Ethical Review Online Application System: User Guide

brighton and sussex medical school

Application to Brighton & Sussex Medical School Research & Governance Ethics Committee

Contents

PURPOSE OF THIS DOCUMENT

This user guide is intended to provide an overview of the University's ethical review online application system for staff and students who are required to submit their research project for the purpose of gaining ethics approval.

This guide aims to provide an overview of the system functionality of the online ethics application process, and is not intended to provide advice or guidance about how to design a good research ethics application. Help text within the online system will assist in clarifying what is expected in each section of the application, and the University's *Guidelines for Completing the Online Application Form for Ethical Review* provides detailed guidance and advice on specific issues relating to good practice in research ethics.

ACCESSING THE SYSTEM

- Log into **Sussex Direct** via the University of Sussex website and go to **'Research > Ethical Reviews'**

- Alternatively you can go directly to the ethical review page by using this link: https://direct.sussex.ac.uk/mle/page.php?realm=research&page=ethical_review_list

Click on 'Research', and then select 'Ethical Reviews'

Sys ▾   Admin ▾   ...es ▾   Research ▾   Library ▾   Personal ▾   Help ▾   Study Direct ▾

Home > Ethical Review Applic...es

Research Grants

Research Process

Ethical Review Applications   Ethical Reviews

Contents: My Ethical Review Appli...   Susx Research   Applications submitted for Supervisor Approval |
Ethical Review Applications submit...   Online

You will need to wait a few seconds before **My Ethical Review Applications**: *Your name* appears.

SETTING INTERNET BROWSERS TO CHECK SPELLING

Internet Explorer

To **enable** the **spell check** feature in **internet explorer**, click on the click on gear icon, which is located towards the top right corner of the window. With the menu opened up, click on the "Manage add-ons" option. Find the "Spelling Correction" option and set English (United Kingdom) by highlighting and selecting the 'Set as Default' button.

Chrome

Enable **Chrome's** Native **Spell**-Checker. To enable or disable **spell**-**checking**, click the **Chrome** menu button in the top right on the browser toolbar. Select Settings and at the bottom click 'Show advanced settings'. Scroll down to Languages and click the Language and input settings… button. By default Chrome will offer English (United States). You will need to choose the Add button to pick out English (United Kingdom).

Mozilla Firefox

Click on the menu button and choose 'Options'. Select the Advanced panel. Click the General tab. Ensure that **Check my spelling as I type** is ticked. To install a specific English language dictionary, Visit the Mozilla *Dictionaries & Language Packs* page. Find in the list the language you want to add, and click the Install Language Pack link next to it. The main page of that language pack will be open.

Click the Add to Firefox button for to install it. Firefox will download the language pack and ask you to confirm the installation.

After the dictionary is installed, you can switch to it, as needed. To switch to a different installed dictionary, Right-click in a multi-line field, select Languages, then select the dictionary you want to use.

Safari

Click in a text field. On the menu bar, go to **Edit / Spelling and Grammar** / 'Check Spelling While Typing'.

To set the language checker to English UK.

Go to System Preferences. Click on 'Language and Text'. Make sure the 'Language' heading is selected.A list of languages is shown .Click on the Edit List button at the bottom of the window. Find 'British English' from the list which pops up and tick/check the box to the left of it.

CREATING A NEW APPLICATION

- After logging into *Sussex Direct* and going into *'Research > Ethical Reviews', then:*

1. Click on the 'New' icon on the 'My Ethical Review Applications' screen:
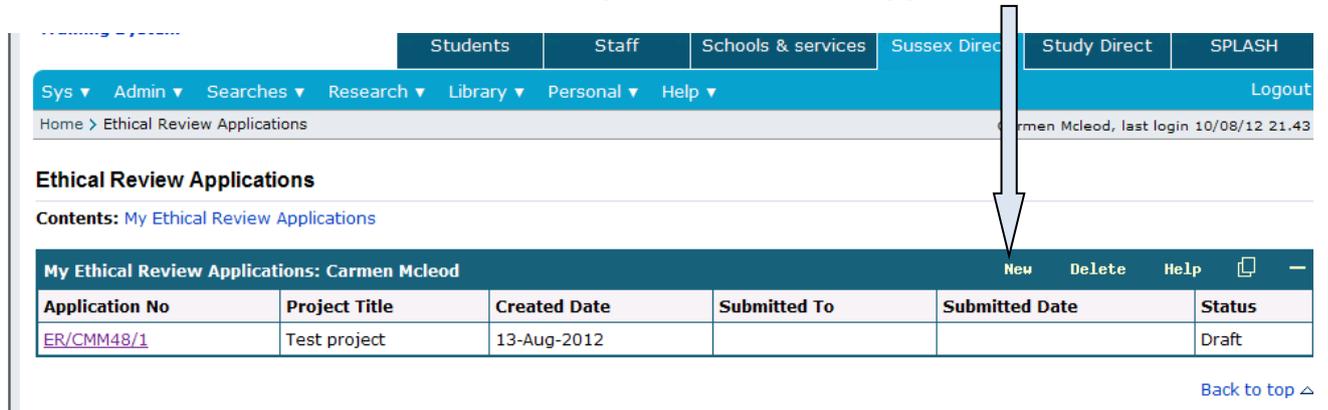
	Students	Staff	Schools & services	Sussex Direct	Study Direct	SPLASH

Sys ▾   Admin ▾   Searches ▾   Research ▾   Library ▾   Personal ▾   Help ▾   Logout

Home > Ethical Review Applications   Carmen Mcleod, last login 10/08/12 21.43

Ethical Review Applications

Contents: My Ethical Review Applications

My Ethical Review Applications: Carmen Mcleod				New Delete Help	
Application No	**Project Title**	**Created Date**	**Submitted To**	**Submitted Date**	**Status**
ER/CMM48/1	Test project	13-Aug-2012			Draft

Back to top △

2. Complete the 'Create Ethical Review Application' screen and click 'Save'; (NOTE: THE SECTIONS MARKED WITH AN ASTERISK* ARE MANDATORY).

- *Project Title

- Phone number

- Applicant Status (automatically populated from the database)

- *Supervisor (if you are a student, you must select the name of your Supervisor. Start typing the first two letters of your Supervisor's surname and a drop down list of University staff will appear from which you can select your Supervisor's name.

- *Project start date (the date you intend starting your research – make sure you allow for the time that the review process will take, as you may not start your research until ethical approval is confirmed).

- *Project end date (the date you anticipate your research will be completed).

- External Funding in place – click to insert a tick of this applies

- External Collaborators – click to insert a tick of this applies

- Funder/Project Title (if you have applied for funding through the University, a list of your active applications will be provided as a dropdown list from which you can choose the relevant funder's name and project title).

- Name of Funder (this box should be completed if you have funding from an organisation where you have not applied through the University).

- *Project Description (Up to 400 words).

Click '**Save**' when you have completed this section (you will be able to go back and edit this section, after you have clicked 'Save')

NOTE: Click on the '**Help'** button if you are need any further information about how to fill out any of these sections.

The sections marked with an asterisk are mandatory

Click on 'Help' for guidance about how to complete this section.

Ethical Review Application Screen:

Create Ethical Review Application		Cancel	Save	Help
Project Title *	A test ethical review application study			
Phone No.	01273 111111111			
Applicant Status	Staff (Research Governance Officer)			
Project Start Date *	25-Nov-2016			
Project End Date *	29-Oct-2016			
External Funding in place	☐			
External Collaborators	☐			
Name of Funder				
Project Description: The project description should be a clear, easy to read summary that is as jargon free as possible. It provides an overview of the whole of your research study that readers can understand the first time they read it. Please see INVOLVE (http://www.invo.org.uk/) for further guidance on how to achieve this. *				

Make a selection and then press 'Save'.

3. **Choose the correct route for application review**

Ethical Review Application   Related Links ▼

Choose routing of application	Cancel	Save	Help
This is a an application for Ethical Review by:			
◯ Supervisor / SREO / Science & Technology or Social Sciences & Arts Research Ethics Committee			
◯ Brighton & Sussex Medical School Research & Governance Ethics Committee			

Select the correct route for your application:

- Supervisor/ SREO/ Science and Technology or Social Sciences and Arts Research Ethics Committee – use this for *all* applications other than those destined for review by the BSMS Medical School Research and Governance Ethics Committee (RGEC)
- Brighton and Sussex Medical Research & Governance Ethics Committee – *Only* ethical review applications to this Committee (RGEC) should make use of this option.

Select 'Save' to progress the next stage

| Choose routing of application | Cancel | Save | Help |

This is a an application for Ethical Review by:

○ Supervisor / SREO / Science & Technology or Social Sciences & Arts Research Ethics Committee

● Brighton & Sussex Medical School Research & Governance Ethics Committee

☐ Tick this box to submit an application for amendment to an approved project submitted before 1 December 2016

APPLICATIONS to Brighton and Sussex Medical Research & Governance Ethics Committee (RGEC)

Having selected the RGEC application route, the first form completed will appear followed by the 'Ethical Review Form (BSMS version)'.

ROLES

At the top of the form you are required to provide the details of all investigators in the project's research team. This will also include Collaborators and Students. Use 'Other', giving information under 'Comments' when other types of investigators are part of the project.

Click on 'Add' to start adding details of investigators in the project's research team

| Roles (ER/AW440/6) | | | | Add | Help |

Please list all investigators in this project's research team. If you specify role "Other" for any investigator please provide further details in the "Comments" field.

| Role | Name | Email | Phone | Institution | Comments |
| No records found | | | | | |

Click on 'Save+Add' to start adding details of investigators in the project's research team

Use the 'Save+Add' option to add new roles

| Add to Roles (ER/AW440/6) | | | | Cancel | Save+Add | Save | Help |

Please list all investigators in this project's research team. If you specify role "Other" for any investigator please provide further details in the "Comments" field.

| Role | Name | Email | Phone | Institution | Comments |
| Principal Investigator ▼ | | | | | |

8

Click on 'Save'' to start adding details of investigators in the project's research team

When complete, choose 'Save' to close the form

Edit Roles (ER/AW440/6)						Cancel Save Help

Please list all investigators in this project's research team. If you specify role "Other" for any investigator please provide further details in the "Comments" field.

Role	Name	Email	Phone	Institution	Comments	
Principal Investigator ▼	Jo Bloggs	jb01@bsms.ac.uk	01273 333333	BSMS		Delete

Back to top ∧

ETHICAL REVIEW FORM

- **Click on the 'Edit' button to start filling out this section**

- Complete the Checklist (you must answer ALL the questions).

Click on 'Edit' to start filling out this section, or to go back and make changes after saving

Ethical Review Form (BSMS version) (ER/AW440/6) Edit Help —

» Checklist

C1. Will your study involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position (e.g. children under 16, individuals with learning difficulties, mental health problems, people in care facilities or over-researched groups)?

C2. Will participants be required to take part in the study without their consent or knowledge at the time (e.g. covert observation of people in non-public places), and/or will deception of any sort be used?

C3. Will it be possible to link identities or information back to individual participants in any way? Will it be impossible to ensure that identities or information cannot be linked back to individual participants in any way (including after anonymisation?)

C4. Might the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks encountered in the everyday life of the participants?

C5. Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use, ethnicity, political behaviour, potentially illegal activities)?

C6. Will any drugs, placebos or other substances (such as food substances or vitamins) be administered as part of this study or physiological interventions or processes outside of standard practice and will any invasive or potentially harmful procedures of any kind will be used?

C7. Will your project involve working with any substances and / or equipment which may be considered hazardous, e.g. such as radioactive materials?

C8. Will financial inducements (other than reasonable expenses, compensation for time or a lottery / draw ticket) be offered to participants?

C9. Will the research involve storage and/or analysis of human biological tissue ?

C9a. If you answered Yes to question C9, will this be carried out under University of Sussex HTA license?

C10. Is there a possibility that your investigations might uncover unexpected and possibly clinically relevant findings?

C11. Will the study include groups where permission is normally required for access to its members, for example groups based in the community, traditional communities or school pupils?

Complete Sections 1-6 of the Form

| Edit Ethical Review Form (BSMS version) (ER/AW440/16) | | Cancel | Save | Help |

» Checklist

C1. Will your study involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position (e.g. children under 16, individuals with learning difficulties, mental health problems, people in care facilities or over-researched groups)?	Yes	No	ⓘ
C2. Will participants be required to take part in the study without their consent or knowledge at the time (e.g. covert observation of people in non-public places), and/or will deception of any sort be used?	Yes	No	ⓘ
C3. Will it be possible to link identities or information back to individual participants in any way? Will it be impossible to ensure that identities or information cannot be linked back to individual participants in any way (including after anonymisation?)	Yes	No	ⓘ
C4. Might the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks encountered in the everyday life of the participants?	Yes	No	ⓘ
C5. Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use, ethnicity, political behaviour, potentially illegal activities)?	Yes	No	ⓘ
C6. Will any drugs, placebos or other substances (such as food substances or vitamins) be administered as part of this study or physiological interventions or processes outside of standard practice and will any invasive or potentially harmful procedures of any kind will be used?	Yes	No	ⓘ
C7. Will your project involve working with any substances and / or equipment which may be considered hazardous, e.g. such as radioactive materials?	Yes	No	ⓘ
C8. Will financial inducements (other than reasonable expenses, compensation for time or a lottery / draw ticket) be offered to participants?	Yes	No	ⓘ
C9. Will the research involve storage and/or analysis of human biological tissue ?	Yes	No	ⓘ
C9a. If you answered Yes to question C9, will this be carried out under University of Sussex HTA license?	Yes	No	ⓘ
C10. Is there a possibility that your investigations might uncover unexpected and possibly clinically relevant findings?	Yes	No	ⓘ
C11. Will the study include groups where permission is normally required for access to its members, for example groups based in the community, traditional communities or school pupils?	Yes	No	ⓘ

» Section 1. Methodology, Data Collection and Analysis (Please provide full details)

1.1. What is the principal research question/objective? Please clearly state the hypothesis to be tested. Please put this in language comprehensible to a lay person.		ⓘ
		0/4000 used
1.2. What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording?		ⓘ

Answers must be provided to each Yes/ No question

Select the (i) icon for help text about each question

| Edit Ethical Review Form (BSMS version) (ER/AW440/16) | | Save | Help |
| [Autosave #1: Updated at 9.40.29am] | | | |

» Checklist

C1. Will your study involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position (e.g. children under 16, individuals with learning difficulties, mental health problems, people in care facilities or over-researched groups)?	Yes	No	ⓘ

A fundamental principle of ethical research is the expectation that participants are able to give consent after fully understanding possible risks, inconvenience or the possibility of any harm. Great care is needed in ensuring consent from a participant regarded as 'vulnerable' is clearly informed. In some instances, achieving this may need the assistance of a parent, guardian or carer.

SUPPORTING DOCUMENTS

Supporting Documents (ER/AW440/16)				Upload Document Edit Help —
You MUST ensure that ALL documents are converted to PDF format before uploading. Otherwise they will not be included in the merged PDF file.				
No.	**Document**	**Document Type**	**Version**	**Upload Date**	**Actions**
	Ethical Review Application [PDF]	Application			
For your own records, you can use the button below to create a merged copy of your application and supporting documents:				
Create Merged PDF				

Having completed the form you will need to attach the supporting documents (i.e. Consent Form, Information Sheet, Recruitment materials etc.).

Each document to be uploaded must be converted to PDF before uploading.

(an explanation of how to do this is found below)

Add to Supporting Documents (ER/AW440/16)			Cancel Save+Add Save Help
You MUST ensure that ALL documents are converted to PDF format before uploading. Otherwise they will not be included in the merged PDF file.			
No.	**Document**	**Document Type**	**Version**	**Upload Date**
	Ethical Review Application	Application		
1	Choose File PIS.pdf *Maximum file size: 60 megabytes*	Consent form ▾ Consent form Information sheet Recruitment material/s Overseas Risk Assessment form Letter for gatekeeper/s requesting permissions Questionnaire or Topic Guide or Interview Questions Other		

Back to top Δ

Submission History (ER/AW440/16)				Help —
Submission Date	**Submitted To**		**Reason(s) for Return**	

Click on the Upload Document button
1. Click on the Choose File button, and select the document you wish to upload

2. Select the Document Type from the Drop down menu (e.g. consent form, information sheet etc.)

3. Click on the Save button if you have no further documents to upload; Click on the Save+Add button if you have another document to add

4. Click Replace or Delete in the Actions column, if you need to replace a document with a different version, or if you want to delete a document.

Supporting Documents Box

You need to upload all your supporting documents in this box. Note: Please ensure that you convert your documents into PDF BEFORE you upload them.

Important note
To make sure your document merges successfully, ITS recommends you follow these instructions:

- ## Using your home PC

    ### *Office 2007 or later*

    If you are using your home PC with Office 2007, 2010, 2013 or 2016 installed you can save your files in PDF format from your Office application. This is also available if you are using OpenOffice.

    In MS Word for example, on the File tab, you will see the option to *Save as Adobe PDF*
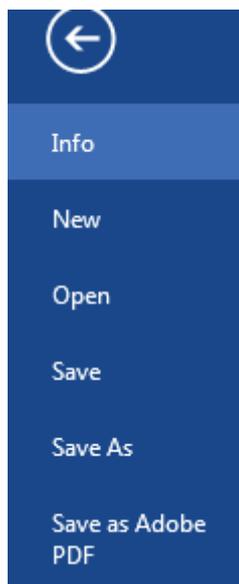
    Should this not be possible it is suggest that you use *Cute PDF* that can be accessed via - http://www.sussex.ac.uk/its/services/software/owncomputer

- ## Using an IT Services PC

    If you are using an IT Services PC you should use Corel PDF Fusion:
    http://www.sussex.ac.uk/its/services/software/list?filter=pc&id=293

    If you need assistance with converting your supporting documents into PDF format, please see the following help page on the IT Services website:
    http://www.sussex.ac.uk/its/help/faq?faqid=729

CREATING A MERGED PDF

For your own records, you can use the button below to create a merged copy of your application and supporting documents:

Create Merged PDF

PLEASE ENSURE YOU HAVE SAVED YOUR ETHICAL REVIEW FORM·BEFORE YOU CLICK THIS BUTTON

This button allows you to create a merged PDF document of your application form and supporting documents. You will be able to download this for checking, or sharing with a supervisor or research collaborators, before you submit your application.

Note: You do not need to click this button as part of your application submission, but may choose to do so if you want to save a copy of your application, print out a copy of your application, or email a copy of your application. Clicking on the Create Merged PDF button does NOT submit your application for review.

DECLARATION

If all necessary sections have been completed you will be presented with a **Declaration** box for you to check before submitting your application to RGEC.

Please use the button below to submit your application for review / approval:

Submit to BSMS RGEC for review

By submitting this application, you are agreeing to the following declarations:

- The information in this form is accurate to the best of my knowledge and belief, and I take full responsibility for it.
- I have read and understand the University's Research Governance Code of Practice.
- I have read the guidelines accompanying this application form and understand that failure to follow these and my approved protocol constitutes academic misconduct and can lead to severe penalties.
- I understand that I am responsible for monitoring the research at all times and recording any unexpected events.
- If any serious adverse events arise in relation to the research, I understand that I am responsible for immediately stopping the research and alerting the C-REC Chair within 24 hours of the occurrence.
- I am aware of my responsibility to comply with the current requirements of the law and relevant guidelines relating to security and confidentiality of personal data.
- I understand that research records / data may be subject to inspection for audit purposes if required in future.
- I understand that I may not commence this research until I have been notified that the project has ethical approval.

You will be sent an automated email to acknowledge that your application has been submitted for review.

Online Ethics Application User Guide – February 2017 – V2.0

AMENDMENTS

AMENDMENTS TO APPROVED APPLICATIONS PRIOR TO THE INTRODUCTION OF THE ETHICAL REVIEW SYSTEM FOR BSMS

Applicants in BSMS who wish to submit amendments to Ethical Review Applications approved prior to the introduction of the Sussex Direct application system should do the following:

Commence a new application (steps 1 and 2 (pp2- 6 above), In doing so you will need to enter the relevant details of the **previously approved** application.

At step 3 (Choose routing of application), you will need to select both

'Brighton & Sussex Medical School Research & Governance Ethics Committee' and 'Tick this box to submit an application for amendment to an approved project submitted before 1 February 2017' and then '**Save**'

A truncated version of the form will appear   -

You will be required to submit a completed 'BSMS Request for Amendment Form' that will need to be converted to PDF (as described above).

This will be added using the section 'Add to Supporting Documents' using the process described in the 'Supporting Documents' section above (p.10).

Any accompanying documents that are relevant to the amendment (i.e. revised Consent Form etc.) will also be added here.

Select 'Save'.

Please use the button below to submit your amended application for review / approval:

Submit to BSMS RGEC for review

You will then see the declaration form appear and the option to 'Submit to BSMS RGEC for review'.

An email will confirm that the application has been submitted.

AMENDMENTS TO ETHICAL REVIEW APPLICATIONS APPROVED WITHIN THE BSMS ETHICAL REVIEW SYSTEM

The Ethical Review System (ERS) is also used to submit amendments to applications that have been submitted and approved within the ERS.

Applicants need to access the previously approved application –

Access the Ethical Review System in Sussex Direct as indicated in pages 3 and 4 above.

After logging in and accessing 'Ethical Review' a list of applications will appear including any that have been approved.
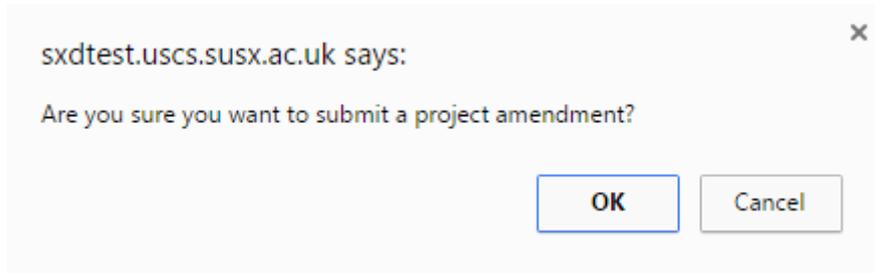
Select the approved application for which you would like to submit an amendment and select 'Amend'
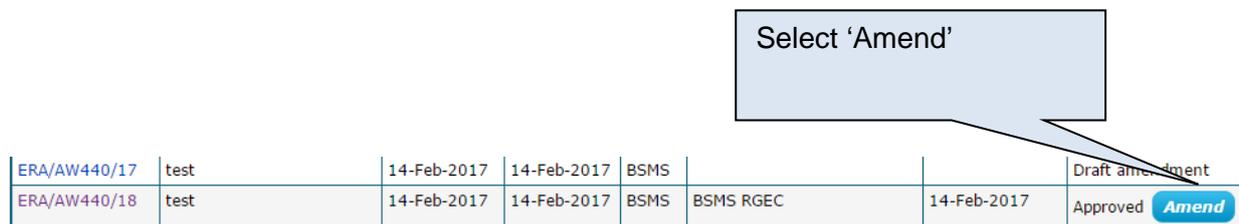
Select 'Amend'

| ERA/AW440/17 | test | 14-Feb-2017 | 14-Feb-2017 | BSMS | | | | Draft amendment |
| ERA/AW440/18 | test | 14-Feb-2017 | 14-Feb-2017 | BSMS | BSMS RGEC | 14-Feb-2017 | Approved | *Amend* |

Confirm by selecting 'OK' that you would like to submit a project amendment

You will be required to submit a completed 'BSMS Request for Amendment Form' that will need to be converted to PDF (as described above).

This will be added using the section 'Add to Supporting Documents' using the process described in the 'Supporting Documents' section above (p.10).

Any accompanying documents that are relevant to the amendment (i.e. revised Consent Form etc.) will also be added here.

Select 'Save'.

You will then see the declaration form appear and the option to 'Submit to BSMS RGEC for review'.

An email will confirm that the application has been submitted.

Online Ethics Application User Guide – February 2017 – V2.0