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Bellberry Limited supporting research and ethics

Investigator e-Protocol User Guide

Investigator User Guide

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Getting Started

Before You Start

Website for Bellberry Human Research Ethics (www.bellberry.com.au)

This website has the answers to many common questions and provides a wealth of information on regulations and guidelines. It has information and links to help get you started. Please visit often for news and updates.

The screenshot shows the homepage of the Bellberry Limited website. The header is orange and features the Bellberry logo (BB, Bb, bB, bb) and the tagline "supporting research and ethics". Navigation buttons for "Subscribe to News" and "Contact Us" are present, along with a search bar. A main navigation menu includes "About Us", "Investigators", "Participants", "Committee Members", and "Resources".

The main content area has a dark background and features a "Welcome to our new and improved website!" message. Below this, there are three paragraphs of text describing the organization and its services. A "Quick Links" sidebar on the right contains buttons for "How to Apply", "eProtocol Help", "Meeting Dates", and a prominent "Log into eProtocol" button.

The footer is dark and contains a "Sitemap" section with a grid of links categorized under "About", "Committee Members", "Investigators", "Participants", "Contact Us", "Disclaimer", and "Privacy Policy".

Header: BB Bellberry Limited supporting research and ethics. Buttons: Subscribe to News, Contact Us. Search bar: search.

Navigation: About Us | Investigators | Participants | Committee Members | Resources | feedback

Main Content:
Welcome to our new and improved website!
Bellberry Limited is a national, private not-for-profit organisation that provides streamlined scientific and ethical review of human research projects across Australia. As a not for profit company, Bellberry donates surplus funds back into the research community.
Bellberry Human Research Ethics Committees (HRECs) are professionally managed and have been established to exclusively service the research community. Bellberry HRECs provide high quality and independent review and guarantee **rapid turn around times** for assessment of ethical and scientific research proposals.
Bellberry Human Research Ethics Committees comply with the strict guidelines as set by the National Health and Medical Research Council (NHMRC) and ensure that 'all kinds of research involving or impacting on humans conform to the highest standards of ethical practice and academic integrity.'
[Click here to find out how to apply and more information about our new streamlined online submission system.](#)

Quick Links: How to Apply, eProtocol Help, Meeting Dates, Log into eProtocol

Sitemap:
About: Committees, Donations, Directors, Newsletter Library, Contact Us
Committee Members: Orientation, Member Requirements, eProtocol, Education, Policies & Links, Minutes
Investigators: Meeting Dates, How to Apply, Guidelines, eProtocol Help, Policies, HoMER, Fees, Monitoring, Forms, Go to eProtocol
Participants: General Information, Information to Consider, Complaints, Resources, Useful Links, Definitions, eProtocol
Contact Us: Feedback
Disclaimer, Privacy Policy

User Identification – Password

In order to access the eProtocol application you'll need a User Name and Password. If you do not have one, click on the registration button, complete and submit the form. Your application will be validated and an email with your access details will be emailed to you. 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)

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**.

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.

- **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.

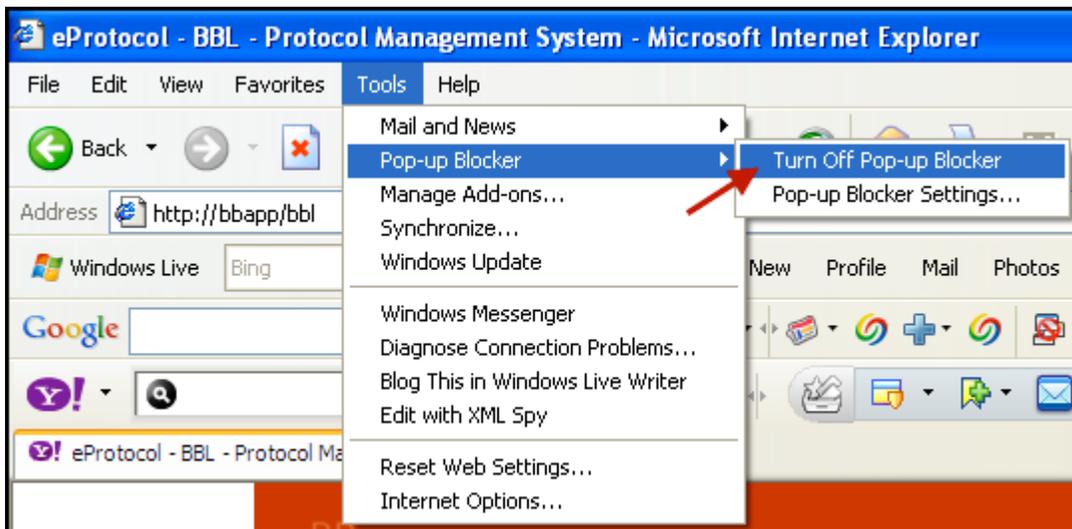
- **Sign Out when done.**

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.

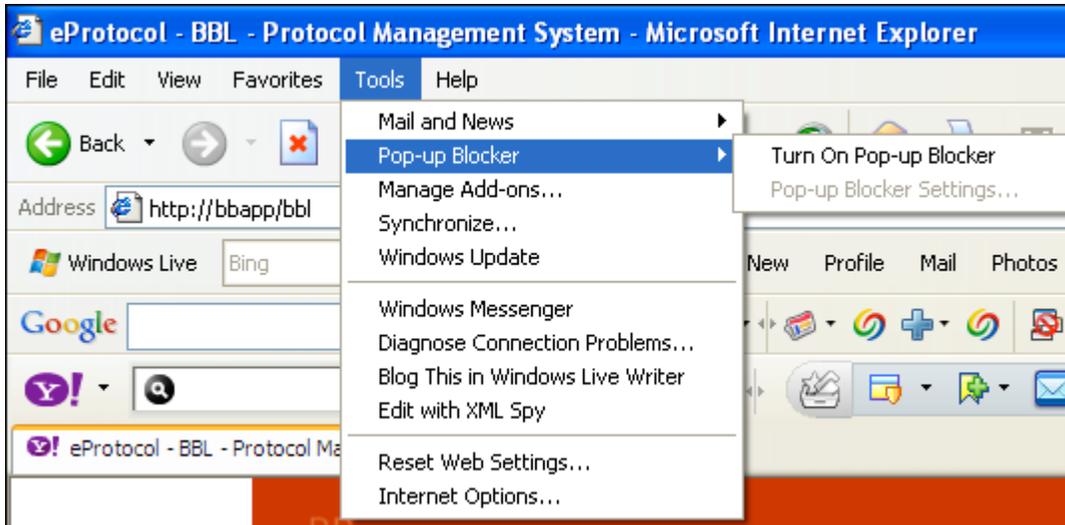
Internet Explorer: allowing pop-ups

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.



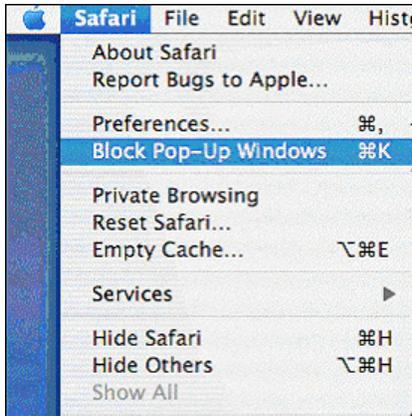
Safari: allowing pop-ups

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.

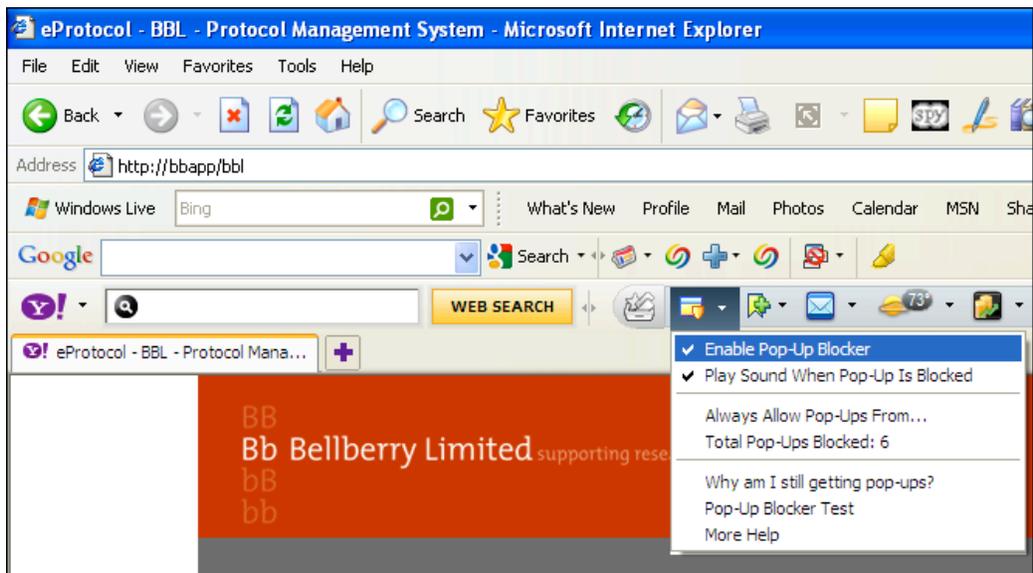


3. When Pop-up Blocker is correctly turned off, it will show Block Pop-up Windows as unchecked.



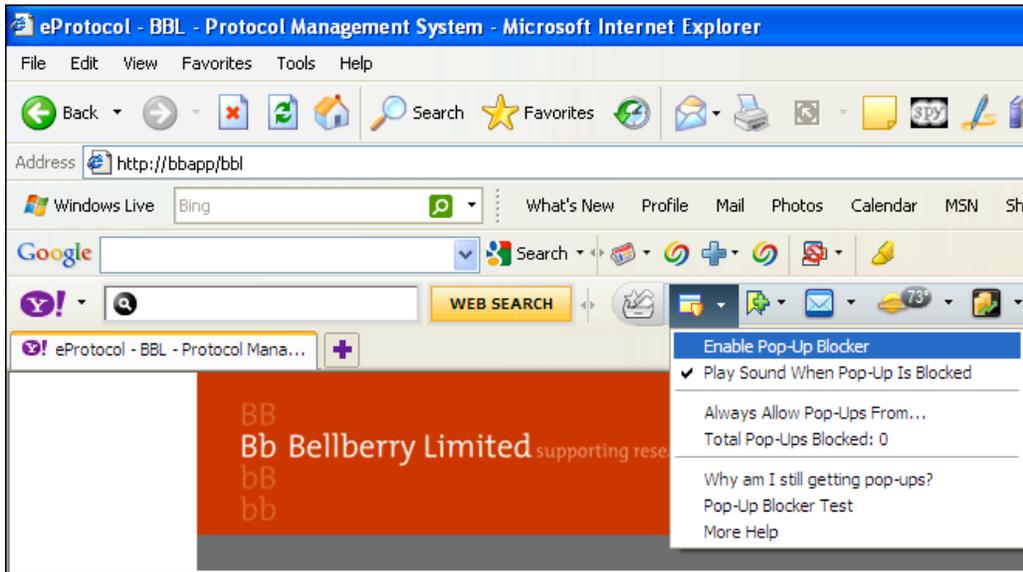
Yahoo Toolbar: allowing pop-ups

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.

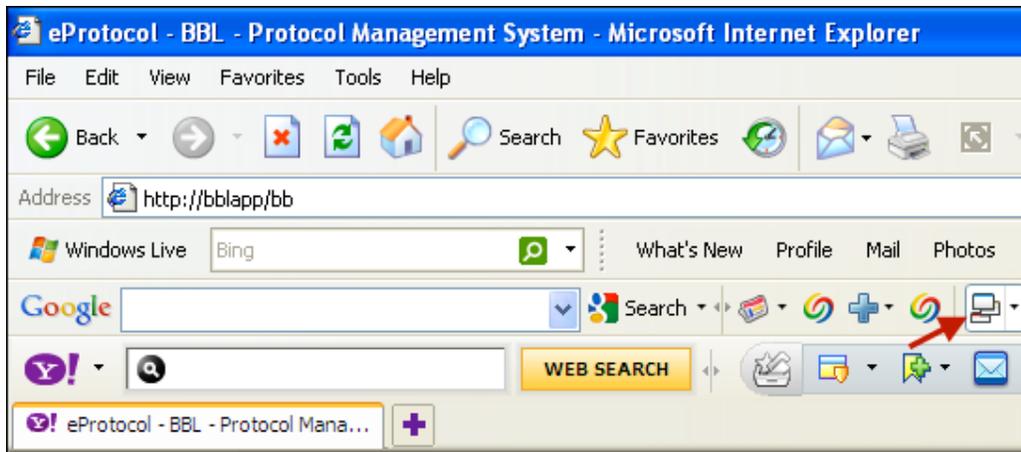


Google Toolbar: allowing pop-ups

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.



Who can log in?

Anyone wishing to submit an application can apply for a User ID and Password by registering on the eProtocol homepage. Select the Register button and complete and submit the form.

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
- Tax Invoice

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

- **PLEASE NOTE:** *If you are listed in the "Other Personnel" section of a study application, you only have read access to that study.*

When is independent ethical review needed?

For a definition of Human Research please click [here](http://www.nhmrc.gov.au/publications/ethics/2007_humans/purpose.htm#d)
http://www.nhmrc.gov.au/publications/ethics/2007_humans/purpose.htm#d

As per the National Statement on Ethical Conduct in Human Research (2007), 'institutions are responsible for establishing procedures for the ethical review of human research. That review can be undertaken at various levels, according to the degree of risk involved in the research (see *Section 2: Themes in Research Ethics: Risk and Benefit, Consent responsibilities*, and *Chapter 5.2: Responsibilities of HRECs, other ethical review bodies, and researchers*).

Research with more than a low level of risk (as defined in paragraph 2.1.6, page 20) must be reviewed by an HREC. Research involving no more than low risk may be reviewed under other processes described in paragraphs 5.1.18 to 5.1.21 (page 92). Institutions may also determine that some human research is exempt from ethical review (see paragraphs 5.1.22 and 5.1.23, page 93).'

A judgment that a human research proposal meets the requirements of this National Statement and is ethically acceptable must be made before research can begin.

For review requirements of activities such as **quality assurance or improvement and clinical audit** [click here](#). 'When does quality assurance in healthcare require independent ethical review? NHMRC 2003
(<http://www.nhmrc.gov.au/publications/synopses/e46syn.htm>)

All applications for studies must be submitted to Bellberry via e Protocol. Approval must be granted before recruitment and data collection may start.

Click [here](#) to access more information that is available on the National Health and Medical Research Council Website . link www.nhmrc.gov.au

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.



The screenshot shows the 'Home' page of the eProtocol system. At the top, there is a 'Home' label. Below it, there are three buttons: 'Create Application', 'Clone Application', and 'Delete Application'. A red text annotation 'Show/hide sections by clicking on these arrows' with two red arrows points to the expand/collapse arrows on the right side of the 'Applications (In Preparation / Submitted)' and 'NEW' section headers. Below these headers is a table with the following data:

Application ID	Principal Investigator	Application Event	Status/Comments	Panel	Meeting Date
10-01-318	Atherton, Michael S.	Responses Sent (Cycle 1)	IN-PROGRESS	BBL	28/01/2010
10-01-316	Atherton, Michael S.	SUBMITTED TO HREC	IN-PROGRESS	BBL	

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.

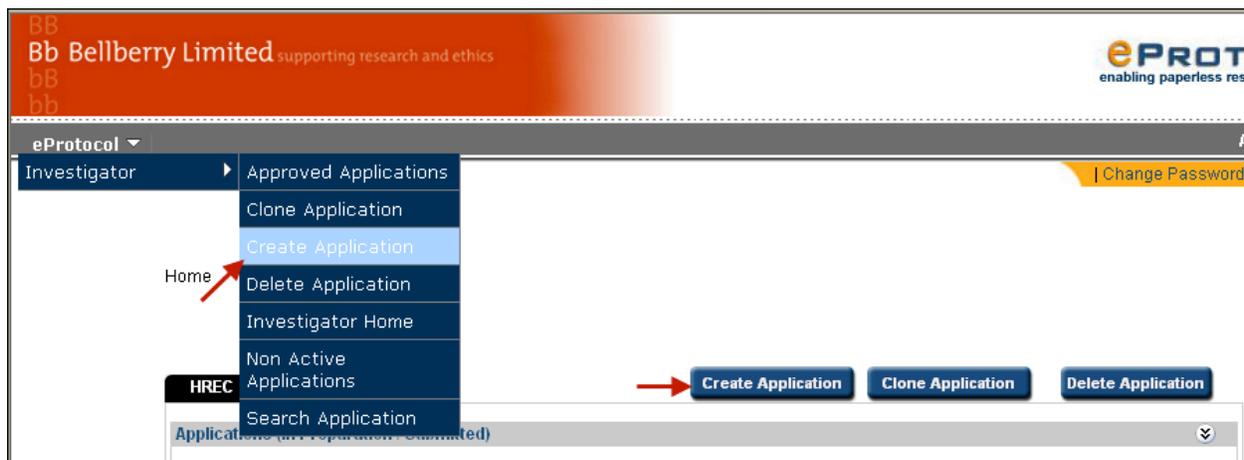
Applications (Approved)

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 Protocol Title, Personnel Information) before your application form is generated, a Bellberry Reference number assigned, and the initial information that you have entered is saved.

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.*

Filling in an Application Form

Study Title

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.	<input type="text"/>	<input type="text"/>
E-mail	Phone	Fax
michael@gmail.com	(999)999-9999 <input type="text"/>	(999)999-9999 <input type="text"/>
Post Code		
<input type="text"/>		

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
<input type="text"/>	<input type="text"/>	<input type="text"/>
E-mail	Phone	Fax
<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>
Post Code		
<input type="text"/>		

Nominated Contact

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

Name	Degree (MD/PhD/MS)	Title
<input type="text"/>	<input type="text"/>	<input type="text"/>
E-mail	Phone	Fax
<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>
Post Code		
<input type="text"/>		

Tax Invoice

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

Name	Degree (MD/PhD/MS)	Title
<input type="text"/>	<input type="text"/>	<input type="text"/>
E-mail	Phone	Fax
<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/>
Post Code		
<input type="text"/>		

- 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.

- 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 *****.

Name of the Site *	<input type="text"/>
Physical Location of the Site *	<input type="text"/>

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

<input type="checkbox"/> Australian/local
<input type="checkbox"/> International

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

<input checked="" type="radio"/> Yes <input type="radio"/> No

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

HREC - HREC Application Form Application ID: 10-01-320 (Atherton, Michael S.)

Application Title: HREC Test Application

← Previous Next →

✓ Spell Check ? Help Save X Close



Site/Location (Where will the study be conducted).

Studies being conducted within hospitals and or institutions must complete a Site Approval Form and attach a copy with this application. Forms available on the website.

For multi-centre studies please attach a list of each Investigator and the names and physical location of each site from which they will conduct the study.

Personnel Information

Study Sites

Sponsor

Application Information

Check For Completeness

Submit Form

Print View

Event History

Site/Location Add Delete

	Investigator Name	Name of the Site	Physical Location of the Site
<input type="checkbox"/>	Simon, Jones	Bellberry Limited	Dulwich

If the Principal Investigator has responsibility for more than one site/location please advise on how supervision will take place at each site.

← Previous Next →

- When you click add, a window will open where you enter the details related to the site. To view or edit the detailed information, click the Investigator Name link, in this case [Simon, Jones](#). 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.
- Principal Investigator Declaration - remember when completing the application form on page 6 of the Application Information the Declarations box must be ticked.

HREC - HREC Application Form Application ID: 10-01-320 (Atherton, Michael S.)
 Application Title: HREC Test Application

← Previous Next →

✓ Spell Check ? Help Save X Close

1 2 3 4 5 6 7

Declarations

Will the consent process comply with the National Statement Item 5.2.16 Section (a)-(f)? Yes No

If Not, why not?

Do you have any Conflict of Interest as per Section 3.3.4 of the National Statement? Yes No

If Yes, please disclose.

Is the Investigators Brochure current, relevant and are all relevant matters relating to the study covered in the application? Yes No

If Not, why not?

Have you signed a Clinical Trial Agreement? Yes No

If yes, and Schedule 7 has been completed, please attach a copy in the Attachments section.

The Principal Investigator has read and agrees to abide by the above Declarations.

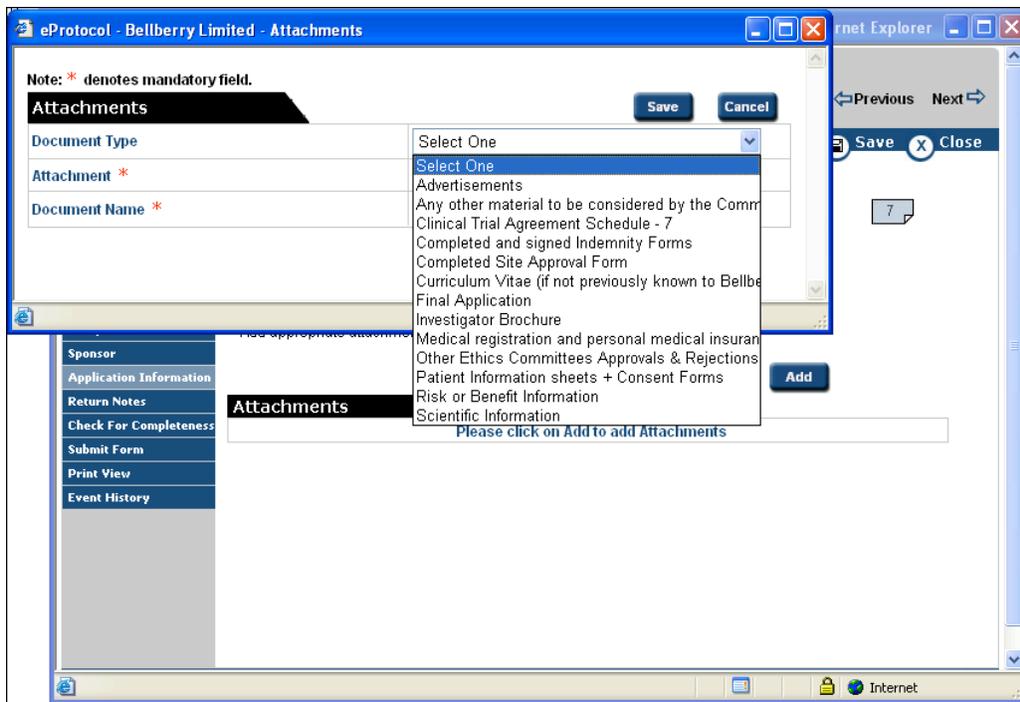
← Previous Next →

- **Attachments** Page 7 of Application Information

This section allows you to attach documentation from the listing above. Ensure that you save the document under the correct heading and that you save the file 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 as reviewed documents.



- 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.

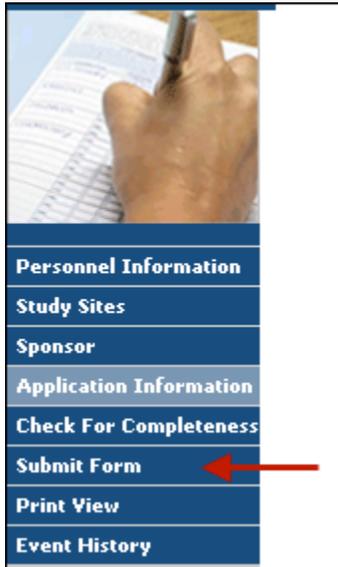
NOTE: The check for completeness feature cannot check to see if all of the necessary supporting documents have been attached. Be sure to double-check that this has been done before you submit your application.

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.

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.

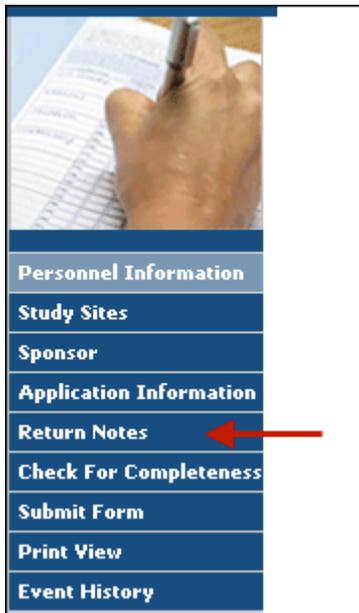
PLEASE NOTE: Once an application is submitted, you will not be able make edits or additions, unless requested as part of the Bellberry HREC review process.

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.

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:

HREC						Create Application	Clone Application	Delete Application
Applications (In Preparation / Submitted)								
NEW								
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:

[Home](#) » Comments

Application ID: [10-01-316](#) (Atherton, Michael)

Cycle: **1**

Comments [Get Application](#) [Show All Comments](#) [Submit to HREC](#)

Comment 1

Select Section : Personnel Information

Please add nominated contact details.

Response Necessary for Approval

Suggestion Not Necessary for Approval

Response :

[Save](#) [Clear](#)

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)
- 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 the application is officially approved in the system, it will no longer appear on the top of your home page in the **Applications (In Preparation / Submitted)** section, but will be visible in the **Applications (Active)** section. To see the listing of your approved applications, you'll need to select Applications Active from the menu bar at the top of the screen.

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** and wait for Bellberry Approval before implementing the change.

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 \(link to instructions\)](#) instead. As part of the Ethics Approval Extension application, you may include any proposed changes to the application.

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.

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

Home

HREC Create Application Clone Application Delete Application

Applications (In Preparation / Submitted)

Approved Applications

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

- 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, Administration Contact, Co-Investigator, Other Contact) 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.

Approved Application Decision

Please select any one of the following:

- Open in View Mode
- Application Details
- Start Amendment/IB
- Start Ethics Approval Extension
- Start Final Report Form
- Start Progress Report Form
- Start Adverse Event Report Form
- Start Protocol Deviation/ Violation Report Form
- Close Application

OK Close

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

PLEASE NOTE: If an Amendment Form does not open when you click OK, then you

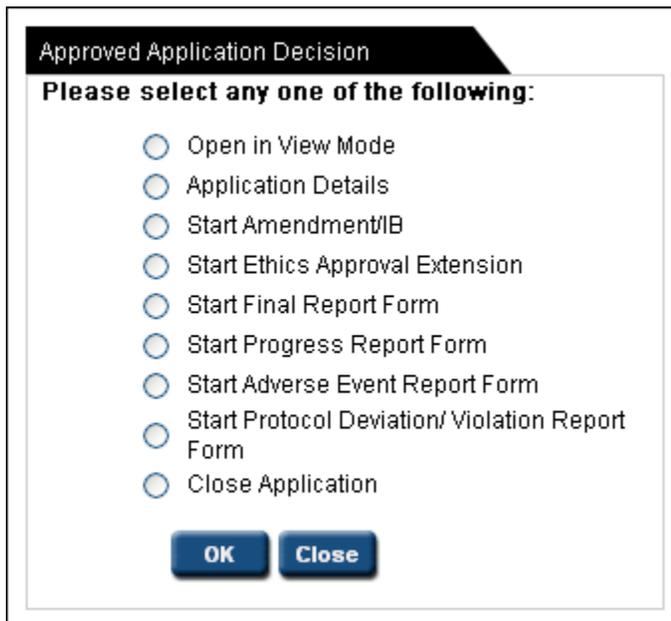
have pop-up blocking software on in your browser. Even if you believe you have allowed pop-ups, there may be additional toolbars, etc. that are blocking your pop-ups. See [instructions](#) for allowing pop-ups in your browser.

5. Answer all of the questions on the Amendment/IB Form 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 update your answers to reflect those changes.**
6. Submit the amendment form when ready by clicking the **SUBMIT APPLICATION** option in the left-hand menu.

Ethics Approval Extension (Renewals)

To start an 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 as shown below:



3. If the option to start an Ethics Approval Extension is not available (you cannot click on it) then:
 - o 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.
 - o 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 application is listed there.
4. Select "Ethics Approval Extension" and click OK.

PLEASE NOTE: If an 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 ID: 09-12-250 (Atherton, Michael S.)

Application Title: HREC Application Form Next →

Spell Check
 Help
 Save
 Close



- Amendment/IB
- Personnel Information
- Study Sites
- Sponsor
- Application Information
- Check For Completeness
- Submit Form
- Print View
- Event History

Amendment/IB Submission Form

Protocol Title
HREC Application Form

Principal Investigator Name Michael Atherton

Protocol No. 33

Date of Report

1. Protocol Amendment Yes No

Version No.

Date

Attach Relevant Documents

Attachments

Select 'Yes' to add Attachments

2. Investigator Brochure Update Yes No

Investigator Brochure Name

Version No.

Date

3. Other Amendment Yes No

Summarise the proposed changes.

Are changes required in the Participant Information Sheet? (Attach tracked copy) Yes No

If not, why not?

[Add](#)

Attachments

Please click on Add to add Attachments

Next →

5. Answer all of the questions on the Ethics Approval Extension Form page.
6. Submit the form when ready by clicking the SUBMIT APPLICATION option in the left-hand menu.

Completing a Progress Report

HREC - HREC Application Form Application ID: 10-01-276 (Atherton, Michael S.)
 Application HREC Application Form Title: Spell Check Help Save Close

Progress Report
 (To be completed for annual monitoring requirements.)

Progress: Report Form
 Submit Form
 Print View
 Get Application

Protocol No. 10-01-276

Research Application Title
 HREC Application Form

Principal Investigator Atherton, Michael S.

Date of Study Approval 11/01/2010

Date of Report

	Number	Comments
Number of Participants screened	<input type="text"/>	<input type="text"/>
Number of Participants enrolled	<input type="text"/>	<input type="text"/>
Number of active Participants	<input type="text"/>	<input type="text"/>
Number of Participants withdrawn.	<input type="text"/>	<input type="text"/>
Number of Local Serious Adverse Events Reported to HREC	<input type="text"/>	<input type="text"/>

Reason for participant withdrawal

Adverse events leading to withdrawal

Serious Adverse Events

Please comment on the following:

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

Attachments

Please click on Add to add Attachments

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

Repeat the above steps and select 'Progress Report Form' from the **Approved Application Decision Box**

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

Adverse Event Report Form

HREC - HREC Application Form Application ID: 10-01-276 (Atherton, Michael S.)
Application HREC Application Form
Title:

✓ Spell Check ? Help Save X Close



Adverse Event Report Form

Protocol No. 10-01-276

Protocol Title
HREC Application Form

Principal Investigator Atherton, Michael S.

Select ONE of the following:

- Individual Event**
This form is to be completed for Local Serious Unexpected Suspected Adverse Events (SUSARs) occurring at a Bellberry approved site.
- Summary Report**
This form is to be completed for Summary Reporting.

ATTACHMENTS FOR SUMMARY REPORTS

Attachments
Please click on Add to add Attachments

1. REPORTING OF INDIVIDUAL EVENTS

Date of Event Report No. _____

Date PI learned of Event _____

Description of Event

Are there any ethical implications of the event on the conduct of the trial?

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

Please indicate if any of the above adverse events necessitates an amendment to the Protocol and/or the Patient Information Sheet/Consent Form.
If yes start and Amendment and reference this report.

Has the Sponsor or Data Safety Monitoring Board been notified of the event (if relevant)?
If no please provide reasons:
 Yes No Not Known

Attach relevant documents

Attachments
Please click on Add to add Attachments

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

Repeat the above steps and select 'Adverse Event Report Form' from the **Approved Application Decision Box**. Select either of – **Individual Event** or **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.

Once completed **Submit Form**.

Start Violation Report

HREC - HREC Application Form Application ID: 09-12-226 (Atherton, Michael S.)
Application HREC Application Form
Title:

✓ Spell Check ? Help Save X Close



Protocol Deviation/ Violation Report

Bellberry requires reporting of all application deviations and/or application violations within 14 days of the event.

Principal Investigator Name

Date of Report 

Research Protocol Title

Protocol No

Participant's ID:

Date of Event: 

Provide a full description of the application deviation/violation as well as why the deviation/violation occurred. What happened, when it happened, where, how, and why it happened. (attach as many pages as necessary):

Attachments

Please click on Add to add Attachments

Describe the action taken in regard to the event.(Attach as many pages as necessary):

Describe the effect the event had on the participant:

Describe the action taken to prevent any future recurrence of this protocol/deviation? (Attach as many pages a necessary)

Who was the violation/ deviation reported to?

Sponsor Yes No NA

Date Notified

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

Repeat the above steps and select 'Start Protocol Violation Report' from the **Approved Application Decision Box**.

Complete required fields.

Once completed **Submit Form**.

Start Final Report Form

HREC - HREC Application Form Application ID: 09-10-175 (Atherton, Michael S.)
Application Title: BBL Test HREC Study Title

Spell Check Help Save Close

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

Protocol No. [REDACTED]

Research Application Title
BBL Test HREC Study Title

Principal Investigator: Michael Atherton

Date of Study Approval: 29/10/2009

Date Study Closed: [REDACTED]

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

	Number	Comments
Number of Participants screened	[REDACTED]	
Number of Participants enrolled	[REDACTED]	
Number of active Participants	[REDACTED]	
Number of Participants withdrawn	[REDACTED]	
Number of Local Serious Adverse Events Reported to HREC	[REDACTED]	

(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:

- Maintenance and security of records held in relation to this study.
- Compliance of the study with the approved application, consent procedures and documentation.
- Any new scientific information that may impact on the current conduct of the study? (Attach relevant information in Attachments table below).
- Any new risk or benefit information related to the research not previously reported to Bellberry? (Attach relevant information in Attachments table below).
- Compliance with any conditions of approval if relevant.
- Any unforeseen events/new information that may affect continued ethical acceptability of the project?
- 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 above steps and select 'Final Report Form' from the **Approved Application Decision Box**.

Complete required fields

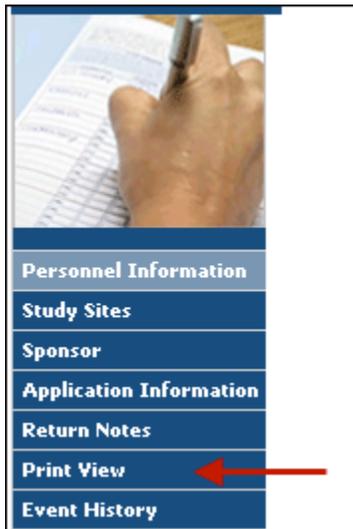
Once completed **Submit Form**

Update Study personnel

If there has been a change in the personnel related to a particular protocol, you'll need to include these changes as part of a Modification (Revision) or Continuing Review (Renewal) application. Follow the instructions on the top of the *Personnel Info* page in the application 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:

Print View

Please select any one of the following:

Application Only
 Application with Comments
 Comments only

Sections to Print	Select Orientation	
	Portrait	Landscape
<input checked="" type="checkbox"/> All		
<input checked="" type="checkbox"/> Personnel Information	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Study Sites	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Sponsor	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Rationale	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Participant Population	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Radiation	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Risks	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Ethics Committee	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Declarations	<input checked="" type="radio"/>	<input type="radio"/>
<input checked="" type="checkbox"/> Attachments	<input checked="" type="radio"/>	<input type="radio"/>

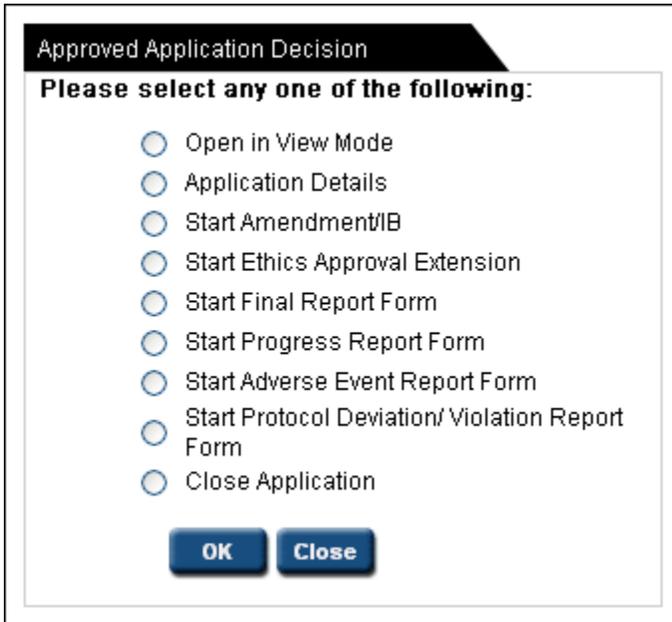
OK

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.

Close a Study

To Close a Study, 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 as shown below:



Approved Application Decision

Please select any one of the following:

- Open in View Mode
- Application Details
- Start Amendment/IB
- Start Ethics Approval Extension
- Start Final Report Form
- Start Progress Report Form
- Start Adverse Event Report Form
- Start Protocol Deviation/ Violation Report Form
- Close Application

OK Close

3. Select Final Report and complete the application and submit to Bellberry.
4. You will see the option to "Close Application" as shown above.
5. Simply select "Close application" and click OK. You'll see another window in which you'll confirm that the application should be closed.

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, Admin Contact, Co-Investigator, Other Contact) 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).