Answers to Frequently Asked Questions

For Applicants Applying Online to BSMS RGEC

These FAQ for BSMS applicants have been updated in June 2020 to include guidance related to tiered ethical review (Standard/High Risk) for undergraduate and postgraduate taught students. Please see questions 14 onwards, which specifically concern standard risk review.

1. What is the online ethical review application system?

The online ethical review application system provides an online Application Form for Ethical Review for applying to the BSMS Research Governance and Ethics Committee (RGEC), and also allows for uploading of supporting study documents required for ethical review.

2. How do I access the online ethical review application system?

You can access the online ethical review application system via Sussex Direct:

https://direct.sussex.ac.uk/page.php?realm=research&page=ethical_review_list

Once you have entered the welcome page, select 'Research' in the list of sub-headings, then 'Ethical reviews' from the drop down list. The accompanying User Guide provides step-by-step guidance on how to prepare and submit a new application for ethical review.

Please note a University of Sussex ITS login is required for BSMS staff and students to access the online ethical review application system in Sussex Direct. For BSMS staff, this is the unique BSMS username assigned to you and required to log on to your work PC, (for e.g. "bsms1719") and your usual BSMS password.

3. I do not have a login to Sussex Direct - what can I do?

If you are a member of BSMS faculty, please contact the Sussex ITS Team who can assist you with obtaining/confirming your University of Sussex ITS login.

Email: support@its.sussex.ac.uk

General enquiries line: Ext 8090 (+44 1273 678090)

ITS Support Portal: https://sussex.saasiteu.com/Modules/SelfService/#home

4. What if I have previously been successful in logging in to Sussex Direct but now can't access the online system?

In this instance please submit a request for support via the University of Sussex ITS Helpdesk:

Email: support@its.sussex.ac.uk

ITS Support Portal: https://sussex.saasiteu.com/Modules/SelfService/#home

5. Who can use the online ethical review application system?

All BSMS staff and students (in consultation with their Supervisor) are encouraged to use the online ethics application form.

For undergraduate Individual Research Projects (IRPs) where the Supervisor is from an external institution (such as an NHS Trust), the medical student is encouraged to submit the ethics application as an integral part of their ethics training. Their Supervisor will also be required to access the online ethical review application system, in Sussex Direct, as part of the ethical review process.

Supervisors who already have an Honorary Contract with the Medical School are entitled to a BSMS, and therefore a University of Sussex email address, which is needed to access the online ethical review application system in Sussex Direct. These should be requested via the academic department at BSMS which the individual belongs to, and well in advance of an ethics submission. Once a University of Sussex email address has been confirmed, the Sussex ITS Team can assist you with confirming your Sussex ITS login, if required.

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6. How is my application reviewed?

A review slot at a scheduled RGEC meeting must be booked in for applications submitted via the online ethical review application system. Please contact RGEC at rgec@bsms.ac.uk to book a slot for the review of your application at a scheduled meeting. A list of scheduled meetings is published annually on the BSMS website here. A finite number of slots are available per meeting and are booked on a first come first served basis.

7. Submitting Amendments for Review

All amendments to previously approved research projects are submitted via the online ethical review application system in Sussex Direct and RGEC unfortunately no longer accepts amendment submissions submitted via e-mail.

Page 14 (this may change) of the user manual provides detailed step by step instructions on the process for submitting amendments, including helpful screenshots.

8. Can I use the old system for applying for ethical review (i.e. downloading the old RGEC Application Form for Ethical Review and submitting via email for review)?

Unfortunately, no, the online ethical review application system is now the sole method of applying to the Committee, and only applications for ethical review made online through Sussex Direct are accepted.

9. Will I be able to save or print out a draft copy of my application?

The online ethical review application system allows you to both save and print out a draft version of your application. Additionally, there is a template of the online ethical review application form available in Word document format, which applicants may wish to use in the preparation of their application.

10. How will the online system deal with applications from students, whose applications need to be seen by various members of the research team before being submitted to RGEC?

A draft version of an application can be saved (in PDF format), printed and shared with Supervisors and members of the research team.

11. Will I be able to upload supporting documents to my online application for ethical review?

Yes - you will need to save your supporting documents as PDFs first, and then you will be able to upload them to your application. The online system will compile your application form and your supporting documents into a single merged PDF document. To ensure your pdf merges successfully, please follow the recommendations in the ITS Guidance on Uploading Documents [PDF 200.58KB]. File not found

12. Is any training available regarding the online ethical review application system?

We have designed the system to be as intuitive and easy to use as possible. A comprehensive manual covers all aspects of completing the application form and submitting supporting documents, including amendments. Individual training sessions can be available on request for staff and students who would like an introduction to the new functionality of the online ethical review application system. Training resources in video format on how to create and submit an ethics application in Sussex Direct for applicants are planned in the near future.

13. What is the new standard risk ethical review pathway?

The online ethics application system in Sussex Direct for applying to the BSMS Research Governance and Ethics Committee has been adapted to include a separate review pathway for undergraduate and postgraduate taught student research projects judged as posing minimal risks.

Expedited review for these projects will occur via the BSMS School Research Ethics Officers (SREO), at BSMS, <u>Dr Trevor Welland</u> and <u>Ceri Butler</u>.

In parallel, the applicant's Supervisor will become an integral part of the reviewing process, first confirming online endorsement for their student's application prior to submission to the SREO for ethical review. The system will generate emails to alert staff that an application requires their review.

It should be noted that emails will be sent to the Supervisor's University of Sussex email address, and a University of Sussex ITS login is needed for the Supervisor to access the online ethics application system in Sussex Direct. Please see question 3, above.

14. I am an undergraduate / postgraduate taught student. How do I know if my project is eligible for standard risk review?

The standard review process only applies to undergraduate and postgraduate taught student research projects judged to pose minimal risks.

The online ethical review application system, within Sussex Direct, will now identify undergraduate and postgraduate taught student projects which are deemed standard risk, using an in-built risk assessment checklist. It has been deliberately designed to introduce quicker turnaround of ethical review for student projects presenting fewer risks to participants. A copy of the Risk Rating Checklist Filter Questions can be found below for reference.

15. How do I apply for standard risk ethical review?

If you think your project is eligible, you should continue to submit your application using the online ethical review application system in Sussex Direct, which is available <u>here</u>. During completion of the online Application Form in Sussex Direct, your responses to the risk assessment checklist will determine whether your project is eligible for standard risk ethical review.

16. If my application has been identified as eligible for Standard Risk ethical review, does my Supervisor also need access to the application in Sussex Direct?

Yes. Supervisors will check and confirming authorisation for the student's application online in Sussex Direct. Once, they have done this, the Supervisor will transfer the application to the SREO for ethical review.

As the online ethical review application system is supported by the University of Sussex's IT infrastructure, a University of Sussex ITS login is needed for the Supervisor to gain access. The Supervisor will also need a University of Sussex email address to receive an email to alert that an application is awaiting review.

17. My Supervisor doesn't appear in the list of Supervisors offered in the online ethical review application system in Sussex Direct?

Your Supervisor will need to be a BSMS member of faculty, recognised by University of Sussex IT systems, or have an Honorary Contract with BSMS in place.

The Sussex ITS Team can be contacted to assist Supervisors who are BSMS members of faculty with obtaining/confirming a University of Sussex ITS login.

Supervisors who have Honorary Contracts with BSMS are entitled to a University of Sussex email address. This will need to be established in advance of submission of an ethics application.

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General enquiries line: Ext 8090 (+44 1273 678090)

18. I submitted my application in error / My Supervisor hasn't responded / I can't find my application in the online system. Help!

Firstly, check that you are logged in correctly. Is your application still in draft mode? Check in the list of applications displayed in the 'My Ethical Review Applications' screen. If the application hasn't yet been sent to your supervisor, it will be marked "Draft" in the Status column.

However, if you have completed and submitted an application to your supervisor for review, and haven't received a timely response, are concerned it was sent to the wrong individual in error, or may be 'stuck' in the system, please contact Caroline Brooks, BSMS Research Integrity, Ethics and Governance Administrator (rgec@bsms.ac.uk) for advice.

19. How do I check the status of my application in the online system?

You can check the status of your application (where it is in the approval process), at any time. Log in to the online system.

Once logged in, go to the 'My Ethical Review Applications' screen and ensure that 'My Ethical Review Applications' is selected from the options presented. The status of each application is displayed in the 'Status' column on the right hand side. Your application may fall into one of the following categories:

- The application status is "Review": You have submitted your application to the Committee for ethical review. The application will no longer be available to amend as it is currently with the Committee for review and locked to the applicant for further editing.
- 'Returned for revision': The Committee has completed its review and transferred the application back to the applicant to enable revisions identified during the ethical review process to now be made by the applicant. These may include wording changes to the online application form, and, often require revised (or new documents omitted from the original submission) to also be uploaded. Applicants should provide a covering letter of response which highlights and itemises where revisions requested by the Committee are located in the online form or supporting documents as part of the re-submission to assist the reviewers in verifying the changes and confirming approval.
- "Approved": The Application has been confirmed as approved by the Committee.

20. How do I receive my Certificate of Approval from the online system?

Once your application has been confirmed "Approved" in Sussex Direct, the individual responsible for confirming approval will generate a Certificate of Approval for your project. This is then sent to the Sussex email address attached to your ITS account. For projects approved via the BSMS RGEC, the BSMS Research Integrity, Ethics and Governance Administrator manually forwards on the Certificate of Approval to the applicants BSMS email address.

21. Where can I get further advice or information about the online ethical review application system, and other guidance relating to research governance and ethics?

Guidance is included with the online form and below, but further advice and support is available from Caroline Brooks, BSMS Research Ethics and Integrity Administrator (rgec@bsms.ac.uk).

General queries about your application can be directed to: <u>rgec@bsms.ac.uk</u>. More complex queries can be directed to the BSMS Research Integrity, Ethics and Governance Administrator, Caroline Brooks c.e.brooks@bsms.ac.uk

If you have a technical problem regarding access to the online ethical review application system, please contact IT Services at the University of Sussex via the details provided above.

Please see the BSMS Research Governance and Ethics web pages and the University of Sussex Research Governance website for further applicant information as well as links to relevant documents and guidelines.