

Bellberry Limited
supporting research and ethics



eProtocol

User Guide for Researchers

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Introduction

Bellberry uses eProtocol for fast, secure, online submissions of all research applications to the Bellberry Human Research Ethics Committees. The online eProtocol application can be used for all types of studies including clinical trials, non-interventional, observational and social science studies.

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

Bellberry Human Research Ethics Committees base their review of research studies on the NHMRC National Statement on Ethical Conduct in Human Research. The National Statement sets out national standards for the ethical design, review and conduct of human research and should be used as a guidance document. It is available at www.nhmrc.gov.au/guidelines-publications/e72.

The National PICF is a standardised Participant Information and Consent Form (PICF) that has been developed by a specialist sub-group and approved by the National PICF Project, including representatives from the Australian research community, to serve as a starting point for researchers. The forms will be reviewed annually and updated as needed. All of these documents were designed to provide guidance and assist researchers, institutions and HRECs in the conduct of multi-centre ethical review. The National PICF templates are available at www.nationalpicf.com.au.

If you would like to discuss the submission of an application, Bellberry staff are available to assist you. Please call 08 8361 3222 to speak to our ethics administration support staff. Alternatively, you can email us at bellberry@bellberry.com.au with any queries.

System Requirements

Recommended Browser

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

- Firefox 48+ and Firefox 50.1.
- Internet Explorer 10+
- Chrome 51.02
- Safari 9.1 (if using a Mac)

Pop-up Windows

Pop-up blocking software must be disabled (pop-ups must be allowed) while using eProtocol.

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

Refer to <http://www.bellberry.com.au/investigators/eprotocol-help/getting-started> for information regarding how to allow pop-ups for each browser.

General Tips

Required Programs

Adobe Reader must be installed in order to be able to open Acknowledgement and Approval letters which are saved as PDF files.

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.

eProtocol Registration

The first step of creating an application is to apply for a User ID and password by registering on the eProtocol homepage.

Please ensure that all people that will be involved in the study, i.e. the Principal Investigator, Co-Investigators and any other nominated contacts are each registered with the same organisation. eProtocol has a workflow function and generates automatic emails whenever a transaction between the site and the HREC occurs, e.g. when an application is submitted, comments are returned etc. Everyone who is listed on this page will receive these automated emails.

PLEASE NOTE: *As per the National Statement guidelines, sponsors are unable to submit applications on behalf of the Investigator. National Statement 5.2.20 – ‘Communication between a research sponsor and a review body should be avoided where it may, or may be perceived to, influence the ethical review and approval of the project’.*

Nominated Contacts

Anyone who is registered can create an application.

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 available on the Bellberry website at <http://www.bellberry.com.au/investigators/forms>.

This form provides authorisation from the Principal Investigator for the Nominated Contact to be linked to their organisation and assists with the management of multiple User ID's. The nominated contact will need to register as an eProtocol user under the Principal Investigator's organisation.

Clinical Research Organisations (CRO)

Applicants from a Clinical Research Organisation (CRO) need to provide authorisation from the Principal Investigator by completing the 'eProtocol Authorisation of User Access – Clinical Research Organisation' form available at <http://www.bellberry.com.au/investigators/forms>.

This form needs to be completed for each separate organisation. It is suggested that CROs use their surname, initial and organisation name for the User ID, i.e. 'SmithJ – organisation name'.

Registration Process

Start the registration process on the Bellberry website www.bellberry.com.au by clicking on the 'Log into eProtocol' button.

- Click on 'Register'.
- Complete the registration form.
 - The User ID needs to be created by the applicant. It is recommended that the user ID should be the applicant's surname then initial e.g. SmithA.
 - Ensure that the organisation's name and site address is included.
 - Organisation – to be able to be added on to an application please register with the same organisation as the Principal Investigator as this is how eProtocol links people together.

- Click on 'Submit'.
- The registration will be processed by Bellberry staff and, once validated, an email with access details will be sent to the applicant.

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)

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). It will prompt you to enter your existing password and then enter in your new password and SAVE.

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
- Co-Investigator
- Nominated Contact

If you are a new Co-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 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 a sponsor you are unable to have edit access to a study.

Working with Applications

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 of the applications on which you have been listed in the *Personnel Information* section. This is how the sections appear:



The screenshot shows the 'Home' page of the eProtocol system. At the top, there is a navigation bar with the 'HREC' logo on the left and three buttons: 'Create Application', 'Clone Application', and 'Delete Application'. Below this, there are two expandable sections: 'Applications (In Preparation / Submitted)' and 'NEW'. Each section has a downward-pointing arrow on its right side. Red arrows point to these arrows with the text 'Show/hide sections by clicking on these arrows'. Below the 'NEW' section 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)

This is the "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 studies, amendments, Ethics Approval Extension etc), 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

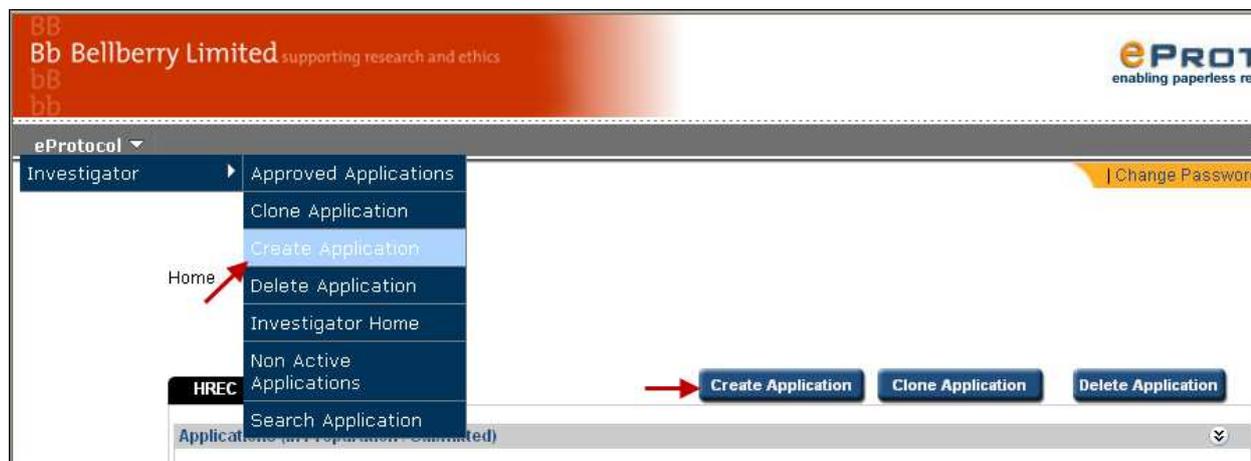
This is the "work-completed" area. It displays a listing of your approved applications. Click on an application ID from the list to have the option to view the most recent approved version of the application, or to start an Amendment or any other study report. Remember, these options are only available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

Non-Active Applications

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

Creating a New Application

To create a new application, login to eProtocol at www.bellberry.com.au.



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.

Basic information will need to initially be entered including the Study Title and Principal Investigator to generate the start of the application.

*Please add the Protocol number (if applicable) in front of the Research Project Title as well as in the Protocol Number section.

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. This will update the Principal Investigator details.
- If the person who created the form needs to have ongoing access to the application, IT IS VERY IMPORTANT to add the name of that person to the relevant section of the Personnel Information page, e.g. Co-Investigator or Nominated Contact before exiting this page. This is done in the same way by clicking on the binoculars and following the previous steps with the relevant name. 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 complete.

PLEASE NOTE: If after entering the title, personnel info, nothing happens when you click CREATE, then you have pop-up blocking software turned 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.

Refer to <http://www.bellberry.com.au/investigators/eprotocol-help/getting-started> for allowing pop-ups in your browser.

Completing the Application Form

Each page of the application is required to be completed.

The application can be used for all types of studies including clinical trials, non-interventional, observational and social science studies. If a question on the application does not apply to your type of study submission you can simply click 'No' or enter 'Not Applicable'.

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 each page is completed select SAVE, and/or NEXT to progress to the next page. If you select 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 page, or click on the page number.

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

PLEASE NOTE: *If you are working on a particular page for a long time, you will need to save frequently to avoid losing work. eProtocol will automatically time out after 60 minutes on one page without saving.*

All fields in the application form are mandatory and are required to be completed.

- 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).

Complete all questions in the application. Depending on the type of research, some of the questions may not be applicable. Mark these as 'No' or 'Not applicable' as appropriate.

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'.

Please note that Bellberry requires a full CV on file for the PI that is less than twelve months old. Please ensure that the CV includes research credentials and relevant publications/research experience.

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 ensure that the name is entered in a different format to the eProtocol registered name for the Tax Invoice. e.g., Tom Smith, and T Smith.

The screenshot displays two overlapping web forms. The top form is titled "Tax Invoice" and includes a "Note: * denotes mandatory field." and instructions: "Please provide organization and contact name in the (Name *) field. Please ensure this contact person name is different to any registered user name." The form contains fields for Name, Title, E-mail, Phone, Fax, Post Code, Address, Company Name, and Purchase Order Number. The bottom form is titled "Find User" and has fields for User ID, First Name, and Last Name, with a "Find" button. A browser window in the background shows the URL "https://epdev.bellberry.com.au/applicationform/FORM_FINDUSER.do".

Study Sites page

This page has two sections:

1. Multi-Centre Studies – the same study is being conducted at other sites independently under supervision of different Principal Investigators.
2. Multi-Site Studies – a Principal Investigator is conducting a study at multiple locations, or where specific aspects of a study under their management will be conducted at a different site.

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

1. Multi-Centre Application

If the site is acting as the Lead Site for a Multi-Centre application, please also add the site details for the other sites that will be submitting their application to Bellberry for review.

- Click 'Add', a window will open. Enter the Principal Investigator's name, site name and address for each site.
- To view or edit the detailed information, click the Investigator name link. This will re-open the window for editing.
- To delete a site, click the check box next to the site's name, then click on DELETE.

PLEASE NOTE: *The additional sites are not approved in the lead site's application and will not be listed on the approval letter. Each site must submit their own separate application in eProtocol (refer to the [Multi-Centre Applications](#) section and Bellberry POLICYI017 Multi-Site Applications available at <http://www.bellberry.com.au/investigators/policies>).*

2. Multi-Site Application

List all other sites at which study activities will occur under '2. Multi-Site Studies'. Please include all locations including full address, what activities will occur at each site and how supervision by the Principal Investigator will be managed. A Site Approval Form will be required for each of these sites.

Site Approval Form - studies being conducted within hospitals and/or institutions and any services external to the study site that are being used outside of their normal scope must complete a Site Approval Form and attach a copy with the application on Page 7. A Sample Site Approval Form is available at <http://www.bellberry.com.au/investigators/forms>.

Sponsor page

If the study is sponsored there must be an Australian, local sponsor to undertake sponsor responsibilities such as monitoring of the study, data collection etc.

The local sponsor must also provide indemnities and insurance to cover the research being conducted. These are required for all studies, not just clinical trials.

Application Information - Page 1

Please complete as required. If the question does not apply to the type of research being undertaken please state 'Not Applicable' or select 'No'.

'Protocol No' – This is the internal reference that is usually provided by the sponsor. If your study does not have a Protocol Number please create a reference for the study (this can be alpha and/or numerical).

'Duration of Project' – please include the amount of time approval is requested for. When any approval is processed this will be the ethics approval expiry date. Please note that this date can be extended if required by submitting a Progress Report/Ethics Extension form.

Application Information, Page 2 – Participant Population

Please detail how participants will be recruited for the study and ensure all recruitment material is attached to page 7 for review by the HREC. If social media advertising is being used, please attach a Social Media Plan. Refer to the Bellberry Advertising Policy available at www.bellberry.com.au/investigators/policies.

Application Information, Page 3 – Ionising Radiation

If the study does not involve Ionising Radiation please select No, no other questions need to be answered.

Please note that if radiation is being used in the study and is above standard of care, a Medical Physicist report must be provided.

Application Information, Page 4 - Risks

Please note that indemnity is required for all studies, not just clinical trials. According to chapter 2.1 of the National Statement "A risk is a potential for harm, discomfort or inconvenience" and therefore encompasses more than just physical harm. The National Statement identifies the types of potential harms in research.

There are two types of indemnities – the Standard Indemnity between the sponsor and the site, and the HREC Only Indemnity between the sponsor and the HREC.

Templates for these two documents can be found on the Medicines Australia or Medical Technology Association of Australia website. These can be used as a guide to the information required, and Bellberry will consider amendments to the template that are relevant to the research study or an alternative that can be provided.

The original version of the HREC Indemnity, signed by the Sponsor, should be posted to Bellberry for signature. We will also accept an electronic version of the HREC Indemnity provided by verified electronic signature software (e.g. DocuSign). Please note that we do not accept scanned copies of the HREC Indemnity with an electronic signature as both parties are required to sign the same original document.

A copy of the fully signed Standard Indemnity should be attached into page 7 of the application.

If the study is non-sponsored the Standard Indemnity is not required. However, the site would then generally take on local sponsor responsibilities and be required to provide the HREC Indemnity and insurance.

In addition to indemnities, a Certificate of Currency to confirm sufficient insurance is in place to cover the research will need to be provided. This, as a minimum, must provide insurance coverage for the amount of AUD\$10 million for any one occurrence and in the annual aggregate. Bellberry reserves the right to review this amount based on the level of risk associated with a trial.

The indemnities and insurance do not need to be included in the initial submission however Bellberry will need to receive these before approval can be granted.

Application, Page 5 – Ethics Committee

Please advise the Committee if the study has previously been reviewed or is currently under review by any other Ethics Committee. Please attach documentation as requested to Page 7 of the application.

Application, Page 6 – Declarations

Please note that any actual, perceived or potential Conflict of Interest must be declared to the Committee. If one is declared, please detail how this will be managed.

If an Investigator Brochure (IB) is applicable for the study, please ensure that the version attached is less than 12 months old. Please attach IBs for all study drugs and a combination IB if applicable.

Principal Investigator Declaration - this box must be ticked before the application can be submitted to the HREC. 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.

Please ensure that the application is complete and correct before ticking this box and submitting the application – this includes attaching documentation to Page 7.

Application, Page 7 – Attachments

Please save the study documents with the file name exactly how you would like it to be recorded on the approval letter. If the documents are incorrectly named in the attachment section the document names on the approval letter will be incorrect.

Please refer to Bellberry guidance on version control for study documents available at www.bellberry.com.au/investigators/policies.

Note: * denotes mandatory field.

Attachments Save Cancel

Document Type Select One

Attachment * Select One

Document Name * Select One

Advertisements

Any other material to be considered by the Comm

Clinical Trial Agreement Schedule - 7

Completed and signed Indemnity Forms

Completed Site Approval Form

Curriculum Vitae (if not previously known to Bellbe

Final Application

Investigator Brochure

Medical registration and personal medical insuran

Other Ethics Committees Approvals & Rejections

Patient Information sheets + Consent Forms

Risk or Benefit Information

Scientific Information

Add

Previous Next

Save X Close

7

Sponsor

Application Information

Return Notes

Check For Completeness

Submit Form

Print View

Event History

Attachments

Please click on Add to add Attachments

- 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

Required Documents

All documents to be used in the study are to be included in the application submission.

- Protocol/Project Plan - For all types of studies a Protocol/Project Plan must be attached. For information about what is required in this document please refer to <http://www.bellberry.com.au/investigators/guidelines>.
- Investigator's Brochure - An Investigator's Brochure is required for clinical trials.
- Participant Information Sheet and Consent Form - For information regarding what needs to be included in a Participant Information Sheet and Consent Form please refer to <http://www.bellberry.com.au/investigators/guidelines>.
- A Sample Participant Information Sheet and Consent Form and other study documents can be found at <http://www.bellberry.com.au/investigators/forms>.
- For information regarding what other documents are required in a submission please refer to <http://www.bellberry.com.au/investigators/how-to-apply> - 'Step 2 – Prepare application documentation'.
- Advertising – All advertising must be submitted for review by the Committee. If social media advertising is being used, please attach a Social Media Plan. Refer to the Bellberry Advertising Policy008 available at www.bellberry.com.au/investigators/policies.

Guidance and templates for key documents can be found on the Bellberry website at www.bellberry.com.au/investigators/policies.

Submitting the Application to Bellberry

When the application is complete

- Click on 'Check for Completeness' in the left hand blue menu options.
- 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.

PLEASE 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.

When the application form is complete it can be submitted through to Bellberry:

- 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.

Please note that once an application is submitted you will not have edit access to make edits or additions until the application is returned to you.

Returned Applications

After your application has been submitted, it will undergo an initial triage by Bellberry staff. The application is checked to make sure it is complete and that it includes all of the necessary attachments and information the Committee will require for their review.

Sometimes it is necessary to return an application. An email will be sent to the contacts on the application to advise of this and 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.

PLEASE NOTE: 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.

After Submission

Please note that the deadline for receipt of applications to be considered for the next available meeting is 5pm every Wednesday.

Once the application is ready it will be added to the Agenda to be reviewed at a Committee meeting two weeks following the issue of the Agenda.

After Review at the HREC Meeting

Comments from the Committee will be sent to the site by 5pm on the Friday following 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.

| 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 |

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.

eProtocol » Investigator » [Home](#) » Comments

Application ID: [2017-11-666](#) (Bellberry Administration)
 Study Title: Sarah Test
 Protocol Number: 5676
 Cycle: [1](#) [2](#) [3](#)

[Get Application](#) [Show All Comments](#)

Comments

Section: Personnel Information

Comment: 1

Test

Response Necessary Suggestion Not Necessary

Response

Test PI



You will need to:

- Make the revisions/updates to the application itself (click the GET APPLICATION button to open up a new window with the application).
- Attach additional or updated documents in Page 7 of the application. Please note that when submitting updated documents as per the HREC comments, both a **tracked changes and a clean version** of the documents must be submitted in order to assist the Committee with review. The Committee requires the tracked version to clearly see the changes made but only clean documents are listed on the approval letter.
- For auditing purposes all previously submitted documents must remain attached to the application, even if they have been superseded by new versions. **Do not delete any documents, all original documents must remain in the application.**
- Update all version and date references in both the document name and document footers.
- 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.

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.

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 screenshot shows the HREC Application Form interface. At the top, it displays 'HREC - HREC Application Form' and 'Application ID: 2017-07-653-A-1 (Bellberry Administration)'. Below this, the 'Application Title' is 'Test HREC'. A navigation bar includes 'Help | Clo' and 'Previous | Next' buttons. On the left, a vertical menu lists options: Amendment/IB, Personnel Information, Study Sites, Sponsor, Application Information, Print View, and Event History (which is selected). The main content area is titled 'Event History' and shows a table for the year 2017. The table has columns for Date, Application ID, Status, View Attachments, and Letters. A red arrow points to the 'Approval Letter' link in the Letters column for the row with status 'NEW FORM APPROVED'.

| Date | Application ID | Status | View Attachments | Letters |
|------------|-----------------|------------------------------------|------------------|---------------------------------|
| 26/07/2017 | 2017-07-653 | NEW FORM CREATED | | |
| 26/07/2017 | 2017-07-653 | NEW FORM SUBMITTED | View Attachments | |
| 26/07/2017 | 2017-07-653 | NEW FORM PANEL ASSIGNED | | |
| 26/07/2017 | 2017-07-653 | NEW FORM PANEL MANAGER REVIEW | | |
| 26/07/2017 | 2017-07-653 | NEW FORM APPROVED | View Attachments | Approval Letter |
| 09/08/2017 | 2017-07-653-A-1 | AMENDMENT 1 FORM CREATED | | |

The approval letter can be accessed in the 'Letters' column. Read the approval letter to confirm all of the conditions of approval and note the date of ongoing reporting requirements such as annual Progress Report and the ethics period of approval.

The Principal Investigator is required to sign the approval letter and send the signed copy to Bellberry by email. Once received by Bellberry a copy of the letter will be attached into the application in eProtocol.

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

Multi-Centre Applications

Additional Site Applications

An application is considered 'Multi-Centre' when the same study is being conducted at other sites independently under supervision of different Principal Investigators.

Each additional site will need to submit a new application, separate from the lead site application. All information needs to be completed as per the lead site's application. Bellberry will link the application to the lead site after submission.

It is very important that the Protocol number is entered exactly the same as the lead site's application (this includes capital letters, spaces and dashes) as this is how eProtocol links the application to the lead site.

Please note that each additional site will need to attach their own regulatory documents into the application including the protocol signature page signed by the PI, Certificate of Currency and a fully executed Standard Indemnity. A HREC Indemnity signed by the sponsor will need to be posted to Bellberry.

Which study documentation needs to be attached depends on when the application is submitted.

Additional site application submitted before lead site approval

No documents need to be attached into the application. Once the lead site has been approved, Bellberry will return the application to the site to then attach the site specific documents (based on those approved for the lead site) and regulatory documents.

Additional site application submitted after lead site approval

All the latest approved study documents will need to be attached in addition to the site specific documents and regulatory documents. Please ensure any Master/Generic PICFs are attached.

Additional sites applications will be sent to the HREC for an expedited review based on the approval of the lead site. This occurs outside of a meeting. Please note, if any new documents are attached that have not received approval for the lead site, this will need to be reviewed by additional Committee members and the review process will take longer.

Amendments

To make changes to a study that has been approved, an Amendment Form will need to be submitted in eProtocol and reviewed by the HREC. The Amendment must receive approval by the HREC prior to initiating any study changes.

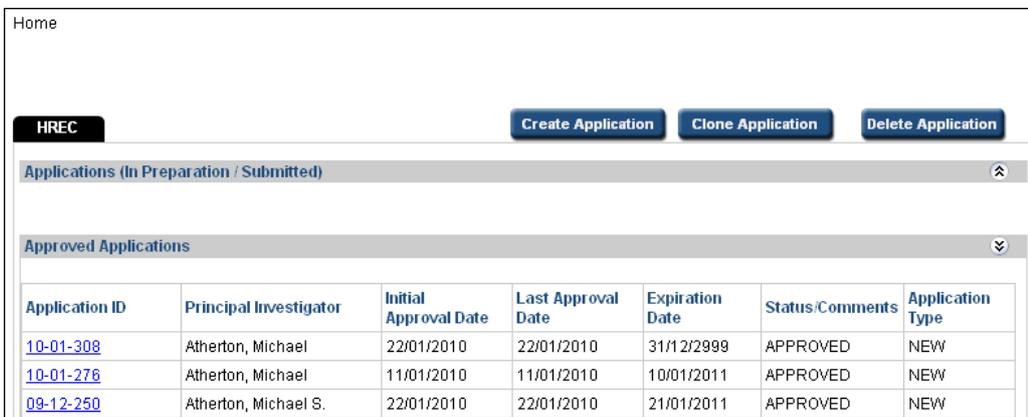
Please note that more than one Amendment cannot be submitted at a time. However, multiple changes/requests can be added to the one Amendment submission.

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 will need to include these changes as an Amendment.

Before you begin an Amendment, you should consider the date that the current approval will expire. Please note that once an amendment has been submitted, you will not be able to start a Progress Report/Ethics Approval Extension application until the amendment has been reviewed and approved. If the ethics expiration date of the application is near, please complete a Progress Report/Ethics Approval Extension instead. Once this has been processed you will then be able to submit an amendment.

To start an Amendment

- On the eProtocol home page find the Application ID number for the study that is to be amended in the **Approved Applications** list (you may need to click the  at the right-side of the section header to expand this section). A small window will open.



The screenshot shows the eProtocol Home page. At the top, there is a 'Home' label. Below it, the 'HREC' section is visible, containing three buttons: 'Create Application', 'Clone Application', and 'Delete Application'. Underneath these buttons, there are two expandable sections: 'Applications (In Preparation / Submitted)' and 'Approved Applications'. The 'Approved Applications' section is expanded, showing a table with the following data:

| 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 then an Amendment, Progress Report/Study 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.

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

PLEASE NOTE: *If an Amendment Form (or any other 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.*

- Section 1. Administration Changes - use this section for any changes or correspondence that is not related to a Protocol Amendment, Investigator Brochure Update or to other changes to approved study documentation. For example, adding/removal of study staff, updating email addresses, Indemnities, Insurance, CV updates etc.
- Sections 2, 3, or 4 – use these sections for any changes to study documentation as applicable.
- Section 5. Attachments - please attach documents at the bottom of the amendment form in this section. A clean and tracked version of any updated documents must be attached. Ensure that all attached documents have been saved with the name that needs to appear on the approval letter
- Answer all of the questions on the Amendment/IB Form page depending on whether it is an update to the Investigator Brochure, Protocol Amendment or Other. Describe the changes that you wish to make. If the amendment includes an updated Protocol or Investigator's Brochure, please attach either a Summary of Changes document or a tracked version. Where there are significant changes provision of both document would help facilitate the review.
- Make any required changes to the appropriate sections in the application form, i.e. update the Personnel Information section with addition/removal of contacts. These changes must be noted for the Committee on the amendment form.
- Submit the amendment form when ready by clicking the SUBMIT FORM option in the left-hand menu.

Progress Reports/Ethics Approval Extension

This Form is used for both Progress Reporting and for requesting an Ethics Approval Extension.

A Progress Report is required to be submitted annually on the anniversary of the study approval date.

If the study period is going to extend beyond the period of ethics approval, an Ethics Approval Extension request is required to be submitted PRIOR to the current expiry date noted on the approval letter.

To submit a Progress Report/Ethics Approval Extension application

- On your eProtocol home page, find the relevant application in the 'Applications (Active)' listing. You may need to click at the right-side of the section header to expand this section.
- Click on the relevant application number. A small window will open.
- 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 as Principal Investigator, Nominated Contact, or Co-Investigator, have access to EDIT the application and can start an Ethics Approval Extension.
 - An Amendment may have been started or is in-progress for this application. Check on the home page in the Applications (*In-Preparation/Submitted*) section to see if the application is listed there.
- Select "Progress Report/Ethics Approval Extension" and click OK.
- Tick the relevant radio button to indicate whether the submission is for a Progress Report or an Ethics Approval Extension.
- Answer all of the questions on the form.
- Add any attachments under the heading "Progress Report/Ethics Extension Form Attachments Only".
- Submit the form when ready by clicking the SUBMIT FORM option in the left-hand menu.

Adverse Event Report Form

Follow the steps as outlined in starting an Amendment but select 'Adverse Event Report Form' from the 'Approved Application Decision Box'.

- On the form select either:
 1. Individual Event
 2. Summary Report
- Complete the relevant fields
- For an Individual Event, Select 1 and complete the report as required. Ensure that all questions are answered including the details of the event.
- For Summary reporting, select 2 and attach relevant documents.
- Once completed click SUBMIT FORM.

Protocol Violation Report Form

Follow the steps as outlined in starting an Amendment but select 'Start Protocol Violation Report' from the 'Approved Application Decision Box'.

Complete all of the required fields. Once completed click on SUBMIT FORM.

Final Report Form

Follow the steps as outlined in starting an Amendment but select 'Final Report Form' from the 'Approved Application Decision Box'.

Complete all of the required fields. Once completed click on SUBMIT FORM.

The Final Report should be completed prior to the ethics approval expiry date. If further time is needed to complete the study or study close out, an ethic approval extension request is required to be submitted.

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

Print 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 (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"/> |

- 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.

Troubleshooting

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 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 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."

The application was left idle for longer than 60 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.