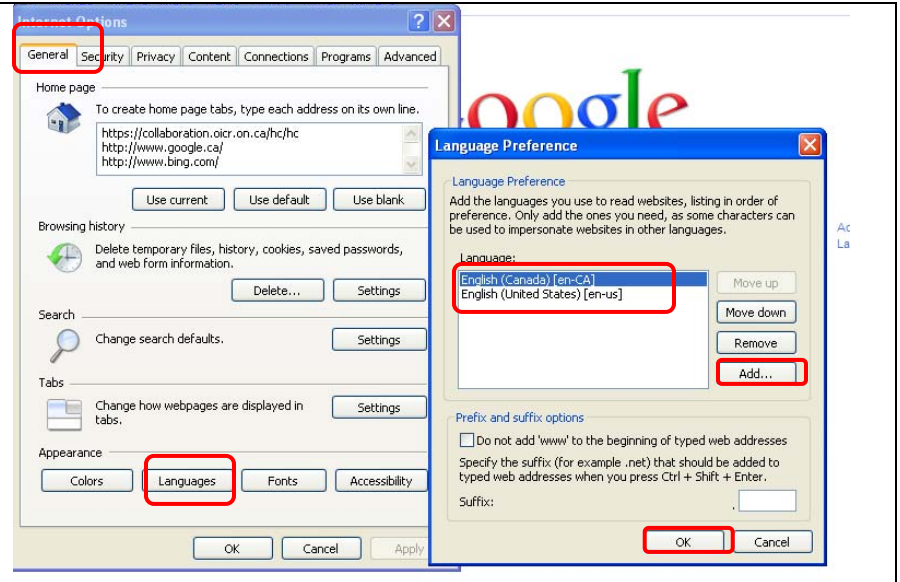
9.5. Changing the Date Format:

9.5.1. Changing the Date Format in the Brower:

Date formats in browsers such as Firefox, Internet Explorer and Safari can be changed. Depending on the browser, there are different methods for changing the date format. Safari's date formats are controlled by the OS X date format and language settings, which can be found in the International Setting section of the Date Time system preference window. Firefox and Internet Explorer date formats are controlled by the language set for each browser in the browser's preferences. We recommend that you change your date formats to "English (Canada)".

To change the date format in Internet Explorer:

1. In the browser, choose Internet Options from the Tools menu.
2. Click the *Languages* button on the **General** tab.
3. Click "*Add*" to add another language to the list. Make sure "English (Canada)" is at the top of the list.
4. Select "*OK*".
5. Restart the browser.

You must also change the date format on your local computer (see next section for Windows)

To change the date format in Firefox (Mac OS X):
1. Choose Preferences from the Firefox menu.
2. Click the Languages button on the General tab.
3. Click "Add" to add another language to the list. Make sure the desired language is at the top of the list.
4. Restart the browser.
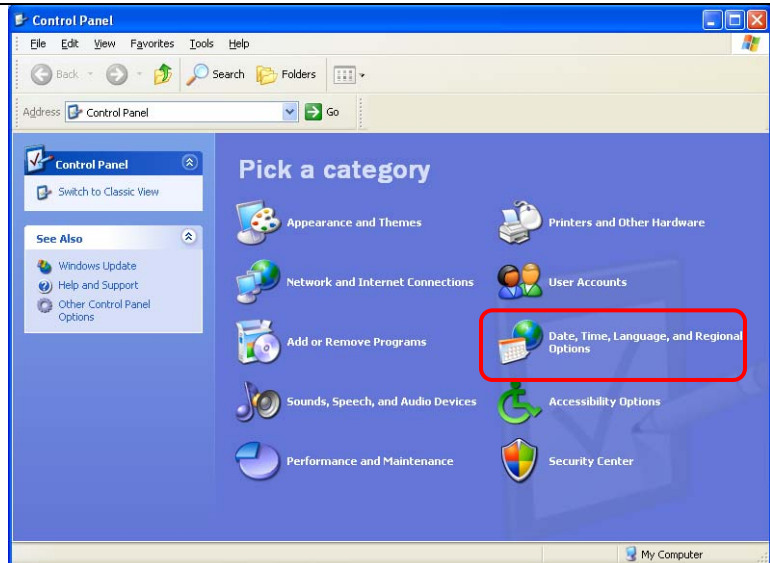
To change the date format in Firefox (Windows):
1. Choose Options from the Tools menu.
2. Click the Advanced icon and choose the General tab.
3. Click the Choose button to select the desired language.
4. Click "Add" to add another language to the list. Make sure the desired language is at the top of the list.
5. Restart the browser.
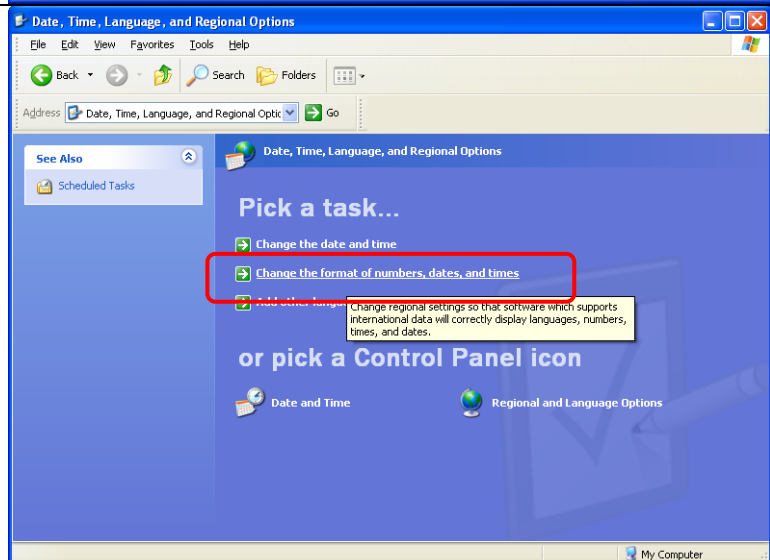
To change the date format in Safari (Mac OS X):
1. Choose System Preferences from the Apple menu and click Date and Time.
2. Click the Open International button.
3. Set the language with the desired format at the top of the languages list.
4. Verify that the desired format appears on the Formats tab. If it does not, switch the Region or click the customize button to modify the format.
5. Restart the browser.

9.5.2. Changing the Date Format in Windows:

1. From the "*Start*" menu, go to the "Control Panel". 2. Select the "*Date, Time, Language, and Regional Options*" category.	
3. Under "Pick a task…" select "*Change the format of numbers, dates and times*"	
4. Select "*English (Canada)*" from the drop-down menu. 5. Select "*Apply*". 6. Restart the computer.	