UNIVERSITY OF SUSSEX

Ethical Review Online Application System: User Guide

For applications to SSARTS and SCITEC SREOs and C-RECs

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

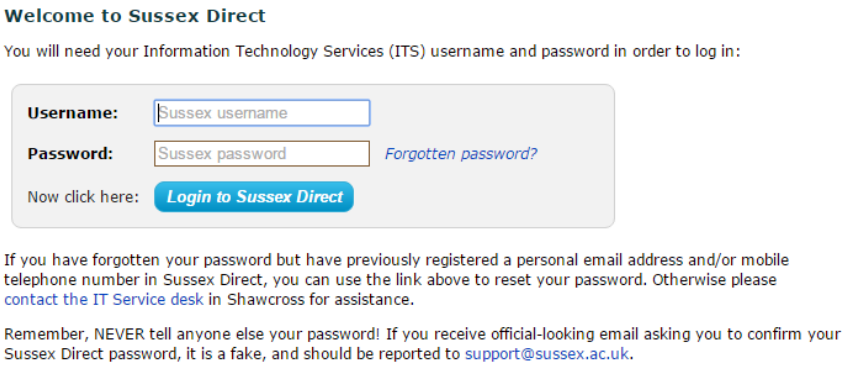
Contents

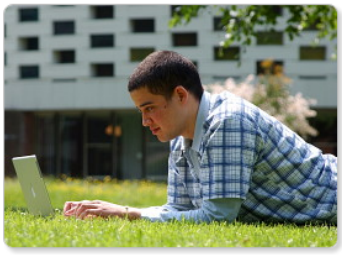
PURPOSE OF THIS DOCUMENT

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 via either the Sciences & Technology Cross-Schools Research Ethics Committee (SCITEC) or the Social Sciences & Arts Cross-Schools Research Ethics Committee (SSARTS). A separate guide exists for applications to the BSMS RGEC.

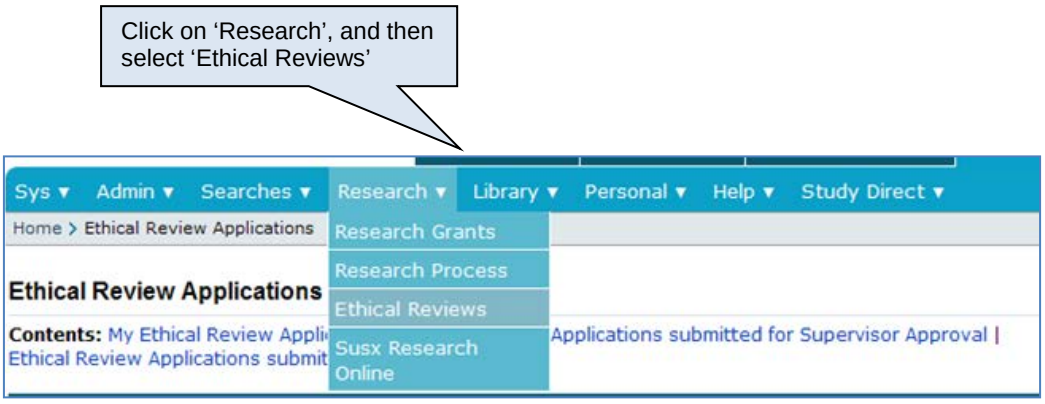
This guide aims to provide an overview of the system functionality of the online ethics application process, and is not intended to provide advice or guidance about how to design a good research ethics application. Help text within the online system will assist in clarifying what is expected in each 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

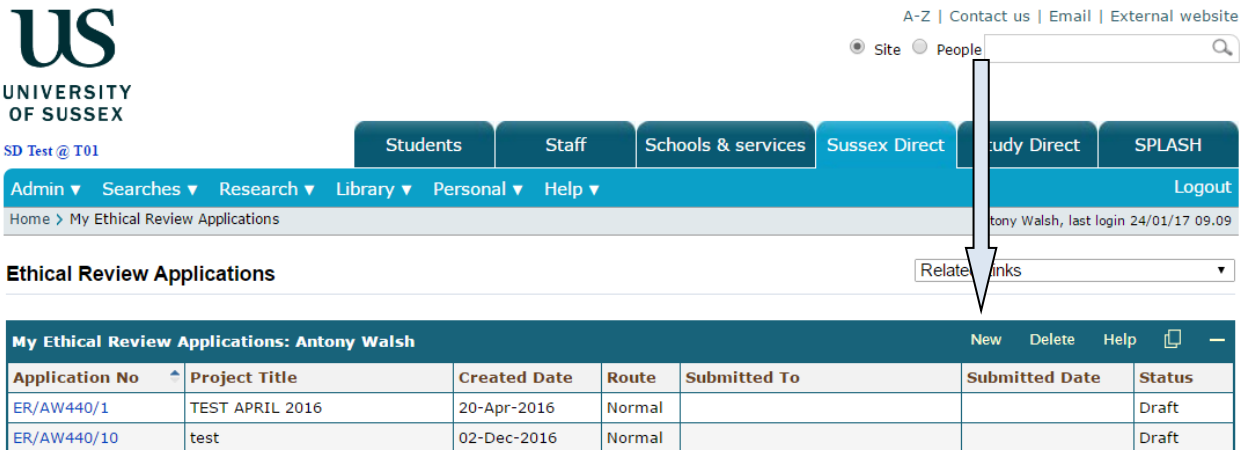


You will need to wait a few seconds before **My Ethical Review Applications**: ***Your name*** appears.

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:**

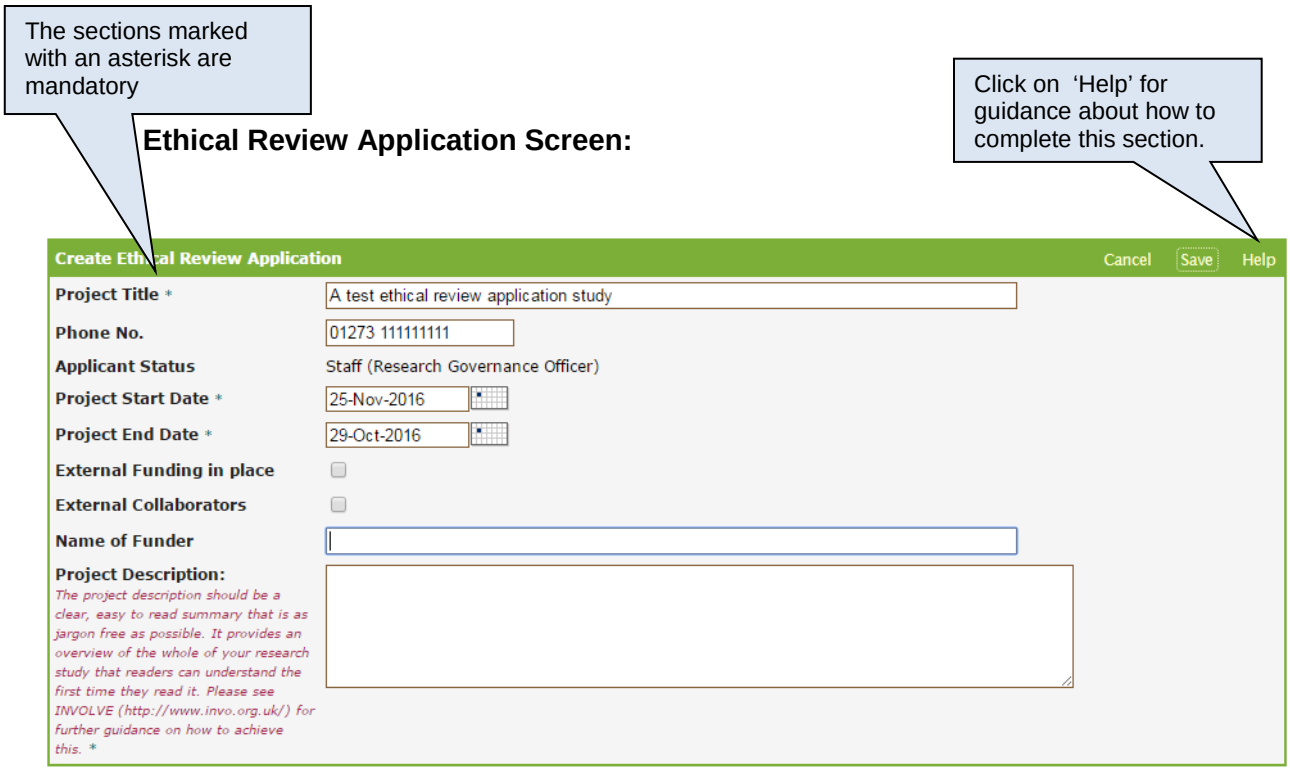


2. **Complete the 'Create Ethical Review Application' screen and click 'Save'; (NOTE: THE SECTIONS MARKED WITH AN ASTERISK* ARE MANDATORY).**

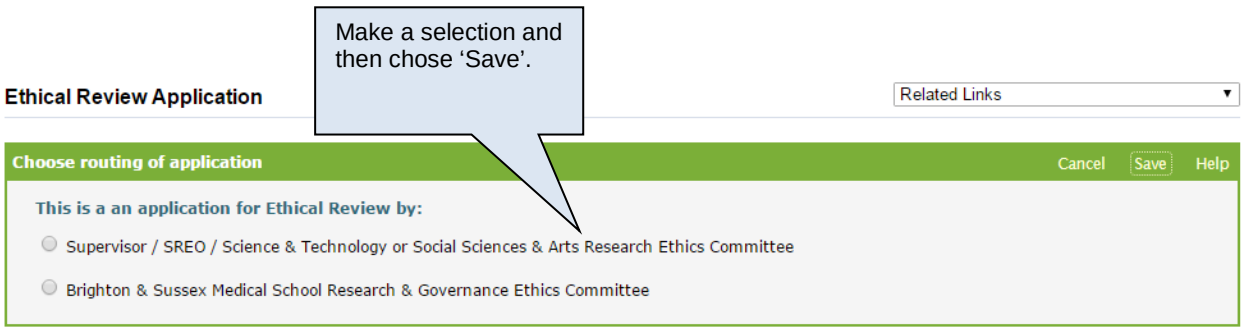
- ***Project Title**
- **Phone number**
- ***Supervisor** (if you are a student, you must select the name of your Supervisor. Start typing the last three letters of your Supervisor's surname and a drop down list of University staff will appear from which you can select your Supervisor's name.
- ***Project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



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



Select the correct route for your application:

- **<u>Supervisor/ SREO/ Science and Technology or Social Sciences and Arts Research Ethics Committee</u>** – use this for *all* applications other than those destined for review by the BSMS Medical School Research and Governance Ethics Committee (RGEC)

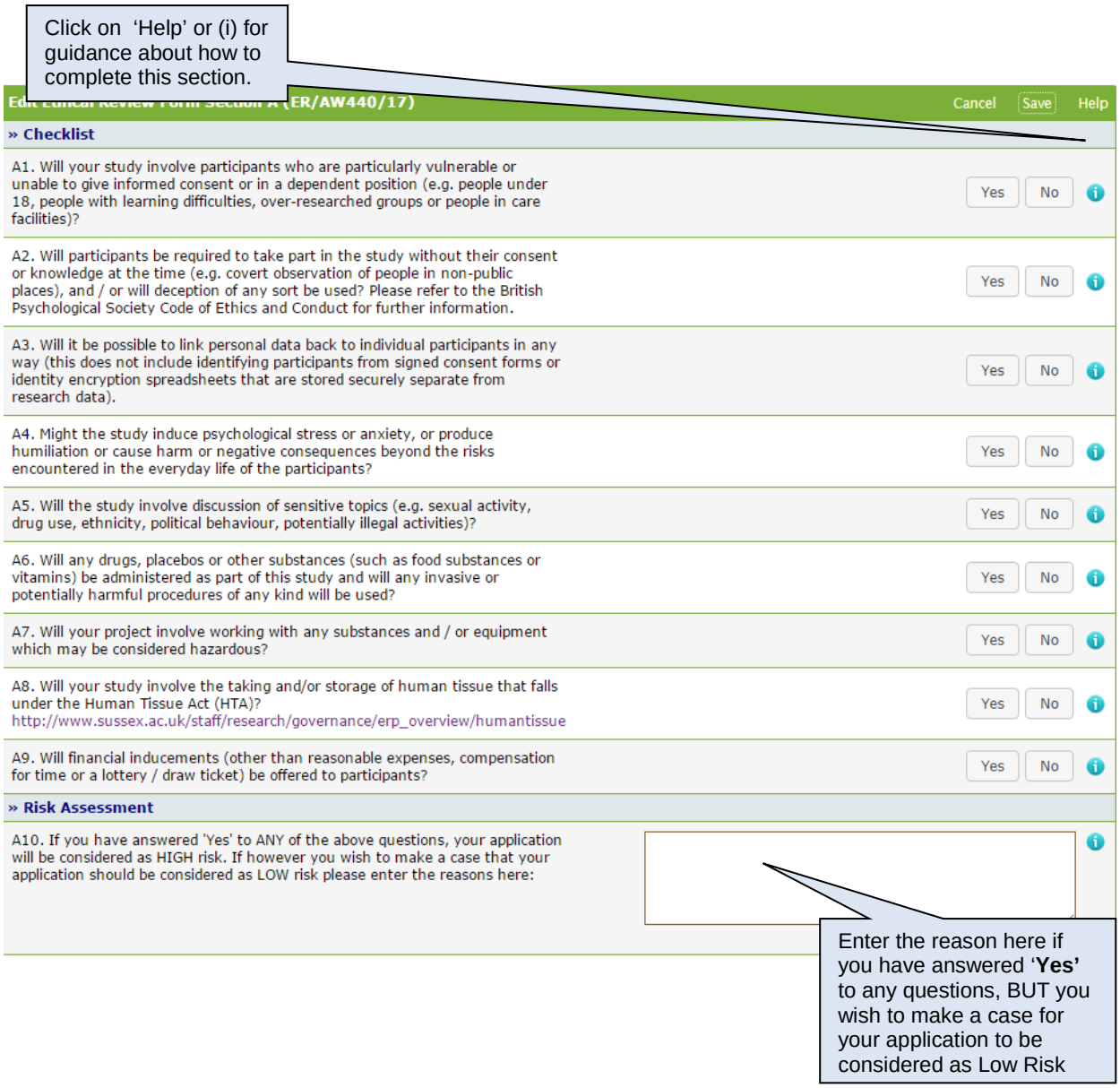
You should note that **only** applications for SSARTS and SCITEC can be transferred (if needed) between Committees. *If an applicant completes a form in error for the wrong route, it will have to be completed again*.

APPLICATIONS to Supervisor/ SREO/ Science and Technology or Social Sciences and Arts Research Ethics Committee

4. Complete the Checklist in Section A

Having selected the desired application route, the first form completed will appear followed by the 'Ethical Review Form Section A – the Checklist that is used to determine whether your application is for High or Low risk work

- **Click on the 'Edit' button to start filling out this section**
- Complete the Checklist (you must answer ALL the questions).
- Click on Help or  for assistance with questions throughout the application form



- If you answer '**No**' to **ALL** the questions, your project is assumed to be low risk and when you click Save you will be presented with PART B of the ethics application form.
- If you answer '**Yes**' to **ANY** of the questions, your project is assumed to be higher risk, and when you click Save you will be presented with PART C of the ethics application form.
- If you think your project is Low Risk despite answering 'Yes' to any of the questions in the checklist, please provide a summary of the mitigating factors which would allow your project to be reviewed as a low risk project. You enter this information in the 'Risk factor' section at the bottom of the Checklist – See above screenshot). If you type any text in this box, you will be presented with Part B when you click Save.
- Click **'Save'** to proceed to SECTION B (Low Risk projects) or SECTION C (Higher Risk projects.

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

5. **Complete the Section B (Low Risk), or Section C (Higher Risk) - answer ALL questions.**

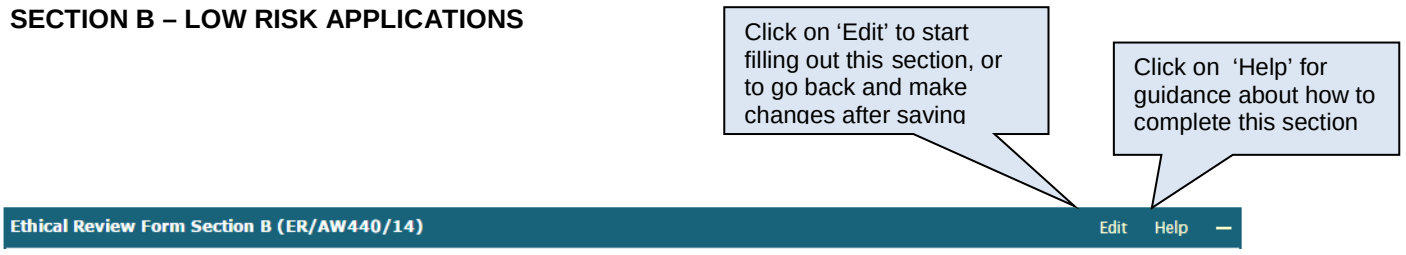
- **Click on the 'Edit' button to start filling out this section**

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

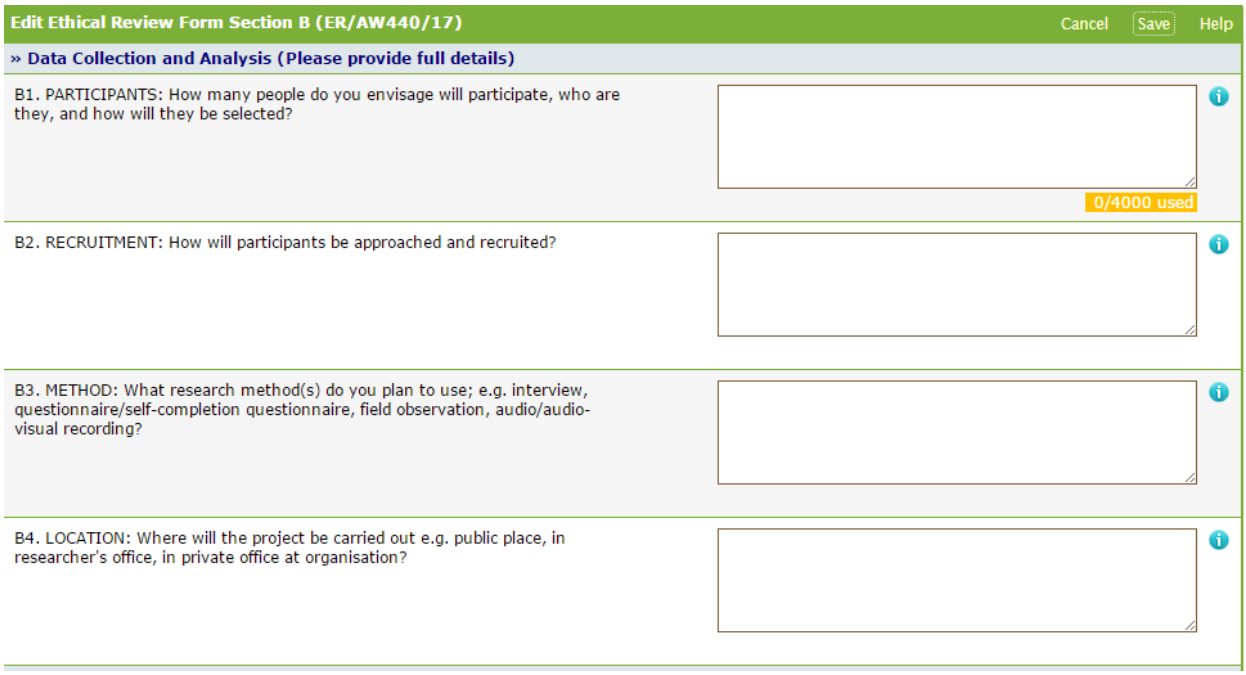
***NB: When you have completed Section B or Section C, make sure you **click Save, BEFORE you move onto the Supporting Documents section**. You will still be able to edit your application once you have clicked Save, but if you do not click **Save** all your data will be lost.

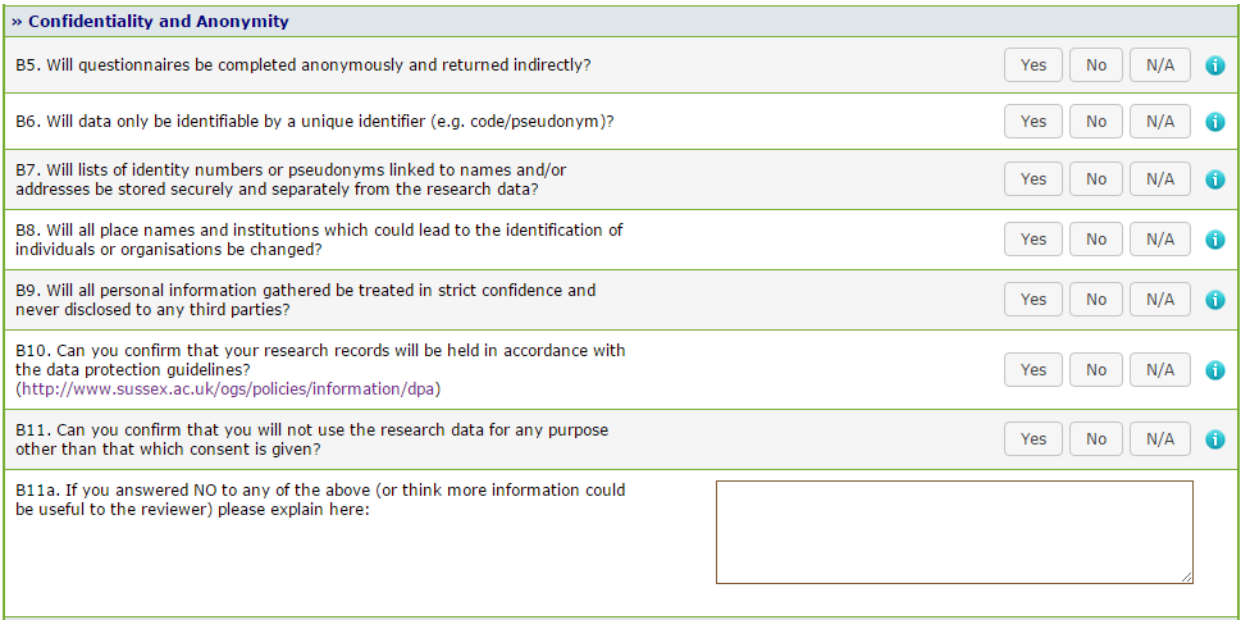
- If you want to go back and edit any part of your application, click the **Edit** button at the top of the section you wish to change.

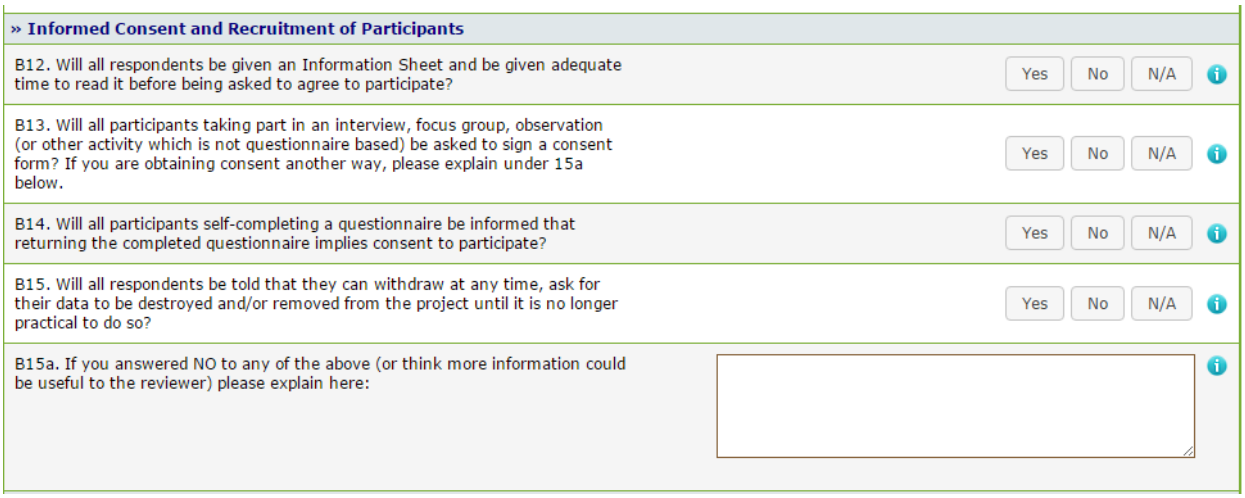
SECTION B – LOW RISK APPLICATIONS

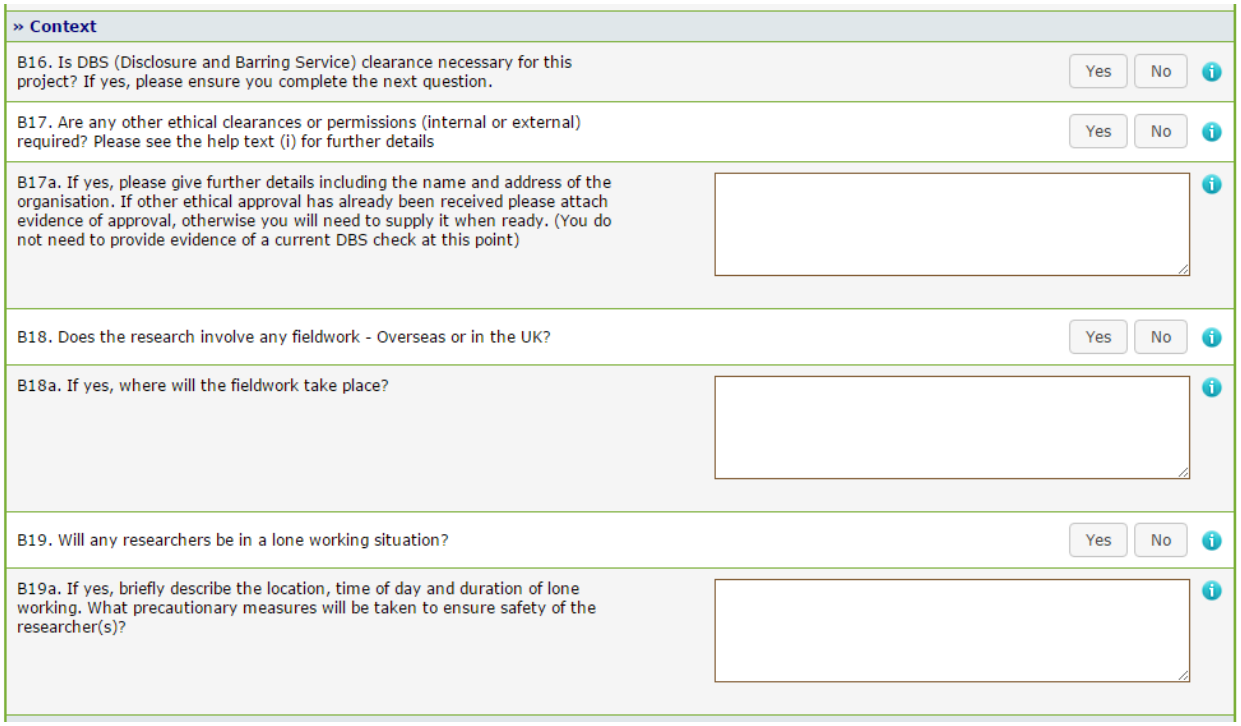


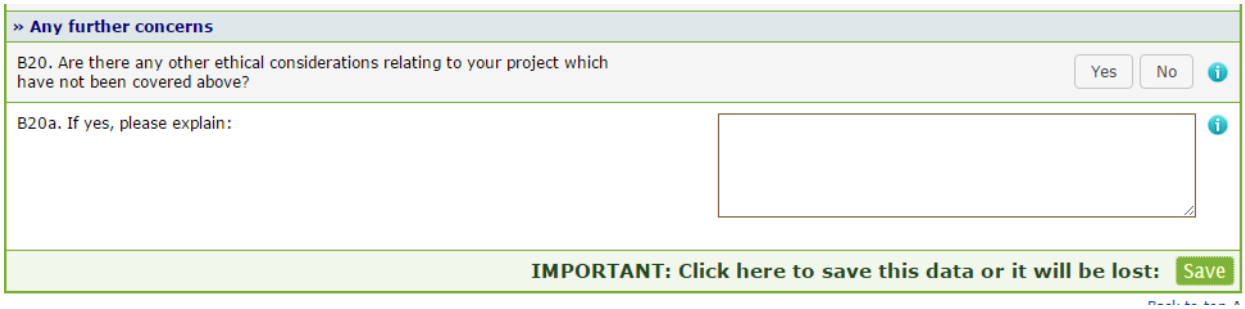
Note that the bar goes green when the section is in edit mode.


Edit Ethical Review Form Section B (ER/AW440/17)
Cancel
Save
Help
» Data Collection and Analysis (Please provide full details)
B1. PARTICIPANTS: How many people do you envisage will participate, who are they, and how will they be selected?
0/4000 used
B2. RECRUITMENT: How will participants be approached and recruited?
B3. METHOD: What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording?
B4. LOCATION: Where will the project be carried out e.g. public place, in researcher's office, in private office at organisation?

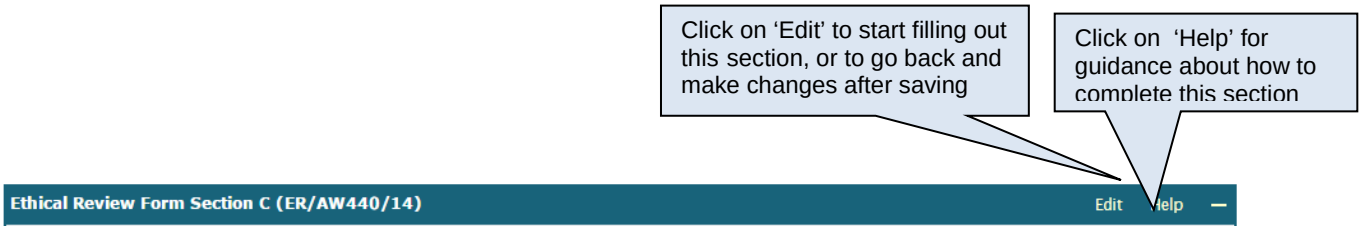

» Confidentiality and Anonymity
B5. Will questionnaires be completed anonymously and returned indirectly?
Yes
No
N/A
B6. Will data only be identifiable by a unique identifier (e.g. code/pseudonym)?
B7. Will lists of identity numbers or pseudonyms linked to names and/or addresses be stored securely and separately from the research data?
B8. Will all place names and institutions which could lead to the identification of individuals or organisations be changed?
B9. Will all personal information gathered be treated in strict confidence and never disclosed to any third parties?
B10. Can you confirm that your research records will be held in accordance with the data protection guidelines? (http://www.sussex.ac.uk/ogs/policies/information/dpa)
B11. Can you confirm that you will not use the research data for any purpose other than that which consent is given?
B11a. If you answered NO to any of the above (or think more information could be useful to the reviewer) please explain here:


» Informed Consent and Recruitment of Participants
B12. Will all respondents be given an Information Sheet and be given adequate time to read it before being asked to agree to participate?
Yes
No
N/A
B13. Will all participants taking part in an interview, focus group, observation (or other activity which is not questionnaire based) be asked to sign a consent form? If you are obtaining consent another way, please explain under 15a below.
Yes
No
N/A
B14. Will all participants self-completing a questionnaire be informed that returning the completed questionnaire implies consent to participate?
Yes
No
N/A
B15. Will all respondents be told that they can withdraw at any time, ask for their data to be destroyed and/or removed from the project until it is no longer practical to do so?
Yes
No
N/A
B15a. If you answered NO to any of the above (or think more information could be useful to the reviewer) please explain here:


» Context
B16. Is DBS (Disclosure and Barring Service) clearance necessary for this project? If yes, please ensure you complete the next question.
Yes
No
B17. Are any other ethical clearances or permissions (internal or external) required? Please see the help text (i) for further details
Yes
No
B17a. If yes, please give further details including the name and address of the organisation. If other ethical approval has already been received please attach evidence of approval, otherwise you will need to supply it when ready. (You do not need to provide evidence of a current DBS check at this point)
B18. Does the research involve any fieldwork - Overseas or in the UK?
Yes
No
B18a. If yes, where will the fieldwork take place?
B19. Will any researchers be in a lone working situation?
Yes
No
B19a. If yes, briefly describe the location, time of day and duration of lone working. What precautionary measures will be taken to ensure safety of the researcher(s)?


» Any further concerns
B20. Are there any other ethical considerations relating to your project which have not been covered above?
Yes
No
B20a. If yes, please explain:
IMPORTANT: Click here to save this data or it will be lost:
Save

SECTION C – HIGHER RISK APPLICATIONS



Note that the bar goes green when the section is in edit mode.

Ethical Review Form Section C (ER/AW440/17) Edit Help
» Risk Checklist - Participants
C1. Is DBS clearance necessary for this project? If yes, please ensure you complete Section C.23a below.
C2. Are alcoholic drinks, drugs, placebos or other substances (such as food substances or vitamins) to be administered to the study participants?
C3. Can you think of anything else that might be potentially harmful to participants in this research?
» Risk Checklist - Researcher(s) Safety and Wellbeing
C4. Does the project involve working with any substances and/or equipment which may be considered hazardous? (Please refer to the University's Control of Hazardous Substances Policy).
C5. Could the nature or subject of the research potentially have an emotionally disturbing impact on the researcher(s)?
C5a. If yes, briefly describe what measures will be taken to help the researcher(s) to manage this.
C6. Could the nature or subject of the research potentially expose the researcher(s) to threats of physical violence and / or verbal abuse?
C6a. If yes, briefly describe what measures will be taken to mitigate this.
C7. Does the research involve any fieldwork - Overseas or in the UK?
C7a. If yes, where will the fieldwork take place?
C8. Will any researchers be in a lone working situation?
C8a. If yes, briefly describe the location, time of day and duration of lone working. What precautionary measures will be taken to ensure safety of the researcher(s)?
C9. Can you think of anything else that might be potentially harmful to the researcher(s) in this research?
» Data Collection and Analysis (Please provide full details)
C10. PARTICIPANTS: How many people do you envisage will participate, who are they, and how will they be selected?
C11. RECRUITMENT: How will participants be approached and recruited?
C12. METHOD: What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording?
C13. LOCATION: Where will the project be carried out e.g. public place, in researcher's office, in private office at organisation?

» Ethical Considerations (Please provide full details)
C14. INFORMED CONSENT: Please describe the process you will use to ensure your participants are freely giving fully informed consent to participate. This will usually include the provision of an Information Sheet and will normally require a Consent Form unless there is justification for not doing so. (Please state this clearly).
C15. RIGHT OF WITHDRAWAL: Participants should be able to withdraw from the research at any time. Participants should also be able to withdraw their data if it is linked to them and should be told when this will no longer be possible (e.g. once it has been included in the final report). Please describe the exact arrangements for withdrawal from participation and withdrawal of data for your study.
C16. OTHER ETHICAL ISSUES: If you answered YES to anything in A.1 above you must specifically address this here. Please also consider whether there are other ethical issues you should be covering here. Please also make reference to the professional code of conduct you intend to follow in your research.
» Data Protection, Confidentiality, and Records Management
C17. Will you ensure that the processing of personal information related to the study will be in full compliance with the Data Protection Act 1998 (DPA)? (http://www.sussex.ac.uk/ogs/policies/information/dpa)
C17a. If you are processing any personal information outside of the European Economic Area (EEA) you must explain how compliance with the DPA will be ensured.
C18. Will you take steps to ensure the confidentiality of personal information?
C18a. Please provide details of anonymisation procedures and of physical and technical security measures here:
C19. Will all data related to this study be retained and shared in a form that is fully anonymised (separated from information that can identify the participant)?
C19a. If you answered "no" to the above question you must ensure that any limitations to full anonymity are detailed in the Information Sheet and that participant consent will be in place. If relevant, please outline limitations here:
C20. Will the Principal Investigator take full responsibility during the study, for ensuring appropriate storage and security of information (including research data, consent forms and administrative records) and, where appropriate, will the necessary arrangements be made in order to process copyright material lawfully?
C20a. If you answered "no" to the above question, please give further details:
C21. Who will have access to personal information relating to this study?
C22. Data management responsibilities after the study. State how long study information including research data, consent forms and personal identification will be retained, in what format(s) and where the information will be kept.
» Other Ethical Clearances and Permissions
C23. Are any other ethical clearances or permissions (internal or external) required? Please see the help text (i) for further details
C23a. If yes, please give further details including the name and address of the organisation. If other ethical approval has already been received please attach evidence of approval, otherwise you will need to supply it when ready.

*Once all sections have been completed, select '**Save'** to commit your work to the database.*

Supporting Documents

Supporting Documents (ER/AW440/11) 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 [PDF]	Application		
1	Questionnaire example.pdf [153Kb : PDF]	Questionnaire or Topic Guide or Interview Questions	1	13-Feb-2017 09.08.09
2	PIS.pdf [99Kb : PDF]	Information sheet	1	13-Feb-2017 09.07.55
3	Consent Form.pdf [101Kb : PDF]	Consent form	1	13-Feb-2017 09.08.27

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

Create Merged PDF

6. You now need to upload any relevant supporting documents such as the Consent Form, Information Sheet, Questionnaire etc.

All documents must be converted to PDF before this can occur.

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.

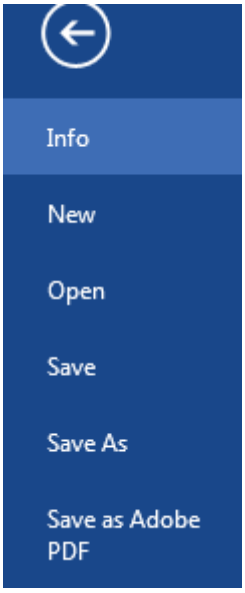
Important note
To make sure your document merges successfully, ITS recommends you follow these instructions:

- ## 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

HOW TO UPLOAD A SUPPORTING DOCUMENT

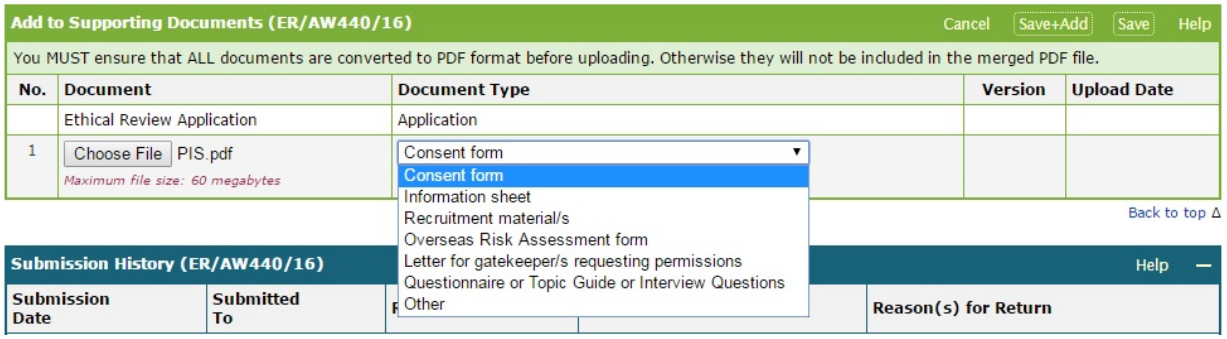
Click on the Upload Document button

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.



CREATING A MERGED PDF

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

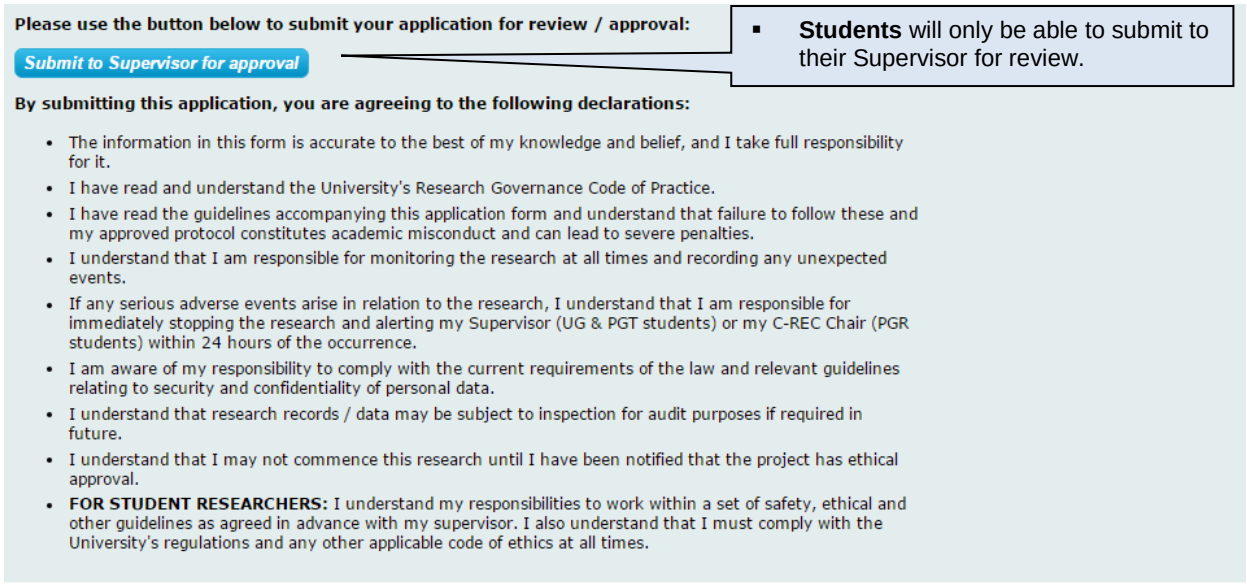
This button allows you to create a merged PDF document of your application form and supporting documents. You will be able to download this for checking, or sharing, before you submit your application.

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.

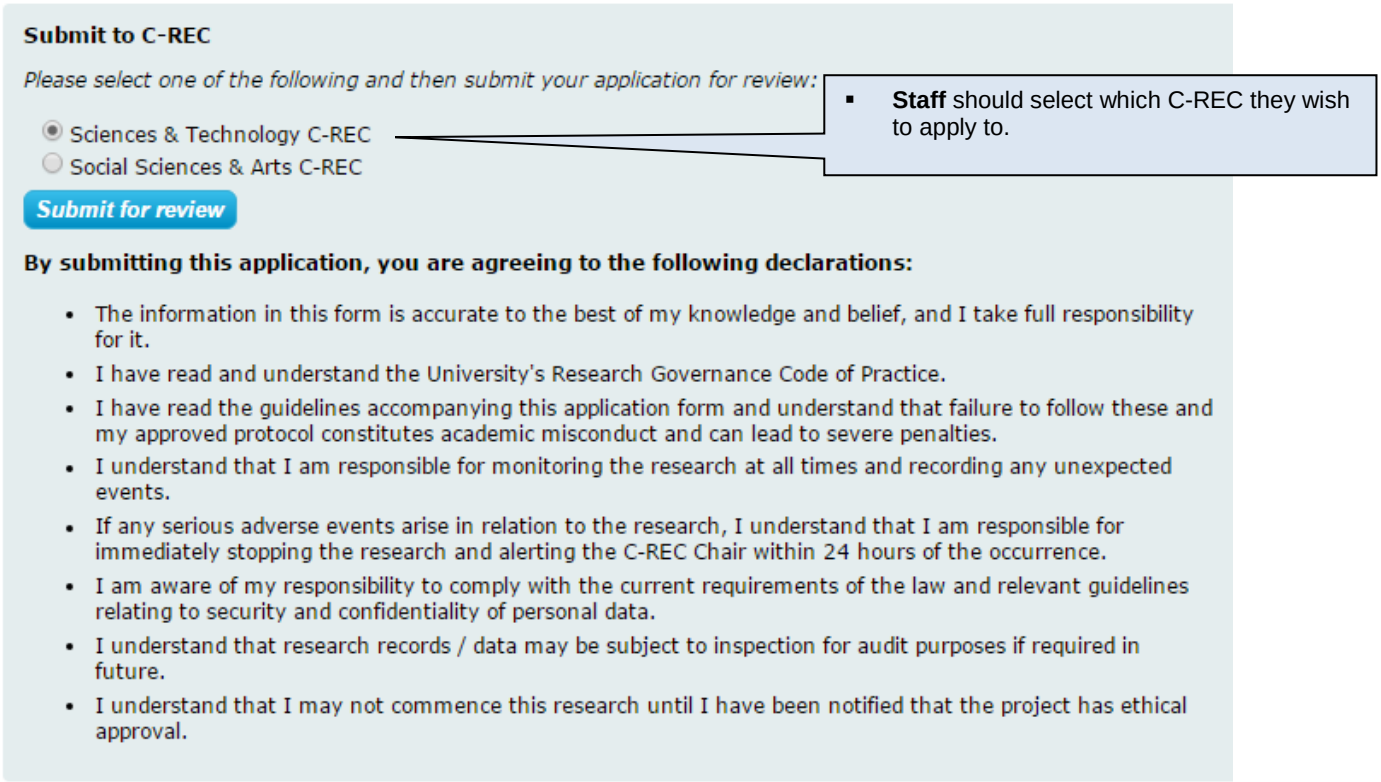
Submission of the Application

7. Read the declaration carefully and then Submit to your Supervisor (students) or a C-REC (staff).

a. Students (UG, PGT, PGR)



b. Staff



AFTER SUBMISSION

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

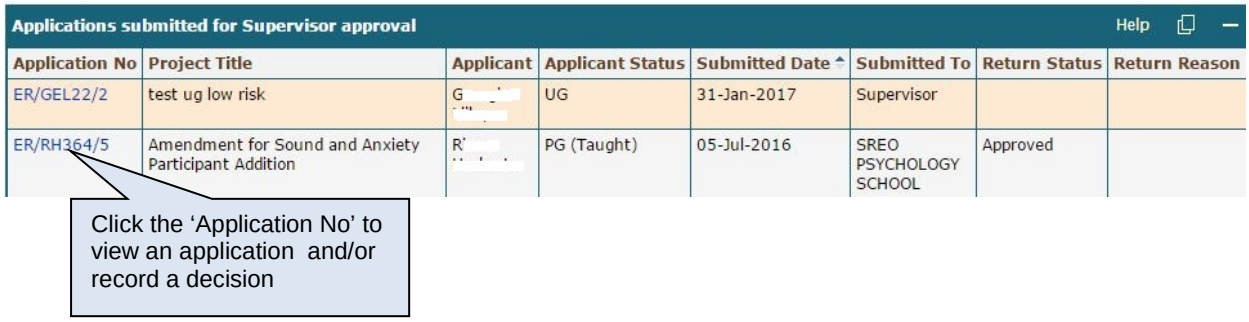
9. You will be sent further email alerts whenever a decision has been entered (by a Supervisor, SREO, or C-REC). See the section ‘Progress of an Application’ on page 21 (below), for more information about what happens after an application has been submitted.

A SUPERVISOR'S VIEW

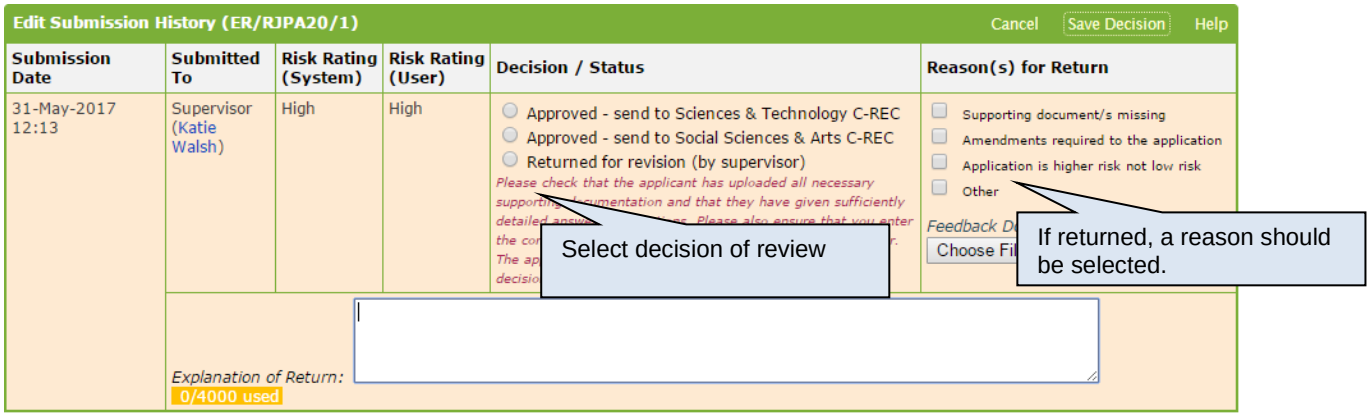
Applications made by students should be sent to their supervisor for approval before they are submitted to a C-REC or SREO.

The Supervisor can:

- ***view*** a list of all applications submitted for their approval;
- ***view*** the full details of an application, including attached documents;
- ***record*** an application outcome of 'approved' or 'return for revision';
- ***record*** the reason(s) why the application is being returned for revision;
- ***send*** the application to the relevant SREO or C-REC, if approved.



Enter decision



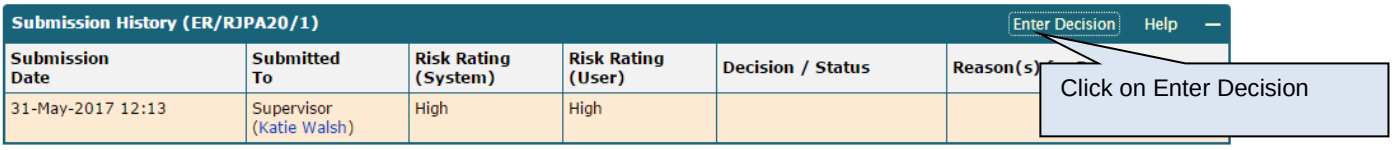
Select one of :

Approved – Send to Sciences & Technology C-REC
Approved – Send to Social Sciences & Arts C-REC
Returned for revision (by supervisor)

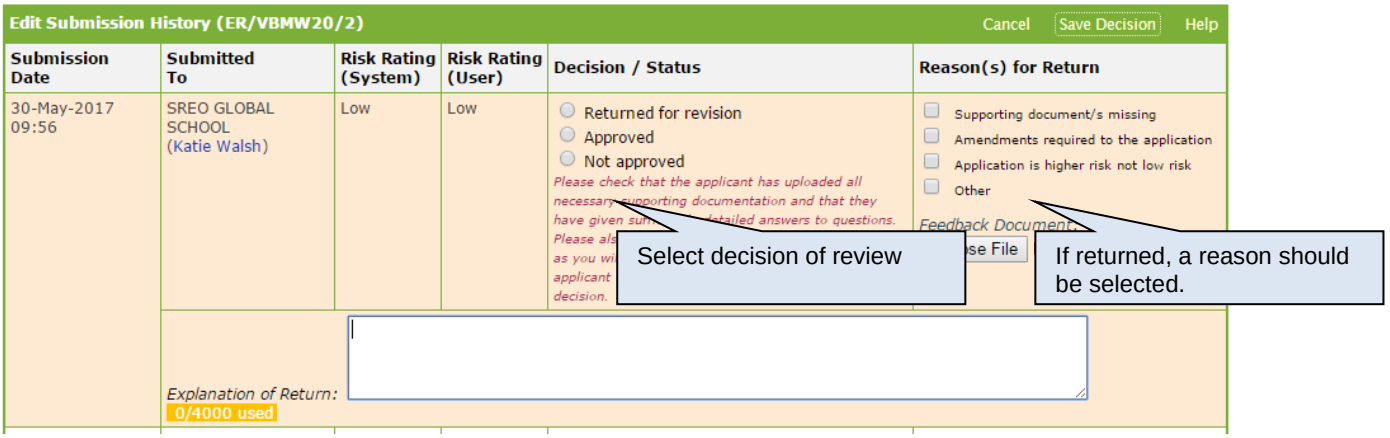
A C-REC/SREO VIEW

A C-REC/SREO can:

- ***view*** a list of applications submitted for their approval;
- ***view*** the full application, including attached documents, by clicking the Application Number;
- ***comment*** **on an application**
- ***record*** an outcome of 'approved', 'return for revision', or 'reject';
- ***record*** the reason(s) why the application is being returned for revision.



Enter decision



Select one of :

- Returned for revision (by supervisor)
- Approved
- Not approved

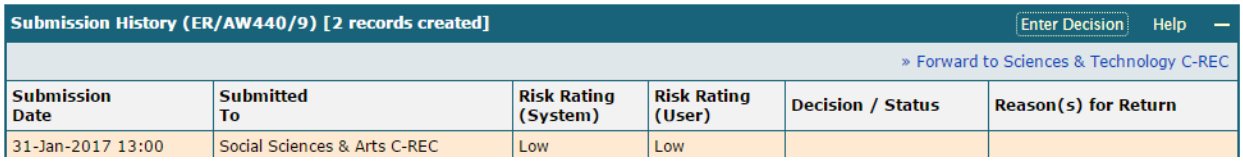
ADMINISTRATOR FUNCTIONS

An Administrator can:

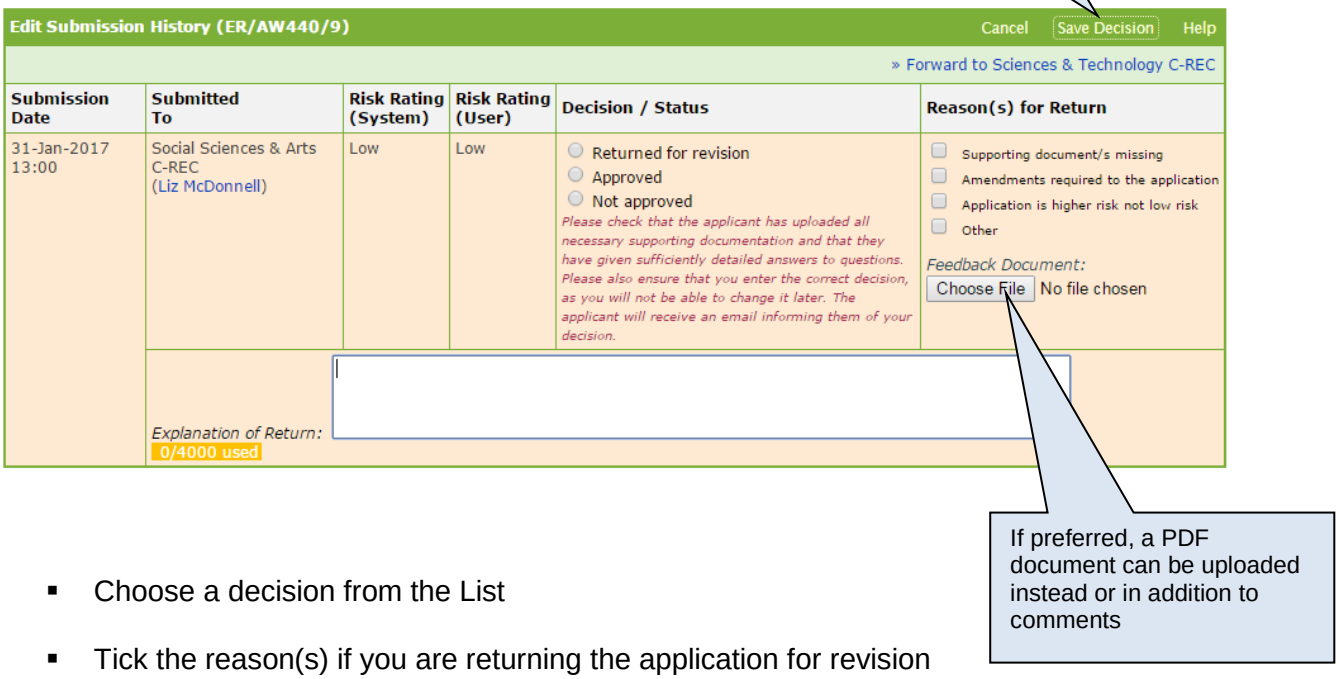
- Record a decision

RECORDING A DECISION

- Click the ‘Application No’
- Page down to the ‘Submission History’ table



- Click the ‘Enter Decision’ option



- Choose a decision from the List
- Tick the reason(s) if you are returning the application for revision
- Enter additional text to explain why it is being returned, if required
- Click ‘**Save**’ to record the decision on Sussex Direct

THE PROGRESS OF AN APPLICATION

If you are a student, your application must be approved by your Supervisor before it is submitted to a C-REC or SREO.

The Supervisor will either:

a) return the application to you for revision – listing the reason(s);
   OR
b) approve the application, and submit it directly to the C-REC/SREO

The system will determine whether the application should be sent to a C-REC or SREO using the information below:

	High Risk	**Low Risk**
UG	Supervisor and C-REC	Supervisor and SREO
PGT	Supervisor and C-REC	Supervisor and SREO
PGR	Supervisor and C-REC	Supervisor and C-REC
Staff	C-REC	C-REC

The C-REC/SREO can record one of the following outcomes:

a) return the application to you for revision;

b) reject the application;

c) approve the application.

The progress of your application (including the reason(s) the application has been returned) will be displayed at the end of your application.

Submission History (redacted) Help

Submission Date	Submitted To	Risk Rating (System)	Risk Rating (User)	Decision / Status	Reason(s) for Return
27-Jan-2017 18:06	Social Sciences & Arts C-REC (redacted)	Low	Low		
27-Jan-2017 17:01	Supervisor (redacted)	Low	Low	Approved by supervisor	
09-Dec-2016 15:21	Social Sciences & Arts C-REC (redacted)	Low	Low	Returned for revision	• Supporting document/s missing • Amendments required to the application
	Explanation of Return: Please can the applicant address the reviewers' requests for amendments below (including additional documents) and resubmit the application (making a copy) indicating where changes have occurred: 1. The 'detailed information sheet' mentioned as something that will designed for the 8 participants with whom intensive time will be spent, needs to be uploaded. Please use the template on the research governance part of the university website. 2. The pamphlets that will be designed for use in the markets with (approx. 100) vendors and their families / communities needs to be uploaded as the equivalent of the above info sheet. 3. The consent process needs to be fully detailed. If verbal consent is to be used, please complete the verbal consent checklist used in Global Studies (your supervisor should / the SREO will have this on file), making sure to explain what and how you will explain the consent process at various points i.e. at the start and then in the on-going discussions you mention. 4. Please also reflect on the issues raised by the use of research assistants in conducting interviews for linguistic reasons, especially where they pertain to the verbal consent procedure.				

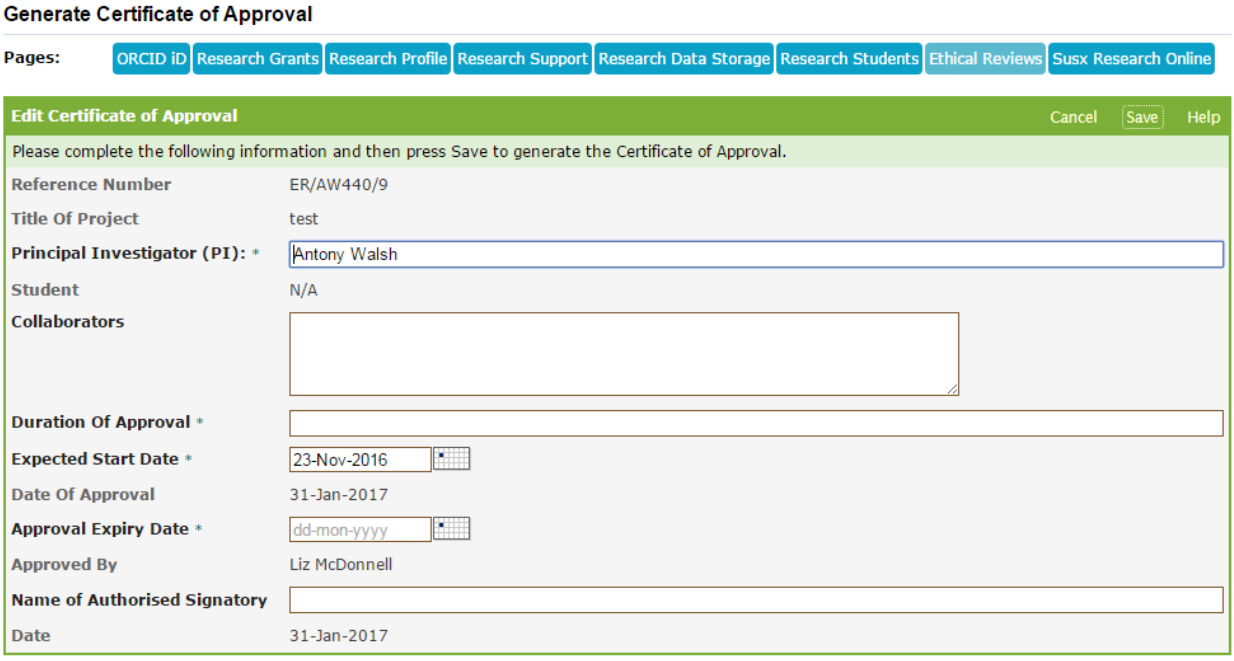
If either the Supervisor, or the C-REC/SREO, return the application for revision, the application will be unlocked for the applicant to edit, including the ability to add, delete, and replace documents.

RAISING A CERTIFICATE OF APPROVAL

This function is only available to the C-REC members and C-REC administrators (for high risk projects) and to the School Research Ethics Officers (for low risk projects).

If enter approve for the application you will be given the option to automatically generate a certificate of approval;

You will then be shown a screen to populate some fields, some fields are already populated;



The certificate is then generated and is automatically saved in the supporting documents section of the application form;

UNIVERSITY OF SUSSEX

Social Sciences & Arts C-REC
c-recss@admin.susx.ac.uk

Certificate of Approval	
Reference Number	ER/AW440/12
Title Of Project	test
Principal Investigator (PI):	Antony Walsh
Student	N/A
Collaborators	None
Duration Of Approval	2 years
Expected Start Date	30-Jan-2017
Date Of Approval	30-Jan-2017
Approval Expiry Date	30-Jan-2019
Approved By	Liz McDonnell
Name of Authorised Signatory	LM
Date	30-Jan-2017

*NB. If the actual project start date is delayed beyond 12 months of the expected start date, this Certificate of Approval will lapse and the project will need to be reviewed again to take account of changed circumstances such as legislation, sponsor requirements and University procedures.

Please note and follow the requirements for approved submissions:

Amendments to protocol

* Any changes or amendments to approved protocols must be submitted to the C-REC for authorisation prior to implementation.

Feedback regarding the status and conduct of approved projects

* Any incidents with ethical implications that occur during the implementation of the project must be reported immediately to the Chair of the C-REC.

Feedback regarding any adverse(1) and unexpected events(2)

* Any adverse (undesirable and unintended) and unexpected events that occur during the implementation of the project must be reported to the Chair of the Social Sciences and Arts C-REC. In the event of a serious adverse event, research must be stopped immediately and the Chair alerted within 24 hours of the occurrence.

Monitoring of Approved studies

The University may undertake periodic monitoring of approved studies. Researchers will be requested to report on the outcomes of research activity in relation to approvals that were granted (full applications and amendments).

Research Standards

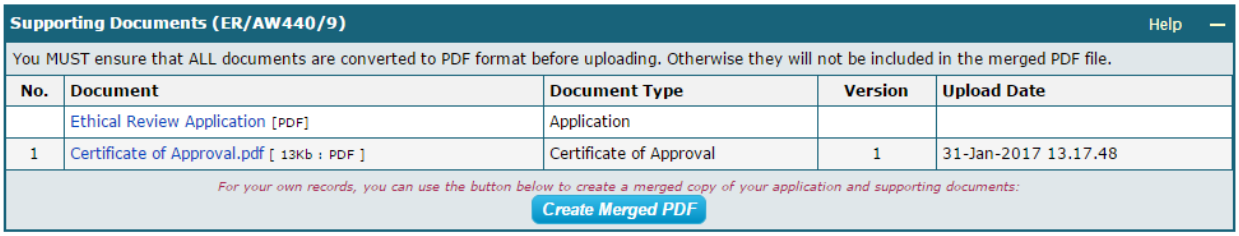
Failure to conduct University research in alignment with the Code of Practice for Research may be investigated under the Procedure for the Investigation of Allegations of Misconduct in Research or other appropriate internal mechanisms (3). Any queries can be addressed to the Research Governance Office: rgoffice@sussex.ac.uk

(1) An "adverse event" is one that occurs during the course of a research protocol that either causes physical or psychological harm, or increases the risk of physical or psychological harm, or results in a loss of privacy and/or confidentiality to research participant or others.

(2) An "unexpected event" is an occurrence or situation during the course of a research project that was a) harmful to a participant taking part in the research, or b) increased the probability of harm to participants taking part in the research.

(3) http://www.sussex.ac.uk/staff/research/rqi/policy/research-policy

Once the certificate is generated and saved it saves into the supporting documentation section of the application;



Supporting Documents (ER/AW440/9) 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 [PDF]	Application		
1	Certificate of Approval.pdf [13Kb : PDF]	Certificate of Approval	1	31-Jan-2017 13.17.48

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

Create Merged PDF