Bellberry Limited supporting research and ethics

Investigator e-Protocol User Guide

Updated 14/6/2012 - Event History Changes

Investigator User Guide

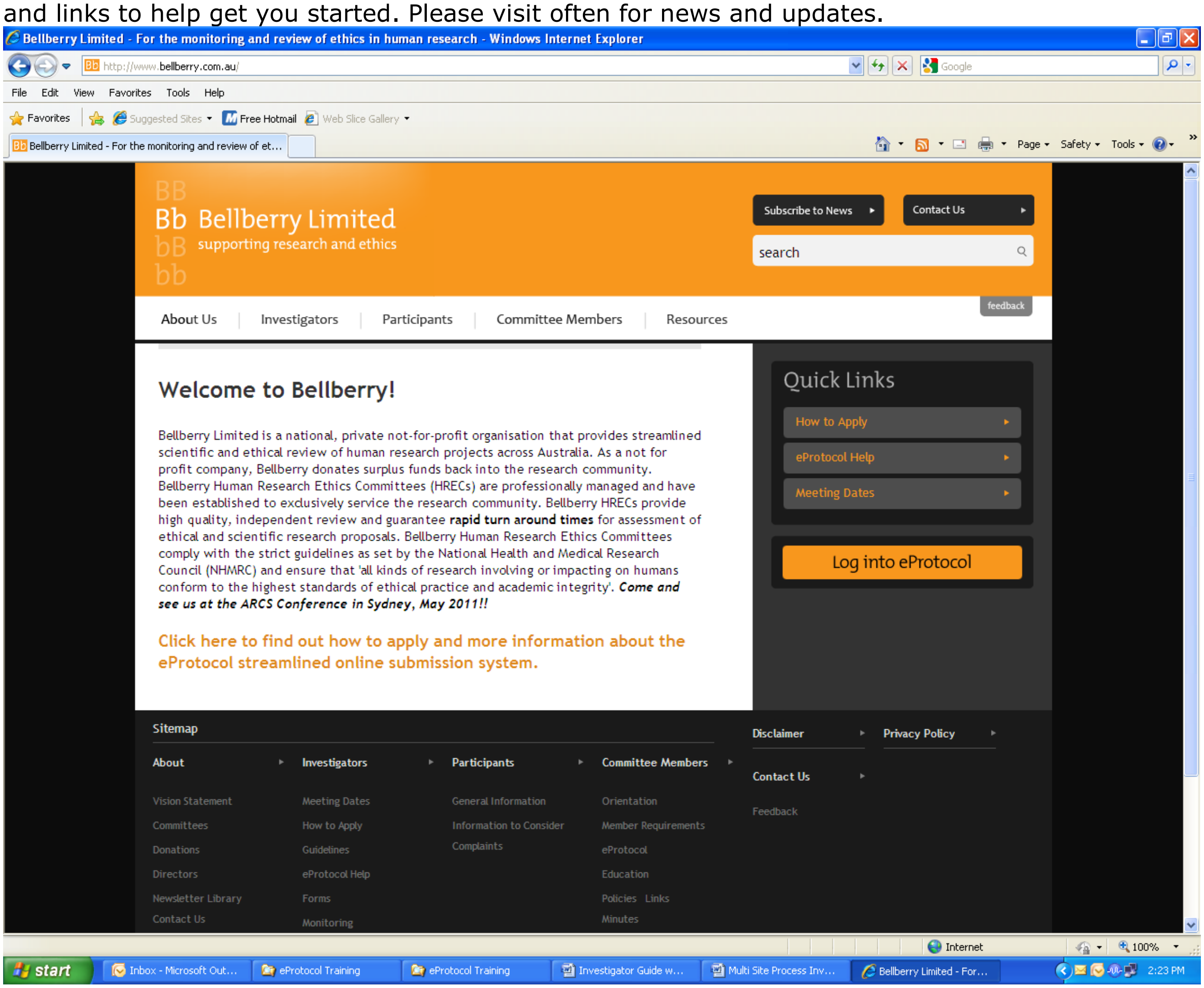
Getting Started

Before You Start

Please log on to www.bellberry.com.au and you will be able to access the eProtocol log in button on the RHS of the screen.

Be sure to click and "subscribe" to ensure you receive Bellberry news and eProtocol updates.

The Bellberry website has the answers to many common questions and the 'Investigator' section provides a wealth of information on regulations, guidelines and Bellbery Policies. It has information and links to help get you started. Please visit often for news and updates.



Here are some Tips for Success in eProtocol

- ***Use a recommended browser.***

eProtocol is compatible with the most popular browsers, including Internet Explorer, Safari, and Mozilla Firefox. However, if you do not have a strong browser preference, we recommend the following:

If you are on a ***Windows*** machine, use ***Internet Explorer V 6 & 7***.
If you are on a ***Mac*** machine, use ***Safari***.

- ***Allow pop-up windows.***

Pop-up blocking software prevents the eProtocol application from opening certain windows. You'll need to make sure that your browser has all pop-up blocking software disabled while using eProtocol.

See link to e-protocol tips in the website for more information on configuring your browser to allow pop-ups or see the Troubleshooting section.

- ***Avoid using your browser's BACK button.***

This will avoid taking you out of the system, instead, use the menus and links within the application to navigate.

- **SAVE frequently**

eProtocol will time out after 5 minutes of inactivity. Only actions which cause the page to refresh or reload (such as saving or navigating to a new section) are indications to the system that your session is active.

- **Read the Instructions/Help**

Many pages in the application offer instructions right on the page to help guide you and answer the most common questions.

- **Be patient.**

Some processes can take a minute to run. Although data is loading, your browser may not indicate activity.

- **Sign Out when done.**

Always click “Sign Out” and shut down your browser completely (close all browser windows) when you are finished using eProtocol. This will not only help keep your information secure, but will also release any edit locks you may have had on protocols, and allow your colleagues on the project to open the protocols in edit mode.

- **Creating Application Tips**
- Ensure you create the application under the correct Investigators Name
- Don't delete documents when updating versions in the Attachments section
- Ensure you use the correct document heading when you attach your document, particularly for multi site applications. The document names are the names of the documents that appear in the Approval/Acknowledgement letters. When updating versions or adding further documents do not delete documents. If you do not want 'clean' to appear in the document heading do not include it.
- If you are copying and pasting from another document into the Study Title when creating the application, if there are ' or " " in the heading please delete these symbols and re enter these characters from the keyboard. The software currently has an issue with these characters.

Who can log in?

Anyone wishing to submit an application must apply for a User ID and Password by registering on the eProtocol homepage. A user ID should be surname then initial e.g. SmithA. ***Ensure you include the Organisation Name and the site address***. Select the Register button and complete and submit the form.   Your application will be validated and an email with your access details will be emailed to you.

Please ensure that all people that will be involved in the study i.e. the Principal Investigator, Co-Investigator and any other nominated contact is registered.   *As per the National Statement guidelines, sponsors are unable to submit applications on behalf of the Investigator.*

When you log on to the system for the first time you will be asked to change your password.

Passwords will need to be a minimum of 8 characters with 3 or 4 of the following:
Lowercase
Uppercase
Numbers
Symbols (!,@,#,$,%,^,&,* etc)

Change Password

If you wish to change your password, click on the **Change Password** button on the Top Right Hand Corner of the Screen (next to the Sign Out button). It will prompt you to enter your existing password and then enter in your new password. SAVE.

Who can create applications?

A nominated contact from another organisation is able to prepare applications. To do so approval must be sought from the Principal Investigator by completing the Nominated Contact Authorisation Form. This form provides authorisation from the Principal Investigator for the nominated contact to create the application. This form now covers all future studies for a PI as a 'blanket authorisation' until otherwise advised by the Principal Investigator. Therefore approval is not required for each study.

CRO's or Lead Sites for Multi-Centre Applications

You will need authorisation from the Principal Investigator as detailed above and a registration (USER ID) for **each** organisation. Please use your surname and organisation name for the User ID i.e. SmithJ – organisation name.

Please ensure that a nominated contact from the site is also included. i.e. the Trial Co-Ordinator.

System Requirements

To access the eProtocol application, you'll need a computer with an Internet connection.

- If on a Windows computer, use Internet Explorer (IE) as your browser.
- If on a Macintosh computer, use Safari as your browser.
- Pop-up blocking software must be disabled (pop-ups must be allowed) while using eProtocol. See instructions for allowing pop-ups in your browser.

Access to Submitted Applications

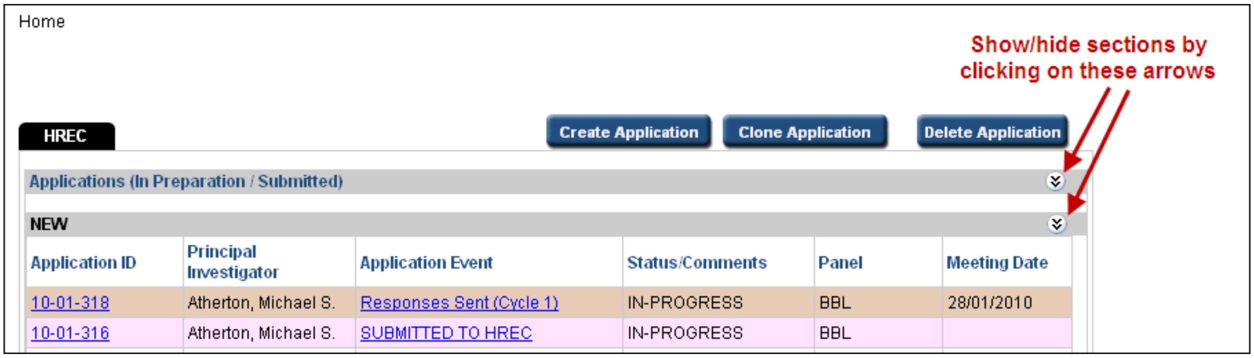
Once logged in to eProtocol, you will have access to see all those (and only those) applications for studies on which you have been listed in the *Personnel Info* section. You will only have access to edit those studies/applications on which you are listed as either:

- Principal Investigator
- Co-Investigator
- Nominated Contact

You must have edit access for a particular study in order to start an amendment or Ethics Approval Extension application for that study.

Understanding your eProtocol HOME page

The first page you encounter after logging in to eProtocol is your HOME page. Your HOME page has two main sections that display all of the studies on which you have been listed in the *Personnel Info* section. This is how the sections appear.



You can expand or collapse these two sections by clicking on the arrows on the right of the grey section bar as shown above.

Applications (In-Preparation/Submitted)

Think of this as your "work-in-progress" area. It displays all of your applications that are not yet approved. This includes applications you have just begun working on (new, amendments, Ethics Approval Extension), as well as those that have been submitted and are in various stages of the Bellberry HREC review process. Applications will be displayed here until they are officially approved in the system.

The application number has been recently updated. The number will have a letter and number after the form to assist in event tracking of the document submitted.

A-1 **Amendment 1** **FR-1 Final Report 1**

AER –1 **Adverse Event 1** **PRE-1 Progress Report/Extension 1**

PVR -1 **Protocol Violation Report 1**

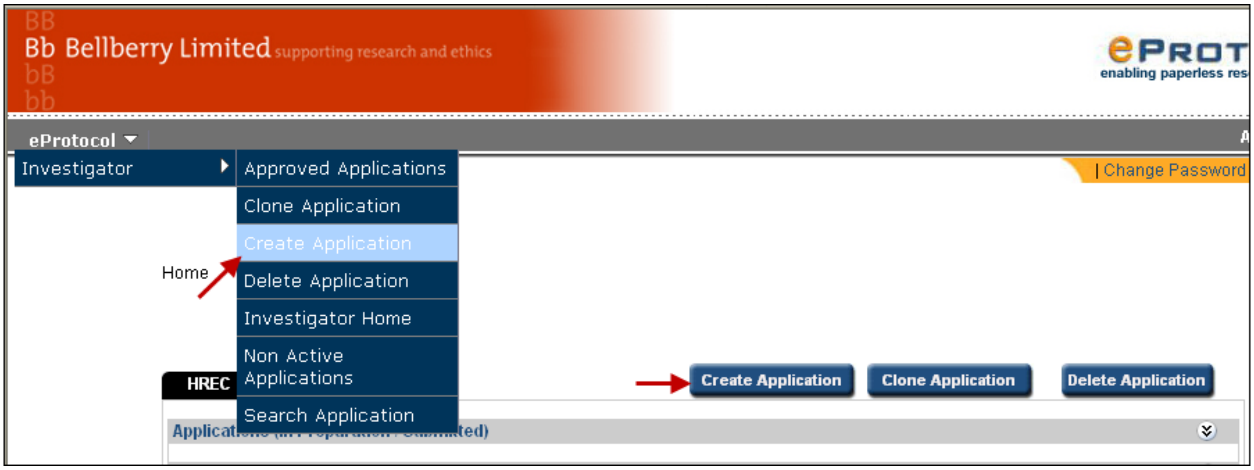
Applications (Approved)

Think of this as your "work-completed" area. It displays a listing of your approved applications. Click on an application number from the list to have the option to view the most recent approved version of the application, or to start an amendment or Ethics Approval Extension. Remember, the option to start an amendment or Ethics Approval Extension is only available to those listed on the application in a personnel role that grants EDIT access.

Working with Applications

Create a new Application

There are two ways you can create a new application, from scratch or from a copy of an existing application/study. LOGIN to eProtocol at www.bellberry.com.au



Create a new application from scratch

To create a new application, simply click on the CREATE APPLICATION button in the upper right-hand corner of your HOME page or click on CREATE APPLICATION option in the menu. You will need to enter basic information (such as Study Title, Personnel Information) before your application form is generated, a Bellberry Reference number assigned, and the initial information that you have entered is saved.

TIP: make sure you include the Protocol Number in the Study Title. This will ensure it appears on your page header in the system.

Once you have your application number, you may continue to complete the application, or exit the system and return at a later time to complete.

PLEASE NOTE: *If after entering the title, personnel info, nothing happens when you click CREATE, then you have pop-up blocking software on in your browser. Even if you believe you have allowed pop-ups, there may be additional toolbars, etc. that are blocking your pop-ups.*
See User Tips/Instructions for allowing pop-ups in your browser.

Multi-Centre/Site Applications

Multi Centre Research – A Research project undertaken by a group of institutions (or individuals) at one or more sites.

Multi Site Research – A research project undertaken b a single institution at more than one location as outlined by the NHMRC.

Multi-Centre Research Procedure

- **CREATE A NEW APPLICATION** (this form is completed in the same way as any new application)
- Click on the CREATE APPLICATION button (upper right hand corner of home page), or CREATE APPLICATION option in the menu
- Enter basic information (such as Protocol Title, Personnel Information)
- Application Form will then be generated
- Bellberry Reference number will be assigned
- Initial Information will be saved

FILLING IN AN APPLICATION FORM
(*see page 11 of Investigator Guide*).
Please complete ALL details for Principal Investigator, Co-Investigator (if applicable), Nominated Contact(s), and Tax Invoice.

Once the form is completed, select **CREATE**.

Are you the lead site?

YES

COMPLETE THE APPLICATION:

- Site/Location Details
- Sponsor
- Application Information pages 1-6
- Application page 7

NO

COMPLETE THE APPLICATION:

- Site/Location Details
- Sponsor
- Application Information pages 1-6
- Application page 7: **No documents will need to be attached until the lead site is approved.**

SUBMIT the application

TROUBLESHOOTING:
If after entering the title and personnel information nothing happens when you click CREATE – check pop up blockers are turned off (there may be more than one toolbar)

TIP: Once you have the application number, you may continue to complete the application, or you can exit the system and return later to complete the application.

TIP: It is recommended that you have at least one additional Nominated Contact to allow for access to studies if one contact is not available.
A new contact can only be created by someone who already has access to the study (an existing investigator or Contact).

TIP: If the Principal Investigator is the Nominated contact then only the PI section needs to be created.

IMPORTANT NOTE: It is very important that the protocol number information be entered in exactly the same format as the Protocol number of the lead site (*this includes capital letters, spaces and dashes*). The study title should also be the same as the lead site study title. The Protocol number creates the link to the lead site application.

IMPORTANT NOTE :
Please name all attachments as you would want them named in the approval letter.

Where possible, name documents that are common to the lead site, in the same format as the lead site.

After Approval of the Lead Site

LEAD SITE: Will receive notification of approval, and the approval letter will be attached in eProtocol.

ADDITIONAL SITE: Will receive notification through eProtocol that the lead site has been approved, and a request to submit the site specific documents based on the approved documents.

REMINDER:
Please name any attached document as you would like it to be listed in the Approval Letter, and where applicable following the format of the lead site

IMPORTANT NOTE: If the additional site application is submitted AFTER lead site approval, a copy of the latest version of ALL approved documents should be submitted in addition to the site specific documents. *This is to ensure that any post approval amendments are included.*

PREPARING SITE SPECIFIC APPLICATION:

- Go to your home page
- Click on the Application ID
- Open in Edit mode
- Go to Application Information (*left hand side blue table*)
- Click on Page 7 (*top of the screen*)
- Attach site documents based on the approved documents from lead site. This includes the PISCF, and any other site relevant documents which may include advertisements, and any state specific requirements.
- **SUBMIT** Form (left hand side blue table)

ADDITIONAL SITE REVIEW

The application will be sent to the HREC for an expedited review based on the approval of the lead site.

This will be conducted outside a meeting. It will therefore not be necessary to a book a meeting date for additional sites.

TROUBLESHOOTING:
Once an application is submitted to Bellberry you cannot add any further documents until the application is returned to you.

If the application is submitted and the Investigator requires further documents to be added:

Contact Bellberry-Depending on the stage at which the application is at, the application will be returned to you to add the documents, or you will be requested to email the document(s) and they will be attached into the eprotool application by Bellberry.

APPROVAL
If the Committee raises any questions they will be sent to the Principal Investigator for response.

If there are no comments, or once Committee comments are addressed, the approval will be completed.

The approval letter will appear on the site's application.

Filling in an Application Form

Home » Create Application

Study Title Create Cancel

☑ HREC

HREC

◉ HREC Application Form

Principal Investigator *

Note: To enable this application to be processed it is essential that proof of current medical indemnity for this research project is attached for each investigator and co-investigator. First time applicants to Bellberry HREC must also attach proof of medical registration and a copy of their Curriculum Vitae. This is to include work history, postgraduate training, professional college affiliations, publications listings, and research trials experience. Please Attach in the Attachments Section.

Name	Degree (MD/PhD/MS)	Title
Atherton, Michael S.		
E-mail	**Phone**	**Fax**
michael@gmail.com	(999)999-9999	(999)999-9999
Post Code		

Co-Investigator

Note: To enable this application to be processed it is essential that proof of current medical indemnity for this research project is attached for each investigator and co-investigator. First time applicants to Bellberry HREC must also attach proof of medical registration and a copy of their Curriculum Vitae. This is to include work history, postgraduate training, professional college affiliations, publications listings, and research trials experience.
You can add multiple Co-Investigators in the Personnel Information section of the Application Form.

Name	Degree (MD/PhD/MS)	Title
E-mail	**Phone**	**Fax**
Post Code		

Nominated Contact Clear

Please provide nominated contact name and address for correspondence from the committee.

Name	Degree (MD/PhD/MS)	Title
E-mail	**Phone**	**Fax**
Post Code		

Tax Invoice Clear

Please provide contact name and address for whom should receive the tax invoice if different from above.

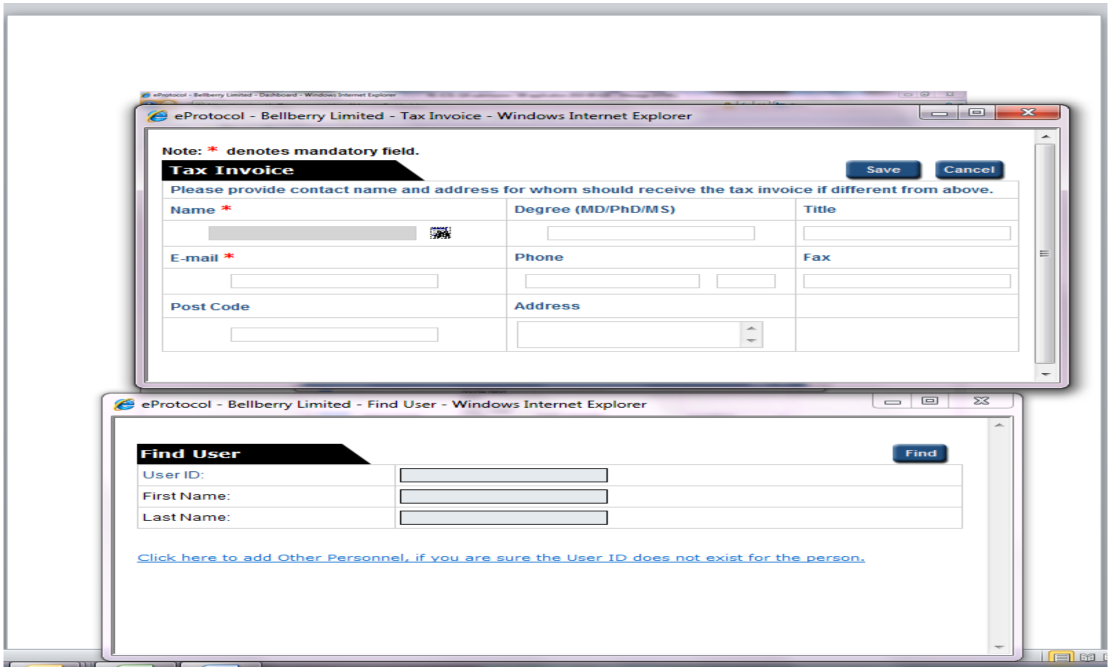
Name	Degree (MD/PhD/MS)	Title
E-mail	**Phone**	**Fax**
Post Code		

Create Cancel

- Enter in the details. Once completed select **Create.**

If the Principal Investigator (PI) is also the Nominated Contact then the PI section only needs to be completed.

- **Input of Tax details**



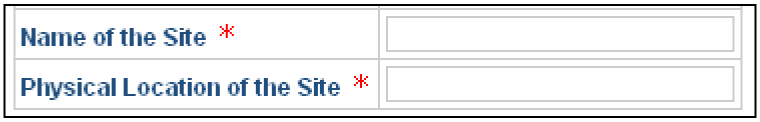
- A contact person cannot be listed twice. However if you click on to the binoculars it comes up with the 2nd screen, then click on the text in blue. This will allow free text. Add the company (sponsor or who the tax invoice is made out to) in the name section. You can then add your email address or the sponsor contact. Please also add the full postal address.

- Navigate using the arrow icons in the upper right corner of page, or jump straight to a particular section using the left-hand menu.

- Each time you advance a page, the application form will be automatically saved. You can also save by clicking the save icon (image of a diskette) in the upper right-hand corner of the page.

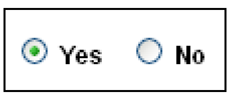
NOTE: If you are working on a particular page for a long time, you'll need to save frequently to avoid losing work. The program will time out after 30 minutes on one page without saving.

• Some special required fields will have a red asterisk *.

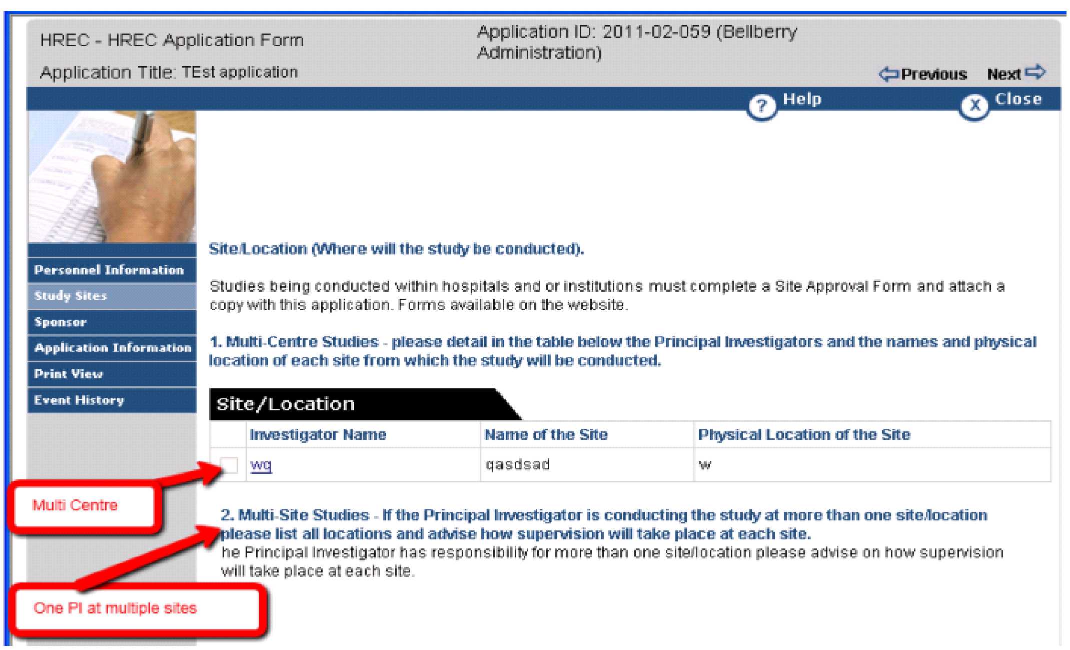


• **Check boxes** mean that you may select more than one item from that group.

• **Radio buttons** mean that you may select only one item from that group.



• **Tables** are used in parts of the application where you may need to add more than one item (for example, Additional Sites).



Multi - Centre Sites/Applications

- When you click add, a window will open where you enter the details related to the site and all Principle Investigators and sites for multi-centre studies.
  To view or edit the detailed information, click the Investigator Name link, in this case Prof Marie Curie. This will re-open the window where you had first entered the site details.
  To delete a site, click the check box next to a particular name, then click the DELETE button.
  To add additional sites, simply click the ADD button again.

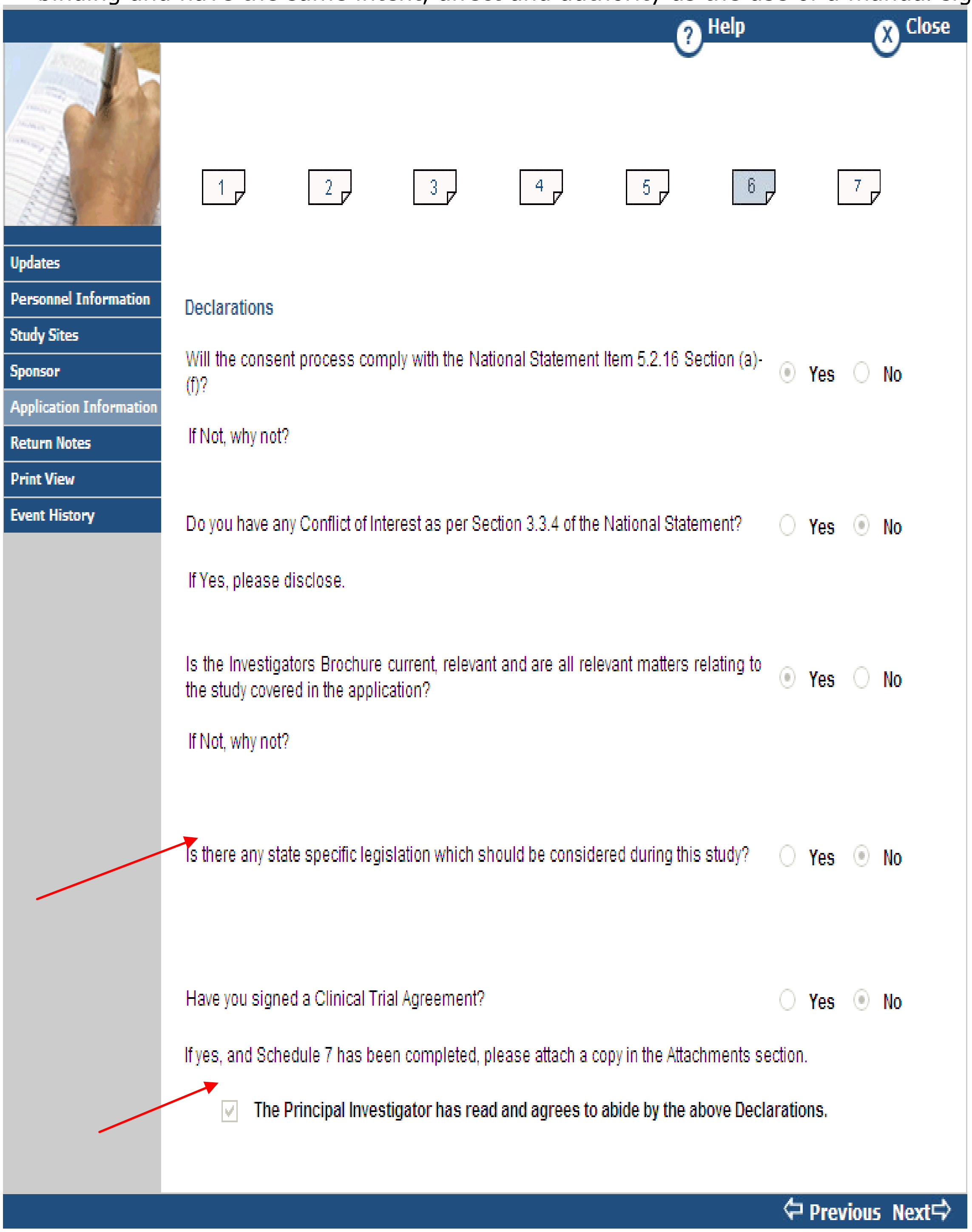
For a Principal Investigator who is conducting a study at multiple sites use the second box as detailed above.

- **Adding additional sites once application is approved**

Create an Amendment as detailed in the User Guide. Open the Amendment Form, complete section 1 detailing the additional site information and then open the application. Click on Application Information – Study Sites and add the site. SAVE. SUBMIT if you do not wish to add any further documents etc to the Amendment.

- **Please make sure you enter the Protocol Number correctly. This number will automatically alert Bellberry when a multi-site application is received.**

- Principal Investigator Declaration - remember when completing the application form on page 6 of the Application Information the Declarations box must be ticked. The Principal Investigator electronically signs the application form by pressing this tick box. e-Signatures are legally binding and have the same intent, affect and authority as the use of a manual signature.



- **Attachments** Page 7 of Application Information

This section allows you to attach all documentation from the listing below.

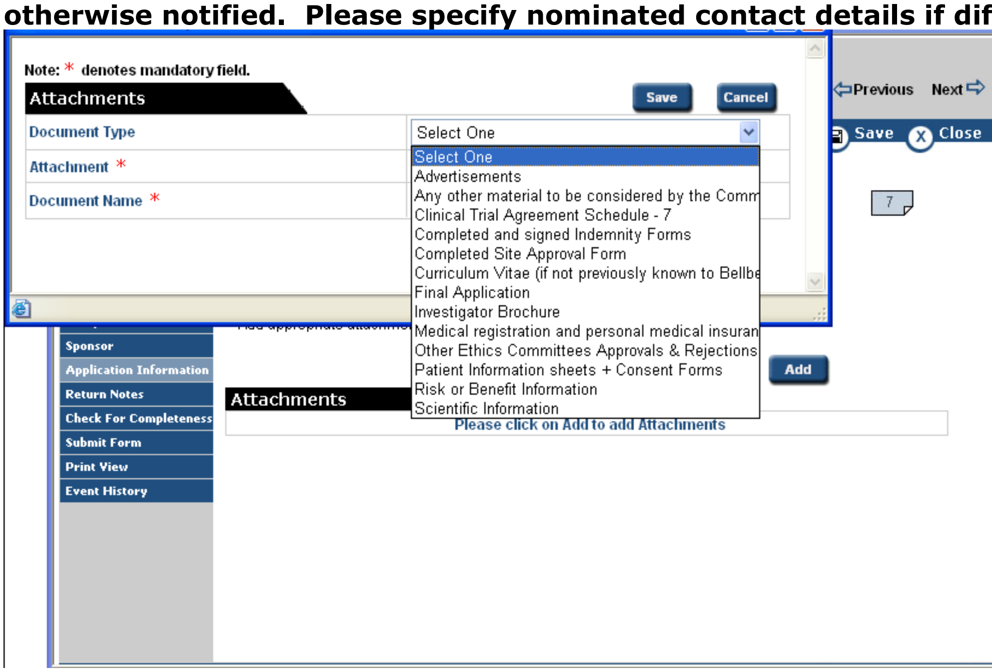
Ensure that you save the document under the correct heading and that you save the file as a PDF using a file name that describes the content.

e.g. for Protocols save file as ProtocolVersionNoxxDate

Please note that the file names used in the attachment section will be the document names that are listed in the approval letter. If the documents are incorrectly named in the attachment section the Approval Letter will be incorrect therefore it is imperative that you name the documents as you want them to appear in the Approval Letter.

Please remember to also attach a scanned copy of the signed Investigators acceptance/declaration page of the Final Protocol.

Documents requiring signatures eg. CTN/CTX, indemnities are required to be sent by standard mail. These documents will be returned to the Principal Investigator unless otherwise notified. Please specify nominated contact details if different from the PI.



• Click on the **Check for Completeness** left-hand menu option when you believe you have finished entering all of the necessary information. You will see a message that will indicate which sections may be missing information.

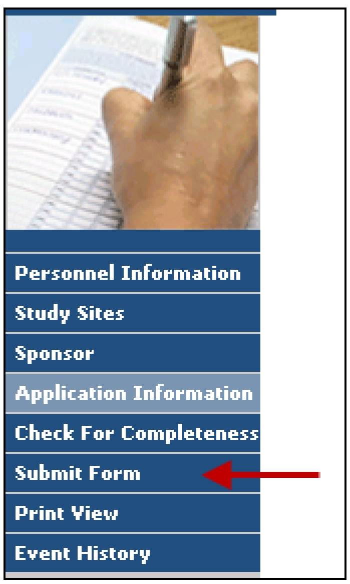
NOTE: The check for completeness feature cannot check to see if all of the necessary supporting documents have been attached. Be sure to double-check that this has been done before you submit your application.

Clone an Application

To create a new application from an existing protocol, click on the CLONE APPLICATION button in the upper right-hand corner of your HOME page and follow the instructions on the page. This function only works for the same Principal Investigator *i.e you can not clone applications between Investigators.*

Submit an application to Bellberry

After completing your application form, you can submit it to Bellberry by clicking on the SUBMIT APPLICATION button in the left-hand menu of the Application Form as shown below. You will need to have the application open in EDIT mode. Select YES and the application will automatically be submitted to Bellberry.



Please be patient after clicking submit. The application will automatically check to make sure that all parts of the application form are complete. If the application is complete, a small window will open thanking you for submitting your application. If the application is not complete, then a window will open indicating the portions of the application that remain to be completed. Navigate to those areas and answer the questions before attempting to submit again.

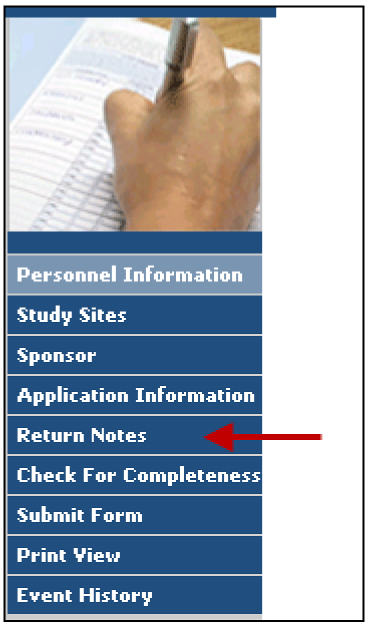
PLEASE NOTE: *Once an application is submitted, you will not be able make edits or additions, unless requested as part of the Bellberry HREC review process.*

Returned Applications

After your application has been submitted, it will undergo an initial check by the Bellberry office staff before it is assigned to a Bellberry Committee for review. The application is checked to make sure it is complete and that it includes all of the necessary attachments, etc.

Sometimes it is necessary to *Return* an application. If you receive an email that your application was returned, go into the application and check the Return Notes section to see why.

This releases the application back to you (with full EDIT capability) so that you may make any necessary adjustments. Also the *Application Status* that displays on your HOME page will be "Submission Returned". You'll need to open the application and click the link in the left-hand menu labeled "Return Notes " as shown below.



This will open a small window with information regarding the reason your application was returned and instructions on how to proceed. When you are ready to re-submit the application, you simply click the SUBMIT APPLICATION button, just as you did for the initial submission.

PLEASE NOTE: *The HREC Return Notes area is only used for instructions relating to returned applications and is not where you can see comments that were entered as part of the full HREC review.*

Application Review Process

Once your protocol has been accepted, it will be assigned to a specific Bellberry Committee A,B or C for review and assigned a meeting date. Check your email regularly. You will receive an email for each major event in the review process. You can also see the status by looking at the application listing on your HOME page in the eProtocol Application Event column as above.

To view the **Event History,** select the relevant application and from the menu on the LHS, last option, select Event History. Each form type is allocated a number for easier tracking.

Event History

Date	Application ID	Status	View Attachments	Letters
31/05/2012	2012-05-832	NEW FORM CREATED		
31/05/2012	2012-05-832	NEW FORM SUBMITTED		
31/05/2012	2012-05-832	NEW FORM PANEL ASSIGNED		
31/05/2012	2012-05-832	NEW FORM REVIEWER(S) ASSIGNED		
31/05/2012	2012-05-832	NEW FORM SUBMITTED (CYCLE 1)		
31/05/2012	2012-05-832	NEW FORM APPROVED		
31/05/2012	2012-05-832-PVR-1	DEVIATION 1 FORM CREATED		
31/05/2012	2012-05-832-PVR-1	DEVIATION 1 FORM SUBMITTED	View Attachments	
31/05/2012	2012-05-832-A-1	AMENDMENT 1 FORM CREATED		
31/05/2012	2012-05-832-A-1	AMENDMENT 1 FORM SUBMITTED	View Attachments	

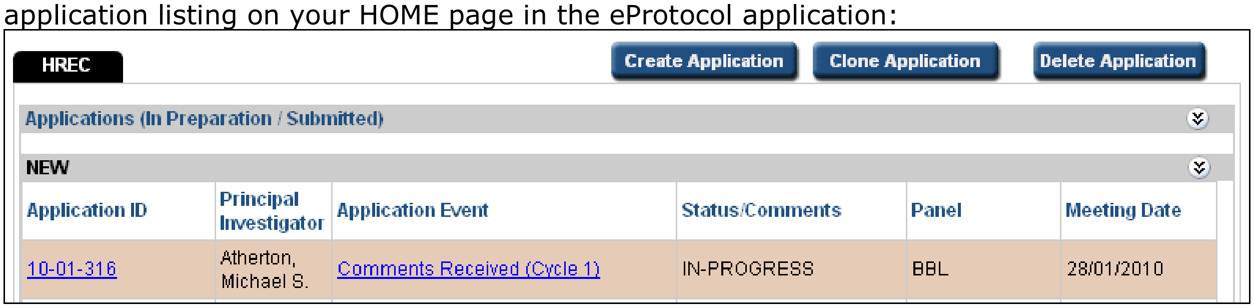
Email History

Email Date	Email Type	Attachments
31/05/2012	Amendment/IB Form has been submitted: 2012-05-832-A-1, Bellberry Administration	
31/05/2012	Protocol Violation Report has been submitted: 2012-05-832-PVR-1, Bellberry Administration	
31/05/2012	HREC Responses sent (Cycle 1): 2012-05-832, Bellberry Administration	
31/05/2012	HREC Comments sent (Cycle 1): 2012-05-832, Bellberry Administration	
31/05/2012	Application Assigned to Committee: 2012-05-832, Bellberry Administration	
31/05/2012	New Application has been submitted: 2012-05-832, Bellberry Administration	

Respond to HREC comments

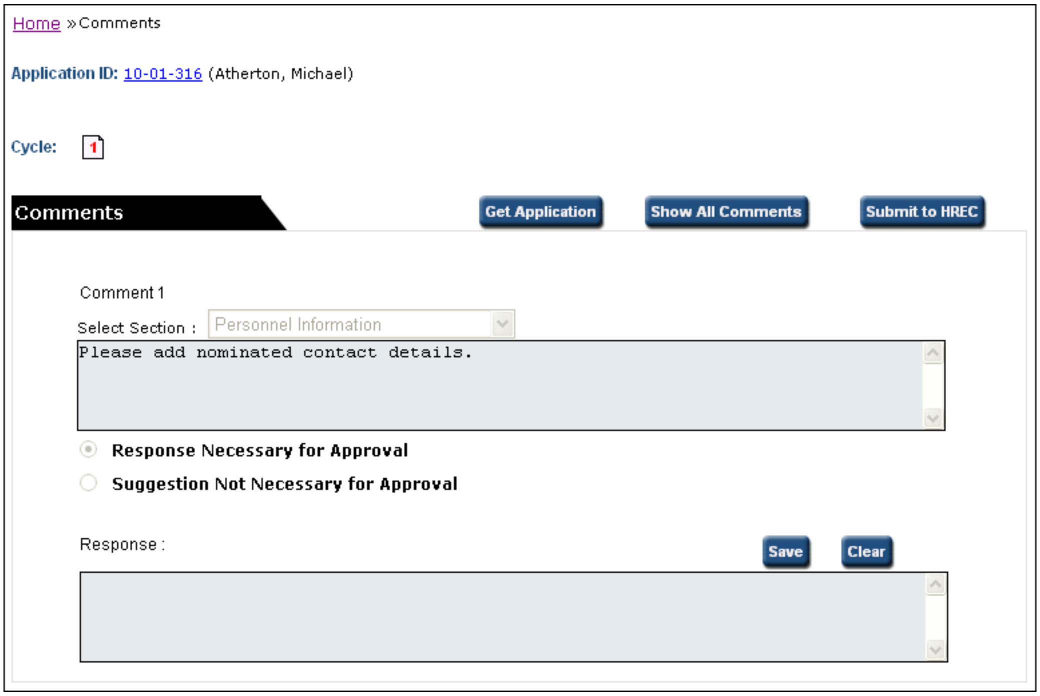
Once your application has been accepted, it will be assigned to a specific Committee A, B or C for review and assigned a meeting date. Check your email regularly.

You will receive an email for each major event in the review process, alerting you to when you need to log into the system and take a particular action. You can also see the status by looking at the application listing on your HOME page in the eProtocol application:



Application ID	Principal Investigator	Application Event	Status/Comments	Panel	Meeting Date
10-01-316	Atherton, Michael S.	Comments Received (Cycle 1)	IN-PROGRESS	BBL	28/01/2010

Click on the link in the Application Status column to access the comments page. A sample of what the comments page looks like is shown below:



Use the *Show All Comments* to list all the comments. Use the print screen button and then right click on your mouse to copy into a word or email document.

You'll need to:

- make the adjustments to the application itself (click the GET APPLICATION button to open up a new window with the application) – **to add additional attachments you will need to go to the Attachments Page 7 and attach and SAVE.**
- enter a response for each comment (and SAVE)
- click the SUBMIT TO HREC button to send your responses back to Bellberry.

PLEASE NOTE: *SAVE will save your responses to the comments. However, these responses are not "sent to the HREC" until you click the SUBMIT TO HREC button.*

Once Application is Approved

You'll receive an email notification when your application is approved with instructions on how to access the approval letter on-line. You will be required to print the letter and sign and send the original copy to Bellberry. Please do the same for the CTN/CTX. Once received by Bellberry we will attach the signed copy to your application in the attachments section in eProtocol.

Once the application is officially approved in the system, it will appear at the bottom of your home page under Approved Applications.

Making Amendments and Investigator Brochure Updates to Approved Applications/Studies

If you would like to make changes to a study that has already been approved, you will need to submit an **Amendment/Investigator Brochure Form.**

Please note that you will be unable to submit another Amendment until you have received approval. You can add multiple changes etc to the one Amendment.

For studies approved prior to eProtocol, these have now been added to the system under the Principal Investigators Name. To add additional nominated contacts to these studies the PI will be required to login and complete an Amendment Form – see below updating study personnel.

Update Study personnel/email addresses

If there has been a change/addition to the personnel related to a particular study or an administration change i.e. change of email address, you'll need to include these changes as part of an Amendment or Ethics Approval Extension application.

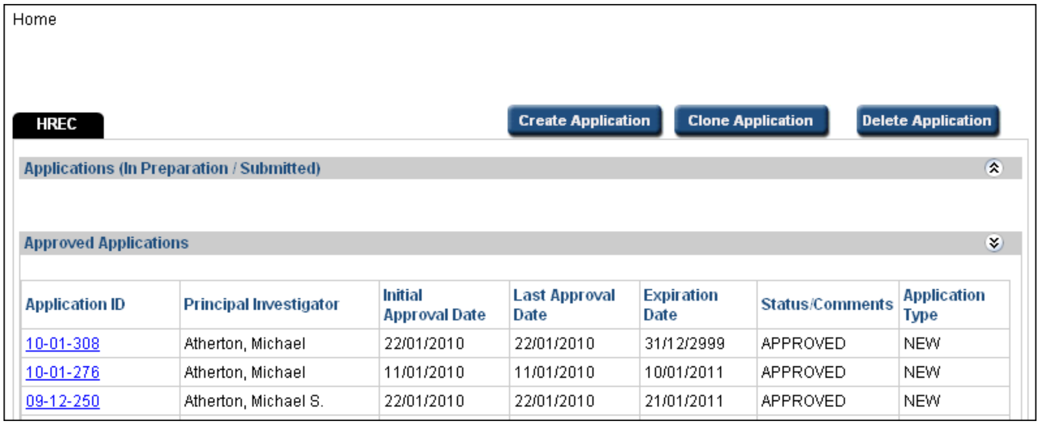
Before you begin an Amendment, you should consider the date that the current approval will expire. Keep in mind that once an amendment is submitted, you will not be able to start an Ethics Approval Extension (Renewal) application until the amendment has been reviewed and approved. If the expiration date of your study is near, you should start an Ethics Approval Extension instead. As part of the Ethics Extension application, you may include any proposed changes to the application.

Please note that approval letters are not generated for administration changes.

To start follow these steps:

1. On your eProtocol HOME page (the page you see when you first log in), look at your **Applications (Approved)** listing. You may need to click the  at the right-side of the section header to expand this section.

2. Click on the number of the study you wish to amend, and you will see a small window open.



Application ID	Principal Investigator	Initial Approval Date	Last Approval Date	Expiration Date	Status/Comments	Application Type
10-01-308	Atherton, Michael	22/01/2010	22/01/2010	31/12/2999	APPROVED	NEW
10-01-276	Atherton, Michael	11/01/2010	11/01/2010	10/01/2011	APPROVED	NEW
09-12-250	Atherton, Michael S.	22/01/2010	22/01/2010	21/01/2011	APPROVED	NEW

3. If the option to "Start Amendment/IB" button (as shown below) is not available ie you cannot click on it, then:

   - You may not have EDIT access to this study. Select "Open in View mode" and click on the left-hand menu option "Personnel Info". Only those people listed in the first four roles (Principal Investigator, Nominated Contacts, Co-Investigator, have access to EDIT the application and start amendments.
   - An amendment or extension may have already been started or is in-process for this application. Check on your HOME page in the *Applications (In-preparation/Submitted)* section to see if the study is listed there.

4. Select "Start Amendment/IB" and click OK.

PLEASE NOTE: *If an Amendment Form does not open when you click OK, then you have pop-up blocking software on in your browser. Even if you believe you have allowed pop-ups, there may be additional toolbars, etc. that are blocking your pop-ups. See instructions for allowing pop-ups in your browser.*

The Amendment Form was updated in October 2011. Please note the following changes required to complete an Amendment Form.

5. **Please use Section 1. For all Administration Changes** Use this section for any change or correspondence that is not related to a protocol Amendment, Investigator Brochure Update or to other changes to approved documentation. For example adding/removal of study staff, updating email addresses, Indemnities, Insurance, CV updates etc.

6. **FOR ANY STUDY DOCUMENT CHANGE USE SECTION 2, 3, OR 4.**

ENSURE ALL DOCUMENTS THAT ARE ATTACHED IN THE ATTACHMENTS SECTION HAVE BEEN SAVED IN THE NAME THAT YOU WANT THAT DOCUMENT TO APPEAR IN THE APPROVAL LETTER.

7. Answer all of the questions on the Amendment/IB Form page (see next page), depending on whether it is an update to the Investigator Brochure, Protocol or Other. Describe the changes that you wish to make. ***You will also need to go to the appropriate sections in the application form and make updates to reflect those changes.*** *i.e update the personnel section with additional contacts or attach updated Protocol, Participant Information Sheet etc.*

8. ***ATTACHMENTS – You will be redirected to the Attachments Section on Page 7 of your application. PLEASE ENSURE YOU USE THE HEADING 'AMENDMENT/IB UPDATE ATTACHMENTS ONLY'. THIS WILL ENSURE YOUR APPROVAL LETTER STATES THE CORRECT ATTACHMENTS TO APPROVE/NOTE.***

9. Submit the amendment form when ready by clicking the **SUBMIT APPLICATION** option in the left-hand menu.

OK

AMENDMENT FORM

Protocol Title

Principal Investigator Name

Protocol No.

Date of Report

1. Administration - Other correspondence — ◯ Yes ◯ No

Please use this section for any administrative change or correspondence that is not related to a protocol Amendment, Investigator Brochure Update or to other changes to approved documentation. For example adding/removal of study staff, updating email addresses, Indemnities, Insurance, CV updates etc.)For any study document change use section 2, 3 or 4.

Complete the box below outlining the changes required. Ensure you make any necessary changes in the Personnel Information section of the Application.

Attach relevant documents in the Attachments section using the document heading name 'Amendment Attachments'

2. Protocol Amendment — ◯ Yes ◯ No

Version No.

Date

Are changes required to the Participant Information sheet? — ◯ Yes ◯ No

(Attach relevant documents in the Attachments section using the document heading name 'Amendment Attachments'.)

If not, please explain.

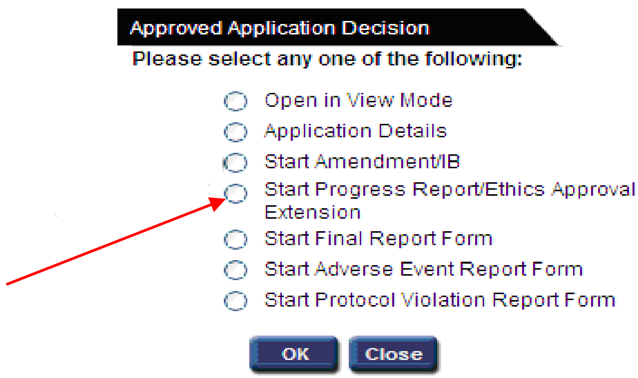
3. Investigator Brochure Update — ◯ Yes ◯ No

Progress Report/Ethics Approval Extension (Renewals)

To start a Progress Report/Ethics Approval Extension (Renewal) application, follow these steps:

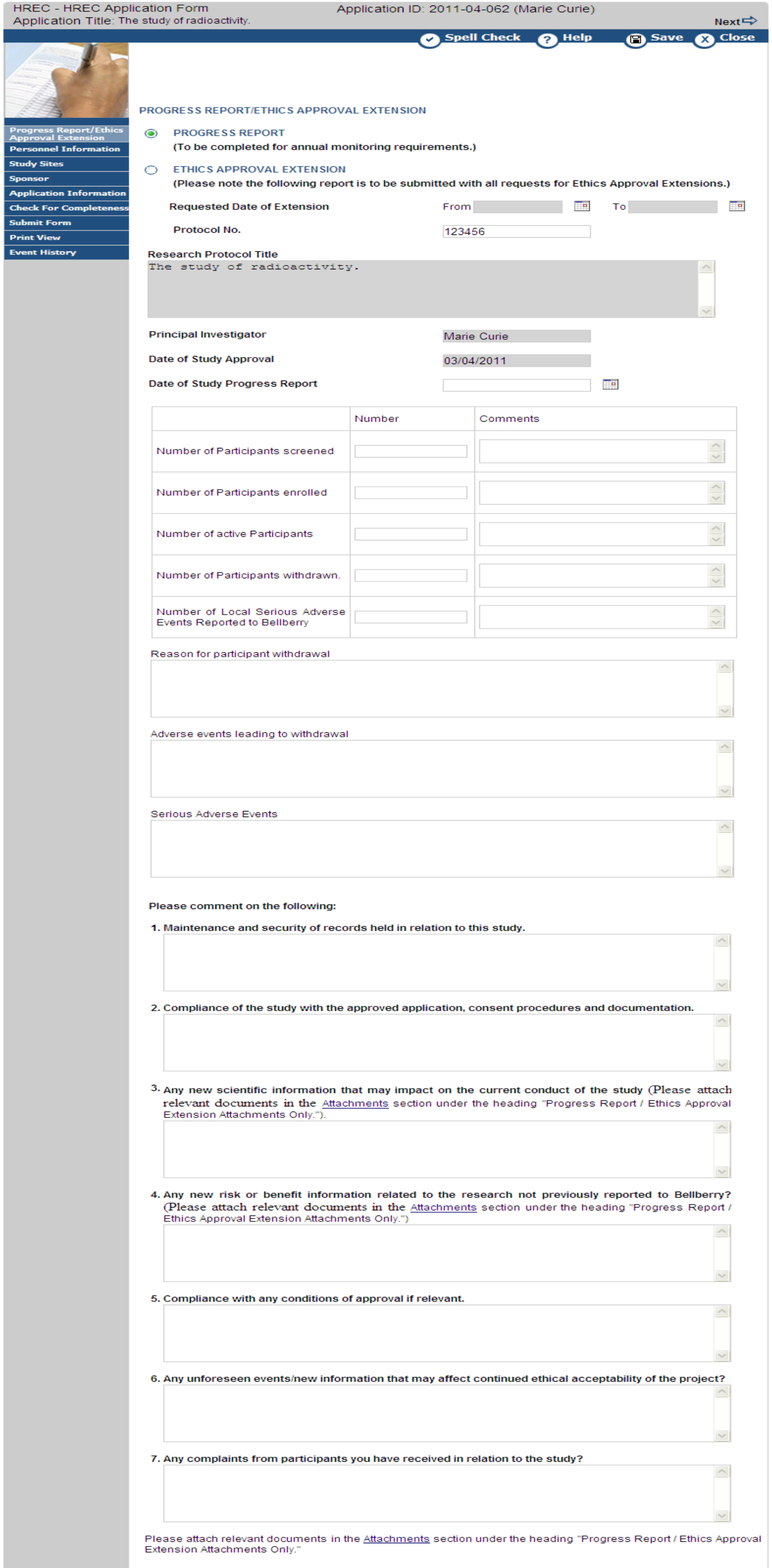
1. On your eProtocol HOME page (the page you see when you first log in), look at your **Applications (Active)** listing. You may need to click the at the right-side of the section header to expand this section.

2. Click on the desired application number. A small window should open see below:



3. If the option to start a Progress/ Ethics Approval Extension is not available (you cannot click on it) then:
   - You may not have EDIT access to this application. Select "Open in View mode" and click on the left-hand menu option "Personnel Info". Only those people listed in the first four roles (Principal Investigator, Admin Contact, Co-Investigator, Other Contact) have access to EDIT the application and start an Ethics Approval Extension.
   - An amendment may have already been started or is in-process for this application. Check on your HOME page in the Applications *(In-Preparation/Submitted)* section to see if the application is listed there.
4. Select "Progress Report/Ethics Approval Extension" and click OK.

   PLEASE NOTE: *If a Progress Report/ Ethics Approval Extension application form does not open when you click OK, then you have pop-up blocking software on in your browser. Even if you believe you have allowed pop-ups, there may be additional toolbars, etc. that are blocking your pop-ups. See instructions for allowing pop-ups in your browser.*



HREC - HREC Application Form
Application Title: The study of radioactivity.
Application ID: 2011-04-062 (Marie Curie)
Next
Spell Check | Help | Save | Close

- Progress Report/Ethics Approval Extension
- Personnel Information
- Study Sites
- Sponsor
- Application Information
- Check For Completeness
- Submit Form
- Print View
- Event History

PROGRESS REPORT/ETHICS APPROVAL EXTENSION

(◉) PROGRESS REPORT
(To be completed for annual monitoring requirements.)

( ) ETHICS APPROVAL EXTENSION
(Please note the following report is to be submitted with all requests for Ethics Approval Extensions.)

Requested Date of Extension — From ____ To ____

Protocol No. 123456

Research Protocol Title
The study of radioactivity.

Principal Investigator: Marie Curie

Date of Study Approval: 03/04/2011

Date of Study Progress Report: ____

	Number	Comments
Number of Participants screened		
Number of Participants enrolled		
Number of active Participants		
Number of Participants withdrawn.		
Number of Local Serious Adverse Events Reported to Bellberry		

Reason for participant withdrawal

Adverse events leading to withdrawal

Serious Adverse Events

Please comment on the following:

1. Maintenance and security of records held in relation to this study.
2. Compliance of the study with the approved application, consent procedures and documentation.
3. Any new scientific information that may impact on the current conduct of the study (Please attach relevant documents in the Attachments section under the heading "Progress Report / Ethics Approval Extension Attachments Only.").
4. Any new risk or benefit information related to the research not previously reported to Bellberry? (Please attach relevant documents in the Attachments section under the heading "Progress Report / Ethics Approval Extension Attachments Only.")
5. Compliance with any conditions of approval if relevant.
6. Any unforeseen events/new information that may affect continued ethical acceptability of the project?
7. Any complaints from participants you have received in relation to the study?

Please attach relevant documents in the Attachments section under the heading "Progress Report / Ethics Approval Extension Attachments Only."

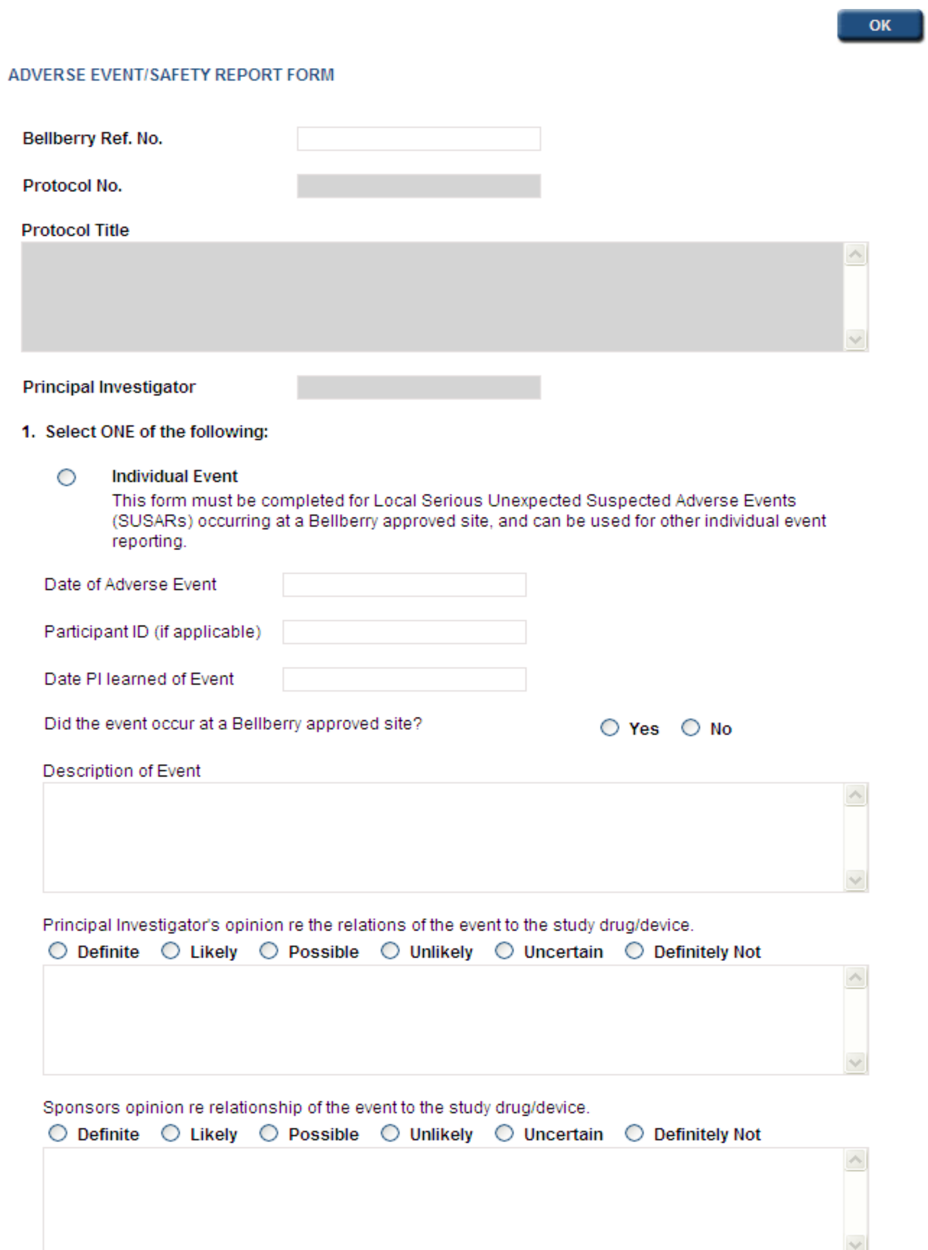
5. Answer all of the questions on the Ethics Approval Extension Form page.

6. ***Add any attachments under the heading "Progress Report/Ethics Extension Form Attachments Only".***

7. Submit the form when ready by clicking the SUBMIT APPLICATION option in the left-hand menu.

Adverse Event Report Form

Please note Form has been Updated October 2011



OK

ADVERSE EVENT/SAFETY REPORT FORM

Bellberry Ref. No.

Protocol No.

Protocol Title

Principal Investigator

1. Select ONE of the following:

Individual Event
This form must be completed for Local Serious Unexpected Suspected Adverse Events (SUSARs) occurring at a Bellberry approved site, and can be used for other individual event reporting.

Date of Adverse Event

Participant ID (if applicable)

Date PI learned of Event

Did the event occur at a Bellberry approved site? Yes No

Description of Event

Principal Investigator's opinion re the relations of the event to the study drug/device.
Definite Likely Possible Unlikely Uncertain Definitely Not

Sponsors opinion re relationship of the event to the study drug/device.
Definite Likely Possible Unlikely Uncertain Definitely Not

Follow the steps as outlined in starting an Amendment and then select 'Adverse Event Report Form' from the **Approved Application Decision Box.** Select either – 1. **Individual Event** or 2. **Summary Report** – and then complete the relevant fields.

For **Individual Event** Select 1 and complete report as required

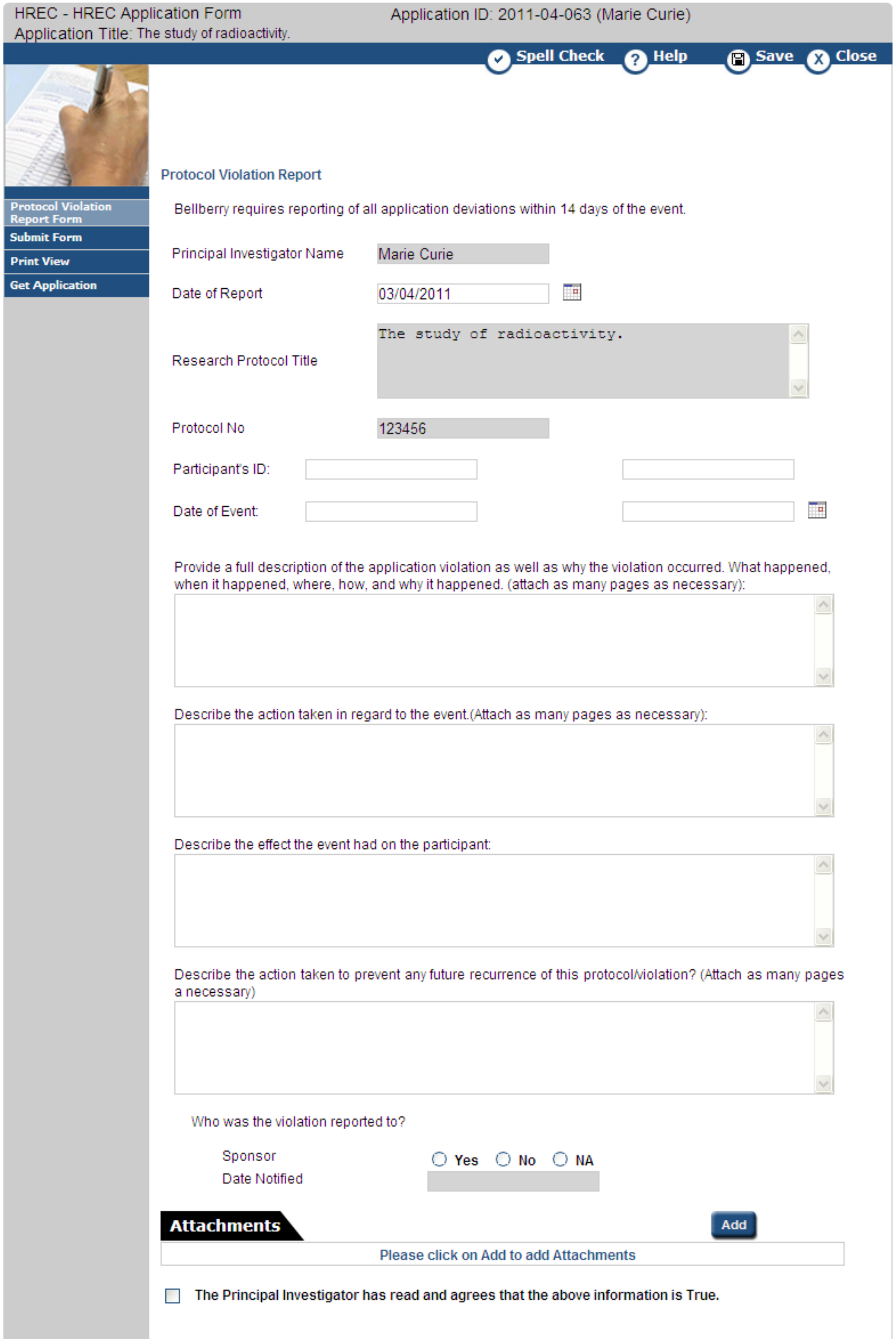
For **Summary reporting** select 2 and attach relevant documents.

Ensure you use the heading "Adverse Event Form Attachments Only" when attaching any documents to the Adverse Event Form.

Once completed **Submit Form.**

If you are requiring a summary SAE template go to www.bellberry.com.au and select 'Investigator' and then 'Forms'.

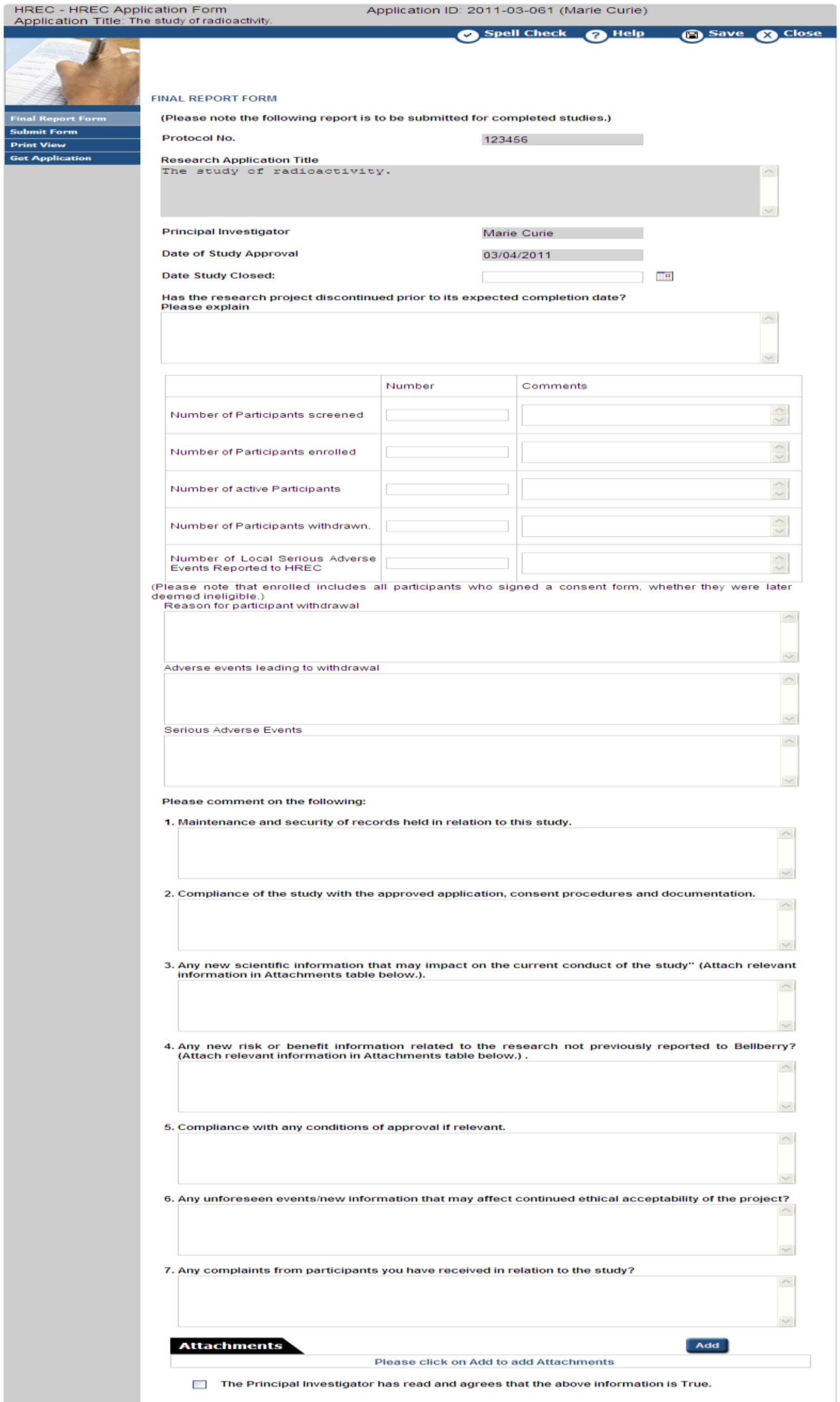
Start Violation Report Form



Repeat the steps as outlined in starting an 'Amendment' and then select 'Start Protocol Violation Report' from the **Approved Application Decision Box. For any Attachments please use the "Protocol Violation Attachments Only" heading.**

Complete required fields and once completed **Submit Form**.

Start Final Report Form – *ensure that this form is only completed once all sites included in the study sites section of the Application that the PI is responsible for, have been finalised as this report can only be submitted once.*



HREC - HREC Application Form
Application Title: The study of radioactivity.
Application ID: 2011-03-061 (Marie Curie)

Spell Check | Help | Save | Close

Final Report Form
Submit Form
Print View
Get Application

FINAL REPORT FORM

(Please note the following report is to be submitted for completed studies.)

Protocol No. 123456

Research Application Title
The study of radioactivity.

Principal Investigator: Marie Curie

Date of Study Approval: 03/04/2011

Date Study Closed:

Has the research project discontinued prior to its expected completion date? Please explain

	Number	Comments
Number of Participants screened		
Number of Participants enrolled		
Number of active Participants		
Number of Participants withdrawn.		
Number of Local Serious Adverse Events Reported to HREC		

(Please note that enrolled includes all participants who signed a consent form, whether they were later deemed ineligible.)

Reason for participant withdrawal

Adverse events leading to withdrawal

Serious Adverse Events

Please comment on the following:

1. Maintenance and security of records held in relation to this study.
2. Compliance of the study with the approved application, consent procedures and documentation.
3. Any new scientific information that may impact on the current conduct of the study" (Attach relevant information in Attachments table below.).
4. Any new risk or benefit information related to the research not previously reported to Bellberry? (Attach relevant information in Attachments table below.) .
5. Compliance with any conditions of approval if relevant.
6. Any unforeseen events/new information that may affect continued ethical acceptability of the project?
7. Any complaints from participants you have received in relation to the study?

Attachments | Add

Please click on Add to add Attachments

The Principal Investigator has read and agrees that the above information is True.

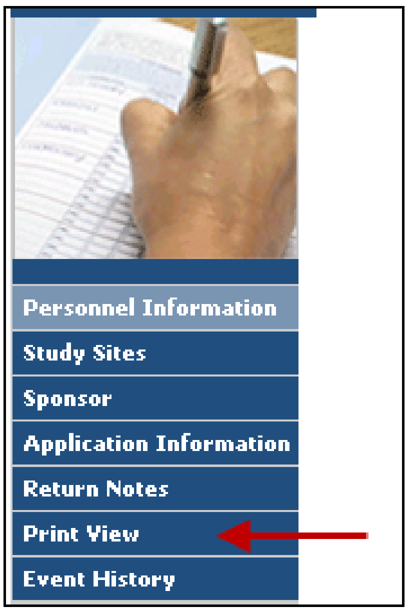
Repeat the steps as outlined in starting an 'Amendment' and select 'Final Report Form' from the **Approved Application Decision Box.**

Use the heading "Final Report Form Attachments Only" when attaching any documents to this form.

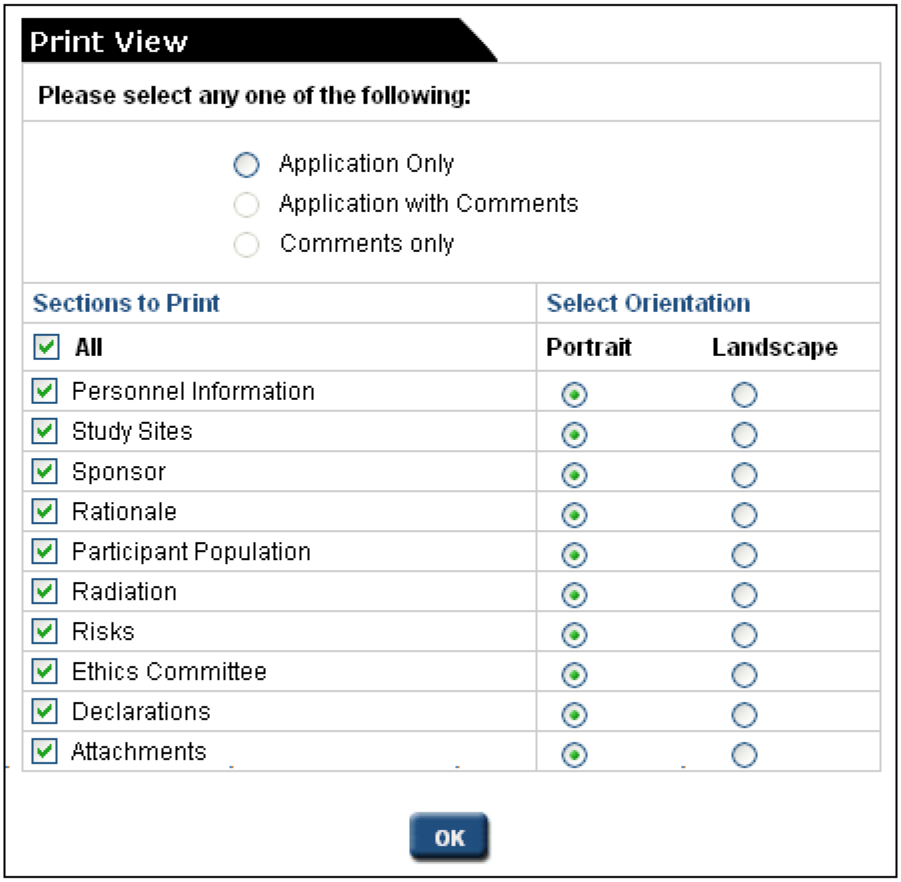
Complete required fields and once completed **Submit Form.**

Print an Application

You may generate an Adobe .pdf file of your application form that can be printed or saved on your computer. In the left-hand menu of the application form, click on the *Print View* option (shown below):



A small window will open:



Select an option, sections and their orientation, and click **OK**. The Adobe .pdf file will be created and opened. You may save it to your computer by clicking *File*, then *save as* in the upper left-hand corner of the window. If you are having difficulty with this function your Windows software may be blocking it. Please go to the application page and Ctrl P to print individual pages.

Trouble Shooting

I click on EDIT but application does not open.

You have pop-up blocking software on in your browser. Even if you believe you have allowed pop-ups, there may be additional toolbars, etc. that are blocking your pop-ups. See instructions for allowing pop-ups in your browser.

I can't see my approved applications.

Your approved applications appear on your eProtocol HOME page (the page you see when you first log in) in the section labeled **Applications (Approved)**. It should appear towards the middle of your page. You may need to click the at the right-side of the section header to expand this section.

I can't find the application I need to amend.

Please refer to the instructions for Amendments if you do not see an application listed in your Applications (Approved) section, it may be that you were not listed as personnel on the study.

The option to "Start Amendment" or "Ethics Approval Extension" is not available; it appears grey.

- You may not have EDIT access to this application. Select "Open in View mode" and click on the left-hand menu option "Personnel Info". Only those people listed in the first four roles (Principal Investigator, Co-Investigator, Nominated Contacts) have access to EDIT the study/application and start Ethics Approval Extension.
- An amendment or Ethics Approval Extension (renewal) may have already been started or is in-process for this application. Check on your HOME page in the Applications *(In-Preparation/Submitted)* section to see if the application is listed there.

I select "Start Amendment" and click OK, but am brought back to the page where I started.

You have pop-up blocking software on in your browser. Even if you believe you have allowed pop-ups, there may be additional toolbars, etc. that are blocking your pop-ups. See instructions for allowing pop-ups in your browser.

I received an error stating "Session expire."

Your application was left idle for longer than 30 minutes and has timed out. Close all of your browser windows and log back in to eProtocol.

I am trying to respond to HREC comments, but it appears as if there are none.

You might be confusing the HREC *Return Notes* item in the left-hand side of the application form with the HREC *Comments* page, which is used during the official review cycle. If you are attempting to access comments from the HREC for an application that has already been assigned to a meeting date, please see the instructions on how to respond to HREC comments. If your application was returned, please see instructions for returned applications.

I can't open the PDF of my application/study or approval letter.

Recent changes in security may require Internet Explorer 7 users to change settings to download PDFs using the Print View (or View Approval Letter) function in eProtocol. Please do the following to adjust your settings.

1. In IE7 click on "Tools" in the Menu Bar
2. Choose "Internet Options"
3. Click on the "Security" tab at the top of the window
4. Click on the "Custom Level" button
5. In the Security Settings Window make sure the following are set to "**Enable**"
    a. ActiveX controls and plug-ins – "Binary and script behaviors"
    b. ActiveX controls and plugons – "Automatic prompting for ActiveX controls"
    c. Downloads – "Automatic prompting for file downloads"
    d. Downloads – "File download"
6. Click "OK" in the Security Settings Window
7. Click "Yes" to the Warning about changing security settings
8. Click "OK" in Internet Options Window

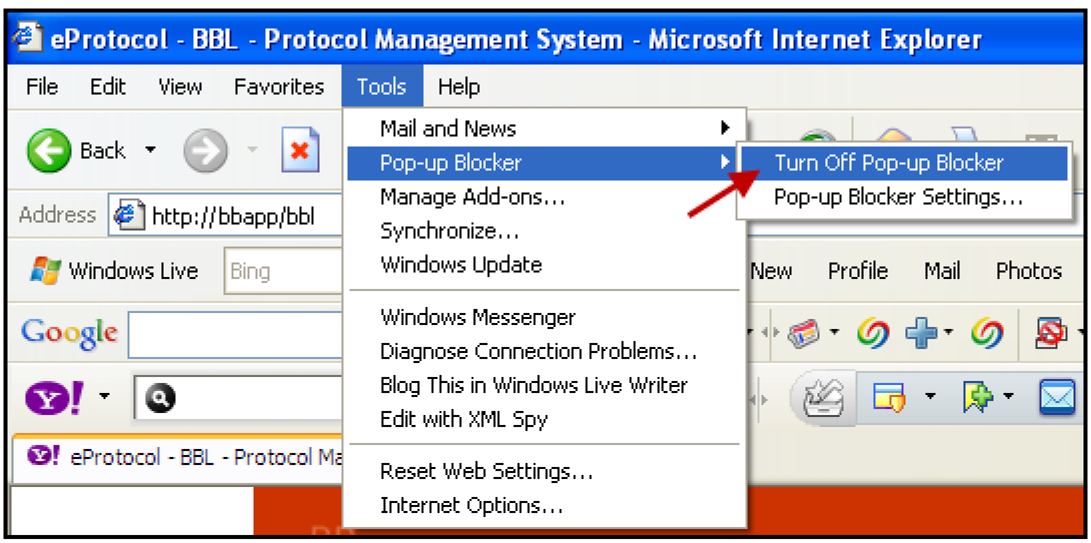
Now you should be able to open the PDF of your application (or approval letter).

How do I allow pop up blockers?

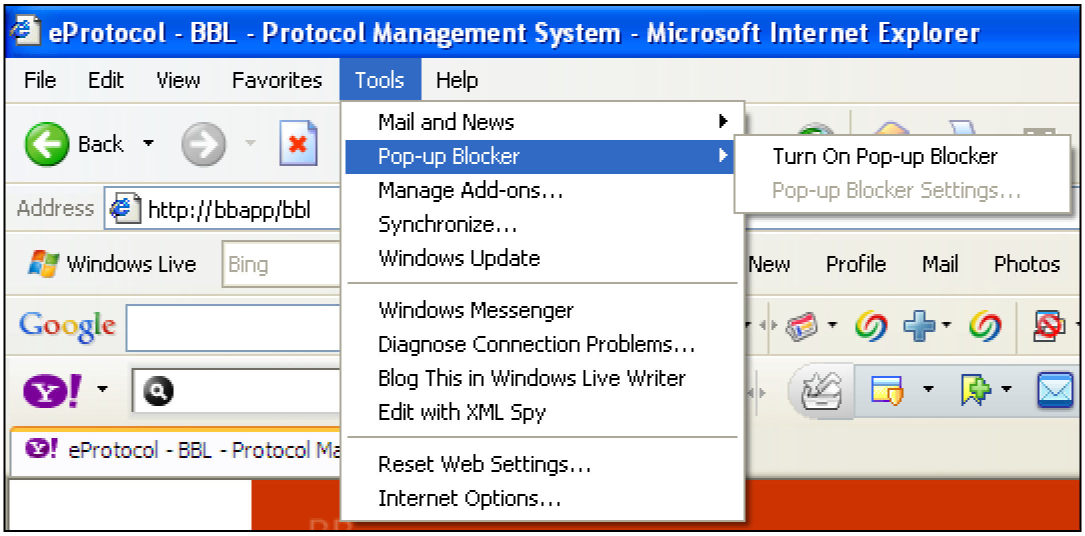
Internet Explorer: allowing pop-ups

1. Start Internet Explorer.

2. On the Tools **menu, click** Pop-up Blocker **and select** Turn Off Pop-up Blocker**.**



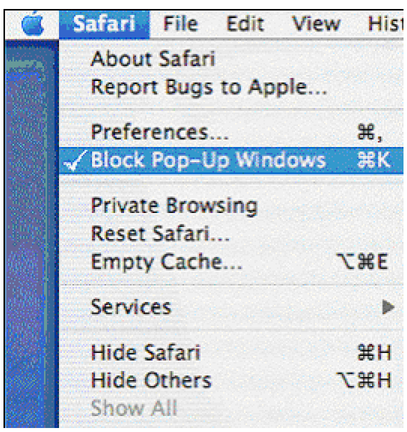
3. When Pop-up Blocker is correctly turned off, it will show Turn On Pop-up Blocker**.**



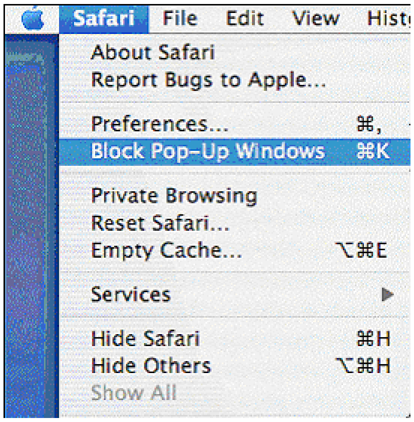
Safari: allowing pop-ups

1. Start Safari.

2. On the Safari **menu, look to see if** Block Pop-up Windows **is checked. If so, click this line once to turn off pop-up blocking.**

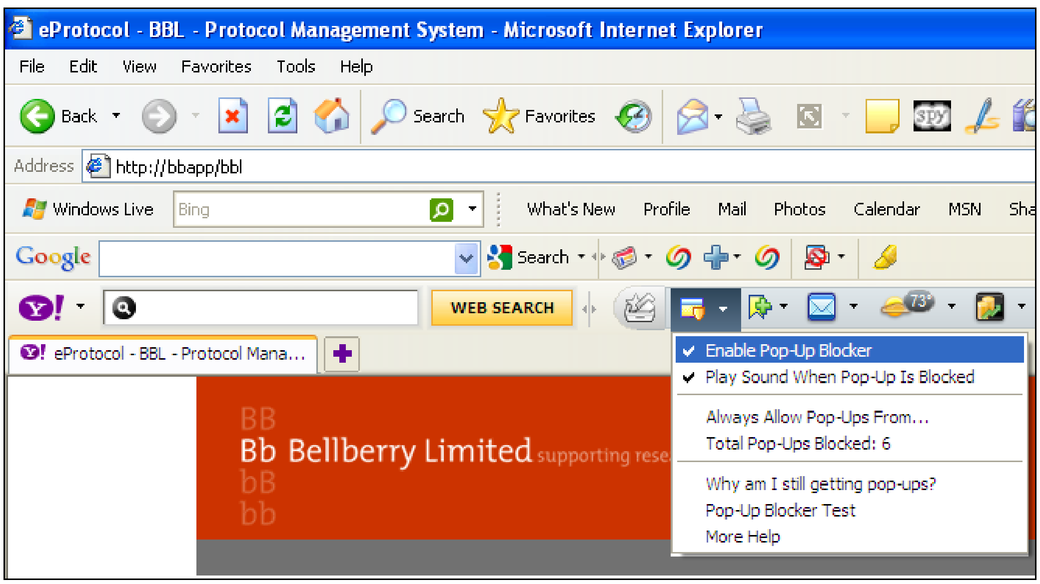


3. When Pop-up Blocker is correctly turned off, it will show Block Pop-up Windows **as unchecked.**

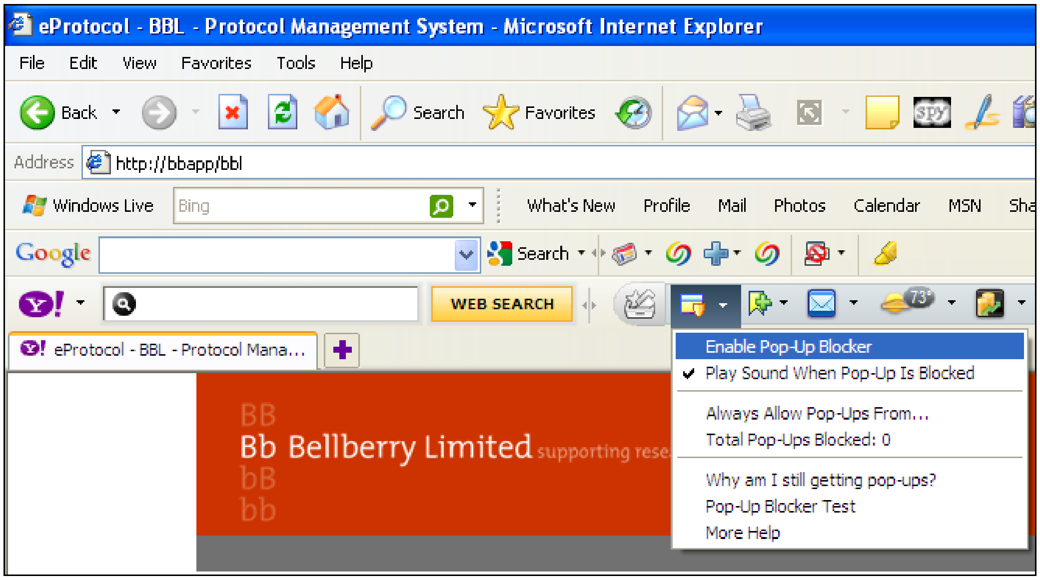


Yahoo Toolbar: allowing pop-ups

1. On the Yahoo Toolbar, click the pop-up blocker icon to see if Enable Pop-up Blocker **is checked. If so, click this line once to turn off pop-up blocking.**

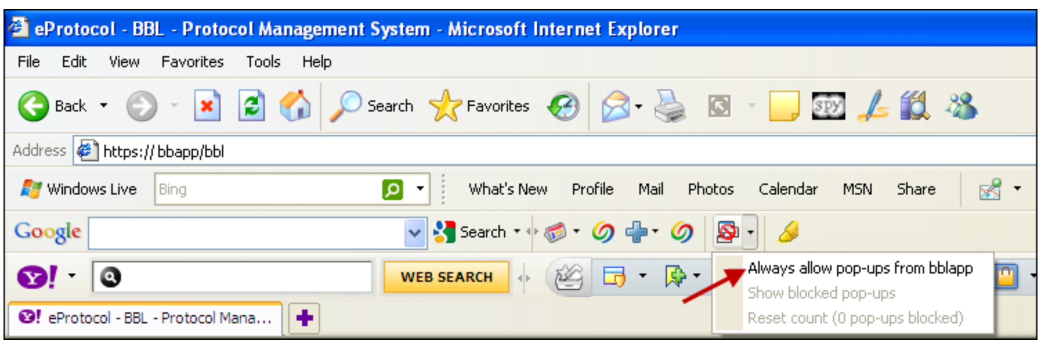


2. When Pop-up Blocker is correctly turned off, it will show Enable Pop-up Blocker **as unchecked.**



Google Toolbar: allowing pop-ups

1. On the Google Toolbar, click the pop-up blocker icon to see if pop-ups from his site are allowed. If not, 'Always allow pop-ups from…' message is displayed. Click this line once to turn off pop-up blocking.



2. When Pop-up Blocker is correctly turned off, the button will show as shown below.