The following guide is a compilation of several individual forms which aim to assist researchers in operating eProtocol.

Index

Software requirements

Recommended browser

eProtocol is compatible with most popular browsers. We recommend using the most recent version of the following web browsers:

- Firefox
- Edge
- Chrome
- Safari (if using a Mac)

Disabling Pop-ups

Pop-up blockers prevent the eProtocol application from opening certain windows.

You will need to make sure that your internet browser has all pop-up blockers disabled or pop-up windows allowed for the eProtocol website. You can usually find how to do this in the 'Settings' of your browser.

Understanding your eProtocol home page

The first page that appears after logging in to eProtocol is your HOME page. Your HOME page has two main sections that display all the applications on which you have been listed in the *Personnel Information* 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.

If you cannot see your applications, you may have to click on 'Show Section' to unhide it. If, after unhiding the relevant section, you are still unable to see your applications, it means you are not listed in the personnel section for that application. To be listed, the nominated contact for the study must submit an amendment adding you to the personnel page. (Refer to the section on registration).

Applications (In-Preparation/Submitted)

This is the "work-in-progress" area. It displays all your applications that yet to be approved, e.g. new studies; amendments; 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/not approved in the system.

Approved Applications

This is the "work-completed" area. It displays a listing of your approved applications. Click on an application ID from the list to have the option to view the most recent approved version of the application, or to start an Amendment or any other study report. Remember, these options are only available to those people listed on the Personnel Information page of the application.

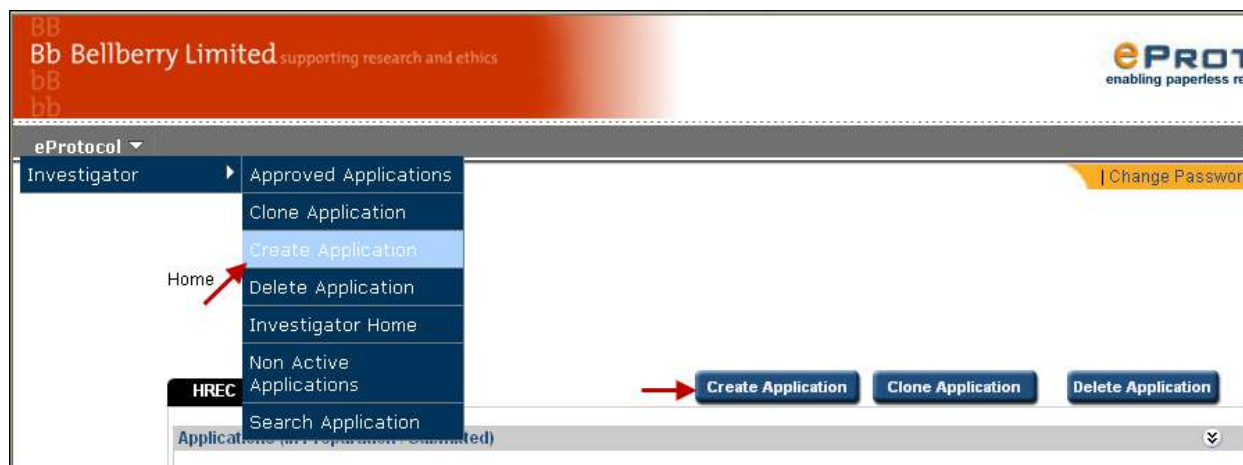| Application ID	Principal Investigator	Title	Approval Date	Last Approval Date	Expiration Date	Review Decision	Form Type
2019-08-232-A-3	Smith, Paul	This is entered manually ' This is pasted n's (manually ...	20/08/2019	20/08/2019	19/08/2029	Administrative Review	AMENDMENT/ IB SUBMISSION

Non-Active Applications

Once a study has closed, and the Final Report is acknowledged, non-active applications will remain in this section. These studies will not be editable but will be available to view for ongoing reference.

Application ID	Principal Investigator	Title	Approval Date	Last Approval Date	Status/Comments	Form Type
2018-09-779	Clark, Sarah	help	27/06/2019	27/06/2019	EXPIRED	

Creating a new application

On the home page, click on the CREATE APPLICATION button in the upper right-hand corner of the home page or click on CREATE APPLICATION option in the menu.

The study title and Principal Investigator's name is required to generate the start of the application.

eProtocol will default to fill the Principal Investigator field with the details of the person who creates the application. To change the name from the person who created the application to the Principal Investigator:

- Click on the binoculars in the Principal Investigator name field,
- Enter the first or last name or User ID of the Principal Investigator. Their name will appear under the table.
- Click on the radio button next to their name, then click SAVE.
- If the person who created the form needs to have ongoing access to the application, it is essential to add the name of that person to the relevant section of the Personnel Information page, e.g. Sub-Investigator or Nominated Contact before exiting this page. Follow the instructions above to ensure this occurs. If you do not complete this step, you will not have access to the study.

A Bellberry application number is assigned at this point, and the initial information that was entered is saved.

Once this page is completed, you may continue to work on the application, or exit the system and return later to finish.

Completing the Application Form

All fields in the application form are mandatory.

· Checkboxes mean that you may select more than one item from that group.

· Radio buttons mean that you may choose 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).

Depending on the type of research, some of the questions may not be applicable (for example clinical trials vs social science studies) — mark these as 'No' or 'Not applicable' as appropriate.

The study title, Principal Investigator and nominated contact details entered on the previous 'Create Application' page will automatically fill into the relevant fields for the rest of the application pages. These also appear at the top of each page for reference.

Once you complete each page, select SAVE, and NEXT to progress to the next page. If you choose NEXT, the details will automatically save before moving to the next page. Navigate through the application form using the arrow icons in the upper right corner of the page or click on the page number.

Personnel Information page

CVs - under Principal Investigator, please note that the 'View CV' section is for Bellberry's use only. Please attach updated CVs on page 7 'Attachments' under the heading 'Curriculum Vitae'.

If the Principal Investigator (PI) is also the nominated contact, then only the PI section needs to be completed.

Input of tax invoice contact details

The Tax Invoice section is a mandatory field and must be completed before the application can be submitted to the HREC.

- To enter the Tax Invoice details, click on the binoculars. A second screen will then show, click on the text in blue. This will allow free text entry. Type in the company and contact name, full postal address and any other relevant details.

- If the tax invoice contact is the same as an investigator or nominated contact, please read: eProtocol does not allow the corresponding PI/Nominated Contact entry in the Tax Invoice field. Please ensure that the name is in a different format to the eProtocol registered name e.g. Tom Smith, and T Smith.

Study Sites page

This page has two sections, Multi-Centre Studies and Multi-Site Studies. In some instances, studies may be either Multi-Centre or Multi-Site or they may be both.

Multi-Centre Studies

Add the Principal Investigator's name, the name of the site, and the physical address of the site into the table under section 1.

Multi-Site Studies

Under section 2, please detail what activities the Principal Investigator is undertaking at each site/location and how supervision by the Principal Investigator will be managed. For example, Principal Investigator X will be consenting participants at Research Centre X. Principal Investigator X will be storing participant files at Research Centre Y. The Principal Investigator will be supervising the research activities at each location by XXXX.

Uploading documents

Application, Page 7 – Attachments

When attaching documents, follow the below steps:

- Select the appropriate document type from the drop-down list
- Click BROWSE to search your directories to add the document
- Repeat this step to add each of the documents to be included in the review
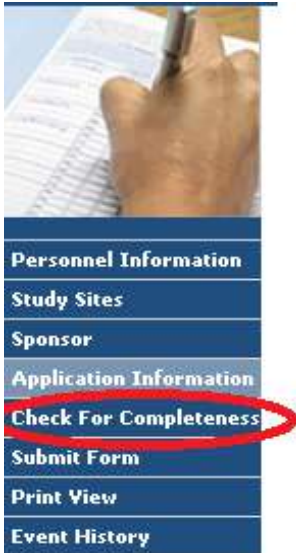
Submitting applications

When the application is complete, a check for completeness is required. This can be access via the left-hand blue menu, as shown below:

- Once you click on the check for completeness, a new box will open with a message that will indicate which sections may be missing information.
- You can click directly on the link to take you to the page where the additional information is required.
- The check for completeness feature cannot check that all necessary supporting documents have been attached. Be sure to double-check that this has been done before you submit your application.

Following the check for completeness, the application can be submitted. Once an application is submitted you will not have edit access to make edits or additions until the application is returned to you.

To submit the application, follow the below steps:
- Ensure the application is open in EDIT mode
- Click on the SUBMIT FORM button in the left-hand menu of the Application Form (as shown below)
- Select YES and the application will automatically be submitted to Bellberry

Please be patient after clicking submit. The system 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.

Returned applications

Sometimes it is necessary to return an application. Return advice will be communicated by email to the contacts on the application. The 'Application Status' displayed on your home page will be changed to 'Submission Returned'.

If you receive an email advising that your application was returned:

- Open the application and click on 'Return Notes' in the left-hand menu to view the comments.

This will open a window with information regarding the reason your application was returned and instructions on how to proceed.

Make the necessary changes and additions to the application and attachments. Please note that to make changes to the application you will need to open it in 'Edit' mode.

When the application is ready to be resubmitted, click the SUBMIT FORM button.

The HREC Return Notes area is used only for instructions from Bellberry relating to returned applications. The Investigator/Contact cannot add text or respond to a Return Note.

Printing an application

You can 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

A small window will open:

- Select an option, sections and their orientation, and click OK

- The Adobe pdf file will be created and will open automatically

- You may save it to your computer by clicking *File*, then *Save as* located in the upper left-hand corner of the window

If you are having difficulty with this function your Windows software may be blocking it. If this is the case, please go to the application page and use the keyboard short cut 'Ctrl P' to print individual pages.

Post HREC meeting & application decisions

After Review at the HREC Meeting

Comments are sent in eProtocol and an automatic email is sent to notify the site that comments are available. The 'Application Status' displayed on the home page will be changed to 'Comments Received (Cycle 1)'. Click in this wording to access the comments.

To copy or print the comments, use the *Show All Comments* to list all the comments. You can use the print screen button and then right click on your mouse to copy into a word or email document.
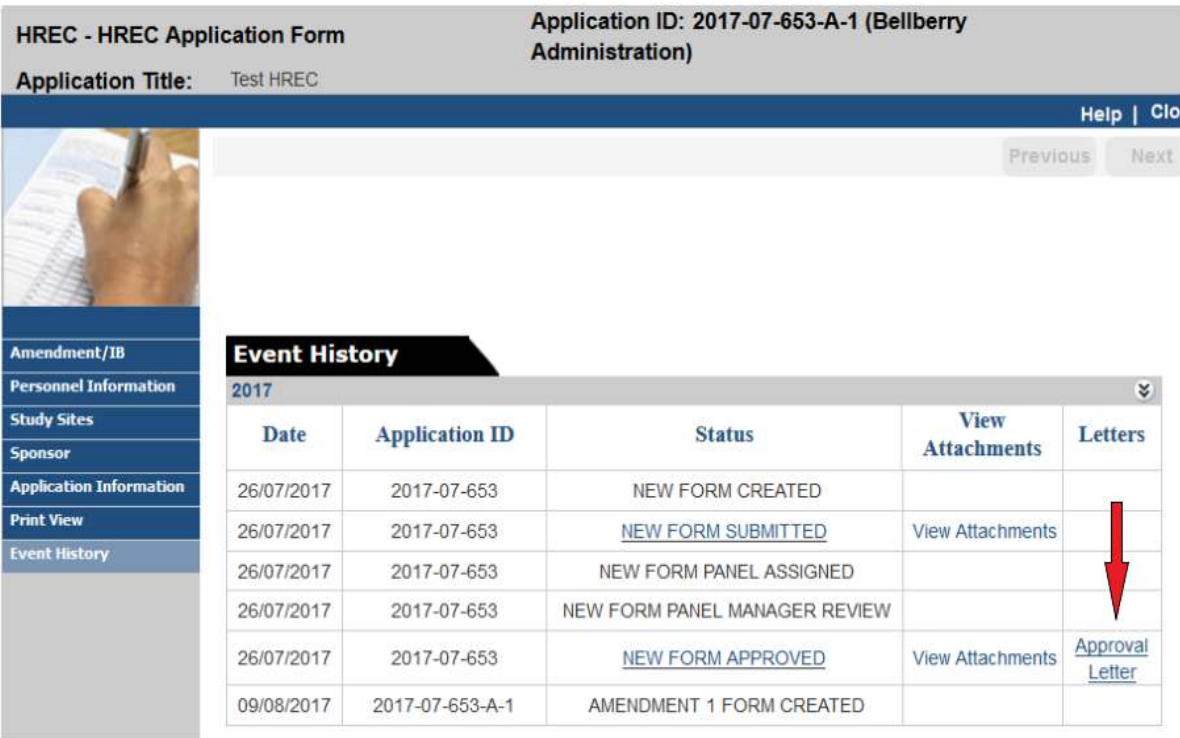
Preparation for resubmission

- Do not delete any documents. For auditing purposes all previously submitted documents must remain attached to the application

- Update all version and date references in both the document name and document footers.

- Attach additional or updated (track& clean) documents in Page 7 of the application

- Make the revisions/updates 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).

- When all the comments have been responded to and updated documents have been attached into Page 7 click the SUBMIT TO HREC button (upper right-hand corner of the page) to send the responses and revised application back to Bellberry.

- 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.

The Committee will review the responses outside of a meeting via the workflow function in eProtocol. Further comments will be sent back to the site if required and this process is repeated until the Committee are either satisfied with the changes made or decide to not approve the study.

Application Approved

Once the application has been approved the contacts listed on the application will receive email notification with instructions on how to access the approval letter in eProtocol. Open the application and, on the left-hand navigation, last option, select 'Event History'.

The approval letter can be accessed in the 'Letters' column. Read the approval letter to confirm all the conditions of approval.

When the approval has been processed in the system it will appear at the bottom of your home page under 'Approved Applications'.

If an application is not approved, a letter will be prepared to the Principal Investigator. A copy will be emailed to the site and will also be attached to page 7 of eProtocol.

Creating an amendment

eP>**H**ome>**A**pproved applications>**A**pplication ID>**A**mendment

A pop-up window will open. Within this window select 'start amendment' and click OK

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, that are blocking your pop-ups.

Alternatively, if this option is still not available, then an amendment or a progress report/ submission may be active. Check the 'Applications (In-preparation/Submitted)' section to see if the study is listed there. Please note that once the submission of an amendment has occurred, you will not be able to start a progress report application until the amendment has been reviewed and approved. If the ethics expiration date is near, please complete a progress report before creating an amendment. Once processed, you will then be able to submit an amendment.

Before attaching your documents, please ensure that they are named correctly. Do not edit the name of the document within eProtocol. Attach your documents at the bottom of the amendment form.

Once completed click SUBMIT FORM

Public

Creating a safety submission

eP >**H**ome>**A**pproved applications>**A**pplication ID>**S**tart adverse event/safety report form

A pop-up window will open. Within this window select 'adverse event/safety reporting' and click OK
If an adverse event/safety report 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, that are blocking your pop-ups.

On the form select either:
1. Individual Event
            OR
2. Summary Report

For an Individual Event**,** select section 1 and complete the report as required. Ensure that all questions are answered including the details of the event and attach relevant documents.

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

Once completed click SUBMIT FORM

Creating a serious breach report

>**H**ome>**A**pproved applications>**A**pplication ID>**P**rotocol violation

A pop-up window will open. Within this window select 'protocol violation' and click OK

If a protocol violation 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, that are blocking your pop-ups.

Please attach any documents at the bottom of the form

Once completed click SUBMIT FORM

Creating a progress report

eP >**H**ome>**A**pproved applications>**A**pplication ID>**P**rogress report

A pop-up window will open. Within this window select 'progress report' and click OK

If a progress report 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, that are blocking your pop-ups.

Alternatively, if this option is still not available, then an amendment submission may be active. Check the 'Applications (In-preparation/Submitted)' section to see if the study is listed there. Please note that once the submission of an amendment has occurred, you will not be able to start a progress report application until the amendment has been reviewed and approved. If the ethics expiration date is near, please complete a progress report before creating an amendment. Once processed, you will then be able to submit an amendment

Please attach any documents at the bottom of the form.

Once completed click SUBMIT FORM

Creating a final report

e P >**H**ome>**A**pproved applications>**A**pplication ID>**F**inal report

A pop-up window will open. Within this window select 'final report' and click OK

If the final report 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, that are blocking your pop-ups.

Once this form is acknowledged by the Committee the study will be closed in eProtocol, and no further submissions can be made. The application will be able to be viewed in the Non-Active Applications section on the home page

Once completed click SUBMIT FORM

Deleting a submission

eP>**H**ome
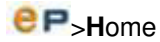
Select 'delete application' from the top of the page.

Select which submission you wish to delete by ticking the corresponding checkbox in the first column on the left. You may tick multiple checkboxes to delete multiple submissions at once. The checkbox at the top of the column will select and deselect all checkboxes.

Once you've selected which submission you would like to delete, select 'delete application' from the top of the page.

A pop-up window will appear. Confirm you wish to delete the selected applications by selecting 'yes'.

Troubleshooting and FAQs

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 60 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.

Be patient
Some processes can take a short time 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.

Changing a 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). Once on this page, if you cannot remember your hint question, follow the 'click here' link. This will take you to a second 'forgot password' page where you must enter your UserID and email address. Follow the steps outlined in the email generated by the system.

Forgot Password	Submit
UserID*	
Email Address*	
Hint Question*	Select Hint Question ▼
Answer*	

Click here to get an email with your login details

Forgot Password	Submit
UserID*	
Email Address*	

Please provide User ID and Email Address used in eProtocol registration   Back

I can't see my approved applications
Your approved applications will appear on your eProtocol home page (the page you see when you first log in) in the section labelled 'applications (approved)'. This section should appear towards the middle of your page. You may need to click on the button located on 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 'creating an amendment' 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' 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, sub-investigator, nominated contacts) have access to edit the study/application.

An amendment or progress report 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 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 HRECs 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 'Post HREC meeting & application decision' instructions on how to respond to HREC comments. If your application was returned, please see instructions for 'Returned applications'.

Access to eProtocol

Once logged in to eProtocol, you will be able to create a new application, and to view and edit any applications on which you have been listed in the Personnel Information section. You will only have access to edit those studies/applications on which you are listed as either:

•   Principal Investigator
•   Sub-Investigator
•   Nominated Contact

If you are a new Sub-Investigator or Nominated Contact for an existing study, you will need to ask one of the existing study personnel listed on the Personnel Information page of the Application to create and submit an Amendment in eProtocol to add your details. Following approval of that Amendment you will then have view and edit access for the specific study. Refer to the Amendments section of this guide for details about how to do this.

If you are added during a study, you will not be able to access previous versions of documents. The PI however will be able to (unless they have taken over from another PI).

Attaching videos into eProtocol

Videos cannot be uploaded directly into an eProtocol application; however, they can be embedded into a document which can then be attached to page 7.

The document should be named as you want the video to appear on the approval letter.

To embed a video into MS Word, PowerPoint or Excel, please refer to the instructions below:

1. On the Insert menu, click Object, and then click the Create from File tab.
2. Click Browse and locate the movie (video clip or sound wave) you want to insert.
3. Select Movie (video clip or sound wave)
4. Click Insert.
5. To play media clip, double-click its icon.
6. Save using the preferred file name.

Searching for a historical submission

From the 'investigator' home page, Principal Investigators will be able to view a complete list of submissions for projects under their responsibility. Applications will be grouped into 'applications (in preparation/ submitted), 'approved applications', or 'non-active applications'.

eProtocol » Investigator » Home

| Create Application | Clone Application | Delete Application |

HREC

Applications (In Preparation / Submitted)

NEW

Application ID	Principal Investigator	Title	Application Event	Panel	Meeting Date
2020-07-712			Yet to Submit to HREC		

From the 'investigator' home page, holding Ctrl+F will display a search bar. Entering an identifier such as the HREC application ID into the search bar will highlight items on the page that match the search criteria.

From time to time a submission may not be visible from the 'investigator' home page. This may occur when a new Principal Investigator has taken over responsibility for a project, or when a Sub-Investigator/ nominated contact completes a submission on behalf of an investigator.

To access a submission that is not visible on the eProtocol landing page:
1. Hover over the eProtocol tab in the top left-hand corner of the page.
2. Move the mouse to hover over 'investigator'. A list of options will display. Click 'search protocol'.
3. Enter the relevant HREC application ID the search box. Click 'search'.

If uncertain of the specific HREC application ID, type a different identifier into one of the search fields. For example, entering the Principal Investigator's name into the search box and clicking 'search' will display a complete list of all submissions made by, or on behalf of, that investigator. Alternatively, selecting the organisation name and clicking 'search' will display a complete list of all submissions for projects occurring at that site.

A combination of search fields may be used, such as:
- study title,
- form type (amendment, progress report, protocol violation report, etc.),
- organisation name,
- committee (panel),
- meeting date.