



Brighton and Sussex Medical School

Standard Operating Procedures (SOP) for Standard Risk Ethical Review

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Review by	BSMS Research Governance and Ethics Committee (RGEN)
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Document description	The following document sets out the standard operating procedures (SOP) for the operation of Standard Risk ethical review at BSMS, including defined roles and responsibilities for individuals involved in submission, authorisation and review of UG and PGT student applications identified as 'Standard Risk'.

Version	Effective Date	Reason for Change
V1.0	6 July 2020	

Disclaimer:

- When using this document ensure that the version you are using is the most up-to-date either by checking on the BSMS Ethics and Governance webpages for any new versions or by contacting the author, Caroline Brooks c.e.brooks@bsms.ac.uk to confirm the current version
- Staff and students may print off this document for training and reference purposes but are responsible for regularly checking for the current version. Any print-off of this document will be classed as an uncontrolled version
- Out of date documents must not be relied upon

Key Contacts:

BSMS Research Governance and Ethics Committee

Chair: [Professor Valerie Jenkins](#)

Deputy Chair: Dr Peter West-Oram [Dr Peter West-Oram](#)

Research Integrity, Ethics and Governance Administrator: [Caroline Brooks](#)

BSMS SREO: Dr Trevor Welland [Dr Trevor Welland](#)

BSMS SREO: [Ceri Butler](#)

Resources:

Please refer to the accompanying [Applicant Checklist Tool](#) and [Supervisor Checklist Tool](#) which have been designed to provide student applicants and their supervisors with specific, accessible guidance on developing robust ethics applications:

(HYPERLINK once available)

BSMS Research Ethics and Governance web pages:

<https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/index.aspx>

University of Sussex Research Governance and Integrity web pages:

<http://www.sussex.ac.uk/staff/research/governance>

University of Sussex Responsibilities for Ethical Review of Research:

<https://www.sussex.ac.uk/webteam/gateway/file.php?name=research-governance-standard-operating-procedures-june-2017.pdf&site=377>

Documents cited:

[University's Code of Practice for Research](#)

[Procedure for the Investigation of Allegations of Misconduct in Research](#)

[University's Research Governance Standard Operating Procedures](#)

[University's Research Integrity Policy Statement](#)

[Universities UK The Concordat to Support Research Integrity](#)

[AfRE Research Ethics Support and Review in Research Organisations](#)

Governance Arrangements for Ethical Review at the University of Sussex

The University of Sussex is committed to promoting and upholding the highest quality academic and ethical standards in all its research activities.

The [University's Code of Practice for Research](#) serves to set out the standards of conduct expected of all staff and students engaged in research. Breaches of these standards are dealt with through the [Procedure for the Investigation of Allegations of Misconduct in Research](#).

Universities UK Concordat to Support Research Integrity

In addition, the University of Sussex fully endorses the UK Concordat to Support Research Integrity. The Concordat demonstrates what is expected of researchers and their employers to ensure the highest standards in research activity.

Amidst the UK research governance landscape Universities are being held to increasing levels of visibility and accountability. Universities UK launched a sector consultation on a revised draft of *The Concordat to Support Research Integrity* which, since it was first published in 2012 has served as a reference point within HEIs for evidencing the sector's commitment to research 'underpinned by the highest standards of rigour and integrity'¹.

The *Concordat* sets out five central commitments:

- Maintaining the highest standards of research integrity
- Ethical, legal and professional frameworks
- Embedding a culture of research integrity
- Dealing with allegations of research misconduct
- A commitment to strengthening research integrity

Each university is expected to publish an annual public statement showing how the commitments are maintained including the numbers of research misconduct cases that have been considered by formal internal processes. The University of Sussex's statement is available at: <https://www.sussex.ac.uk/research/about/standards/research-integrity-policy-statement>

Following a parliamentary inquiry into Research Integrity (Science and Technology Committee), the *Concordat to Support Research Integrity* has been revised with a remit that it 'should be tightened so that compliance can be more easily assessed, with a timetabled route-map to securing 100% compliance'

Another keynote reference point for HEIs is *Research Ethics Support and Review in Research Organisations*, published by the Association for Research Ethics (AfRE) in 2020, establishing sector expectations that universities should have a common set of principles and standards of ethical review for research. The document comprised basic guiding principles for the governance arrangements of ethical research. University Research Ethics Committees should be able to demonstrate:

- **Independence**
- **Competence**
- **Transparency**

¹ <https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/research-concordat.aspx>

- **Facilitation**

It is a fundamental principle that the process of ethical review should be careful and rigorous but at all times transparent, proportionate and supportive. **Ethical review should support researchers of all levels to develop excellent research and ethical research practice.** Those responsible for ethical review have a responsibility to undertake rigorous, transparent reviews of proposed research and to provide feedback which is clear, timely, supportive, and sensitive to disciplinary or methodological diversity.

To this end, robust research governance procedures and policies underpin all research and the University's Research Governance Framework ensures that discipline-appropriate ethical review occurs in a timely manner. For further information, the [University's Research Governance Standard Operating Procedures](#) can be read in conjunction with this document.

Ethical Review in the Context of BSMS

Much of the research undertaken at BSMS requires specialist ethical review via the Health Research Authority (HRA). It may be Sponsored by the University of Sussex, or in some instances an NHS Trust (see the [Sponsorship](#) section on the BSMS and [University](#) websites for details).

For other types of non-clinical research, the Medical School's Research Governance and Ethics Committee (RGEC) operates devolved ethical and governance review for a breadth of studies under the auspices of the University of Sussex University Research Ethics and Integrity Committee (REIC). The Research Governance and Ethics Committee is supported by the University's policies, Code of Practice for Research, Standard Operating Procedures (SOPs) and research misconduct procedure.

To date, RGEC has fulfilled its responsibilities by scrutinising proposals from BSMS faculty, postgraduate research (PGR), postgraduate taught (PGT) and undergraduate (UG) student applicants, and has a remit to consider relevant health and medical related projects by staff and students from other Schools at Sussex. This has entailed undergraduate and post graduate taught proposals being subjected to an equivalent level of scrutiny as fully-fledged staff and postgraduate research student submissions.

However, following extensive development and user testing, the online ethics application system in Sussex Direct for BSMS has been significantly adapted to introduce a stratified ethical review process at BSMS, offering a separate, proportionate review pathway for Undergraduate and Postgraduate Taught student research projects judged as posing minimal risks.

BSMS's new standard risk pathway (implemented in July 2020) will bring the Medical School in line with all Cross-School Research Ethics Committees operating across the University of Sussex.

The ethics application system, within Sussex Direct, will 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.

Sussex Direct has been configured to offer proportionate review for these projects which will occur on an expedited basis via the School Research Ethics Officers (SREOs), a new role at BSMS (refer to page 12 for a comprehensive role description).

Who Should Apply for Ethical Review?

All BSMS researchers are required to apply for ethical review and approval of their research via the appropriate pathway for their study prior to commencing any primary research.

Research projects undertaken by members of Brighton and Sussex Medical School that involve human participants either directly (e.g. being interviewed, answering questionnaires) and/or indirectly (e.g. accessing personal data) should be ethically reviewed via the BSMS Research Governance and Ethics Committee (RGEC).

Projects generally falling into any of the following categories will require approval from the RGEC prior to commencing research activity:

- Research involving human participants recruited outside the NHS (i.e. where they are not recruited by virtue of their status as patients or carers via NHS channels).
- Research involving members of the public or specific groupings of individuals for e.g. parents and carers; performance testing in the sports sciences; men who have sex with men; survivors of suicide, recruited via community settings and groups (i.e. not recruited by virtue of their status as patients or carers via NHS channels).
- Studies involving recruitment of healthy volunteers, such as University staff and students occurring on University premises.
- Staff led medical education projects involving medical students as the research population. Projects seeking participation of medical students (for e.g. a simple online survey) proposed by staff from the local partner NHS trust.
- All imaging research projects utilising fMRI or MRI scanning at the Clinical Imaging Sciences Centre (CISC) involving imaging of healthy volunteers, tissue or biological specimens.
- Pedagogical studies involving participation of BSUH staff (but not patients) with exclusively educational aims.
- Studies involving the development of devices for medical purposes.
- Studies involving traditional and alternative medicine service providers, practitioners or clients.
- Overseas research involving human participants for e.g. from rural communities (e.g. MSc in Global Health projects).
- BSMS MSc projects taking place at host Universities elsewhere involving interventions with patients or healthy volunteer populations.

From July 2020, ethical review at BSMS will now entail assessment of the level of risk associated with student projects to make certain that the ethical review process is duly proportionate. Therefore, the respective pathway for ethical review will, to a large extent, be defined according to the applicant's status as either a student (undergraduate/postgraduate taught) or a doctoral / academic staff researcher.²

These categories of researcher are assigned a corresponding risk rating of either 'Standard' or 'High' Risk review which will operate as follows:

² With the exception of postgraduate taught students conducting fieldwork overseas as part of MSc Global Health dissertation projects, for whom High risk review via RGEC will still apply.

i) Standard Risk ethical review applies to undergraduate and taught postgraduate students who envisage undertaking primary research. This rating is judged where the nature of the research potentially raises no significant ethical issue and does not fall within the categories indicating mandatory referral to the Research Governance and Ethics Committee (RGEC). Applications from undergraduate and taught postgraduate students that result in a 'standard risk' rating in Sussex Direct will be directed first to their Supervisor for authorisation and then to a designated BSMS SREO for ethical review.

ii) High Risk is judged where the proposed research engages more than one mandatory referral category in the ethical review risk assessment checklist in Sussex Direct requiring automatic referral to the Research Governance and Ethics Committee for ethical review.

The pathways for Standard and High Risk ethical review are graphically represented in the figure below:

Risk	UG Student / Postgraduate Taught	PGR (Including PGT MSc Global Health students conducting fieldwork overseas)	Faculty
Standard	Supervisor reviews and authorises the Application Form in Sussex Direct. Application progresses to SREO review. SREO formally signs the project off.	Not Applicable	Not Applicable
High	RGEC reviews the Application Form and formally signs the project off.	RGEC reviews the Application Form and formally signs the project off.	RGEC reviews the Application Form and formally signs the project off.

Risk Assessment Filter Checklist

The assessment of the risk level of a project is supported by a dynamic online ethics application system that is accessed within the University’s intranet, Sussex Direct.

The ethical review application system is accessed via logging into **Sussex Direct** via the University of Sussex website (direct.sussex.ac.uk):

US
UNIVERSITY OF SUSSEX

A-Z | Contact us | Email | External website
 Site People

Students Staff Schools & services **Sussex Direct** Canvas

Welcome to Sussex Direct

You will need your Information Technology Services (ITS) username and password in order to log in:


Username:

Password: [Reset your Password](#)

Now click here: [Login to Sussex Direct](#)

If you have forgotten your password but have previously registered a personal email address and/or mobile telephone number in Sussex Direct, you can use the link above to reset your password. Otherwise please contact the IT Service desk in Shawcross for assistance.

Remember, NEVER tell anyone else your password! If you receive official-looking email asking you to confirm your Sussex Direct password, it is a fake, and should be reported to itservicedesk@sussex.ac.uk.



Once logged on, ‘Research’ is select in the list of sub-headings, then ‘Ethical reviews’ from the drop down list.

The online ethical review application form is selected for applying for ethical review to the BSMS Research Governance and Ethics Committee (RGEC), or BSMS School Research Ethics Officer.

The following questions appear forming an in-built risk assessment checklist designed to identify undergraduate and postgraduate taught student projects which are judged to pose minimal risks and are eligible for ‘standard’ risk review.

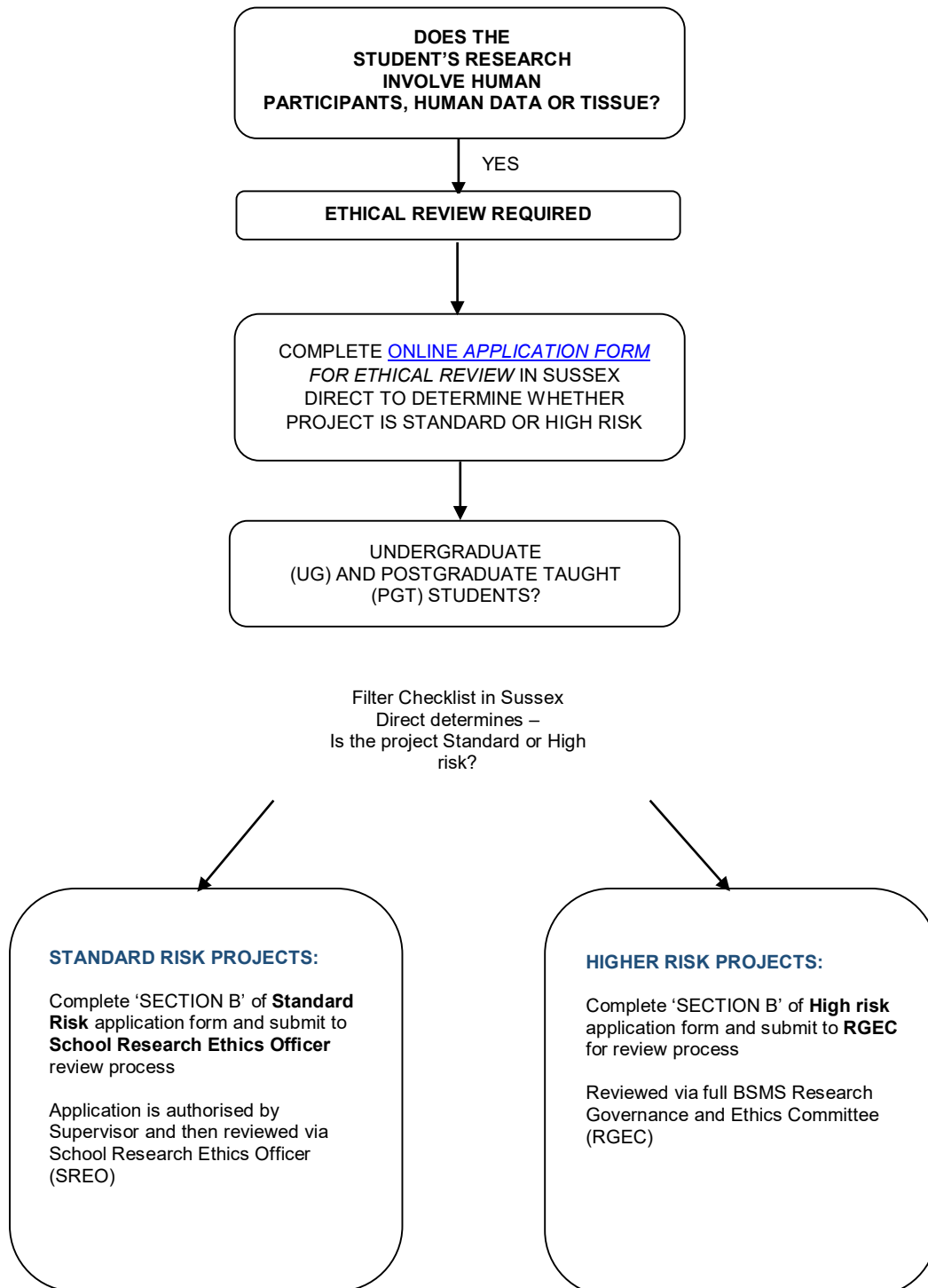
In completing the Checklist, the student is asked to reflect on the common types of ethical issues that can increase risk levels in research.

Risk Assessment Checklist		
C1.	Will your study involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position (e.g. young people under 18, individuals with learning difficulties, or people with conditions associated with social stigma including mental health concerns, people in care facilities, including prisons, or over-researched groups)?	Y/N
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, mining of data from social media sources), and/or will deception of any sort be used. Will access to non-anonymised personal data previously taken for another purpose be utilised?	Y/N

C3.	Will the study include groups where permission is normally required for access to its members, for e.g. non-NHS support groups and organisations supporting public health based in the community, traditional communities (at home and overseas), school pupils, or an overused population such as Medical Students?	Y/N
C4.	Will it be impossible to ensure that identities or information cannot be linked back to individual participants in any way (including after anonymisation) in the final writing up of the research?	Y/N
C5.	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 participants? Will the study involve psychological interventions or processes outside of standard practice and will any invasive, significantly burdensome, or potentially harmful procedures or activities of any kind be undertaken?	Y/N
C6.	Will the study involve discussion of sensitive topics (e.g. health status, sexual activity, drug use, ethnicity, political behavior, potentially illegal activities), or those where researchers may have a duty to report (e.g. safeguarding concerns; possible fraud; terrorisms; money laundering)?	Y/N
C7.	Will your study involve staff or students of the University of Sussex travelling to any country with a current Foreign and Commonwealth (FCO) warning against travel?	Y/N
C8.	Will your study involve visiting participants in their home, public spaces or a similarly uncontrolled environment, unaccompanied?	Y/N
C9.	Will your study involve the use of chemicals which could expose members of the University to carcinogens, mutagens, sensitizers, toxins, flammables/explosives, risk of asphyxiation? Or, any Chemical Weapon Precursors or Schedule 5 toxins?	Y/N
C10.	Will your study involve the use of radioactive materials, X-rays (i.e. CT scanner or similar imaging equipment), Class 3 or 4 lasers, or strong magnetic fields?	Y/N
C11.	Will your study involve the use of any scheduled drug/s, drug precursors or the synthesis of novel psychoactive substances? Are alcoholic drinks, drugs, placebos or other substances (such as food substances or vitamins) to be administered to the study participants?	Y/N
C12.	Will your study involve work with: An identifiable risk of contracting a communicable disease from study participants? Biological agents in group 2, 3 or 4? Creation/use of genetically modified organisms. Storage and/or analysis of human biological tissue whether or not this will be carried out under the University of Sussex HTA license?	Y/N
C13.	Is there a possibility that research activity might uncover unexpected and possibly clinically relevant findings? For e.g. MRI scanning projects, taking bloods, cheek swabs that may or may not have ethical consequences.	Y/N
C14.	Does your study pose any other ethical, safety, regulatory or reputational risk not covered above?	Y/N
C15.	TAUGHT STUDENTS ONLY If you have answered Yes to ANY of the above questions, your application may be considered as HIGH risk. If, however, you wish to make a case that your application should be considered as STANDARD risk please enter the reasons here. Researchers should note that the SREO or RGEC may decide NOT to agree with the case that you have made.	Y/N

- **Standard Risk Projects:** If the student is able to answer 'No' to all fifteen statements in the checklist of the BSMS online ethical review application form, then the project is assumed to be standard risk. The student will then be presented with SECTION B of the Standard risk application form for completion. Once the application form is completed, it should be submitted along with supporting documents for review: UG and PGT students submit their application for review from their School Research Ethics Officer review process (described on page 15), and Staff and PGR students apply to the Research Governance and Ethics Committee for review, which remains unchanged.
- **Higher Risk Projects:** Those projects where the student has been unable to answer 'No' to one or more statements in Section A are regarded as higher risk projects, unless a strong case is made. In these cases, the student will then be presented with SECTION B of the High risk application form for completion. Once the application form is completed, it should be submitted along with supporting documents for review by RGEC at a scheduled meeting (see BSMS website for applicant information <https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/index.aspx>).

Standard Operating Procedure (SOP) Risk Flowchart



Responsibilities for Ethical Review, Oversight of Procedures and Reporting at BSMS

The responsibilities for ethical review of research and for ensuring that ethical and governance policies and guidelines are adhered to will be jointly shared at BSMS. How this is practically expected to operate within the School is set out below:

BSMS Research Governance and Ethics Committee (RGEC)

- Maintains Research Ethics Code and Procedures and supporting guidance
- Reviews all BSMS Staff and PGR ethics applications
- Reviews all BSMS PGT ethics applications for research conducted overseas
- Reviews any items referred from the BSMS School Research Ethics Officers (SREOs)
- To monitor learning needs in relation to training and development for Staff and PGR researchers
- To provide advice to PIs, research active staff and support staff and research teams, PGRs and their Supervisors, on ethical issues in relation to Staff and PGR student research proposals
- To monitor the operation of RGEC review and provide regular reports to the University Research Ethics and Integrity Committee on High Risk Staff and PGR student research

BSMS Supervisors and School Research Ethics Officers (SREOs)

- Manage local practice for reviewing ethics applications from Undergraduate and Postgraduate Taught students undertaking dissertation projects
- Reviews all UG and Postgraduate Taught ethics applications identified as posing minimal risks
- To monitor learning needs in relation to training and development for UG and PGT researchers and make recommendations to the Research Governance and Ethics Committee and the University Research Ethics and Integrity Committee
- To provide advice to UG and PGT supervisory teams and individual UG and PGT students on ethical issues
- To monitor the operation of SREO review and provide regular reports to the University Research Ethics and Integrity Committee on Standard Risk Undergraduate and Postgraduate Taught research

Individual Roles and Responsibilities for Ethical Review at BSMS

The following outlines the procedures for student applicants, their supervisors and School Research Ethics Officers.

1. BSMS Undergraduate (UG) / Postgraduate Taught Student (PGT) Students:

The [University's Research Governance Standard Operating Procedures](#) requires students, under the guidance of a supervisor, to apply for written, auditable ethical approval via the online ethical review application process provided in Sussex Direct.

It is the student's responsibility to submit applications in a timely and appropriate format. Ethics applications should outline a strategy to respond to anticipated ethical complexities and risks.

As a mandatory requirement, ethics applications from Undergraduate / Postgraduate students must be reviewed and approved by their Supervisor and a School Research Ethics Officer (SREO).

For Undergraduate / Postgraduate students undertaking primary research for their IRP or dissertation project, it is the student's responsibility to:

- 1.1. Complete, together with their supervisor, the online Application Form for Ethical Review via the BSMS Research Governance and Ethics Committee in [Sussex Direct](#).
- 1.2. Ensure their submission is accompanied by supporting study documents appropriate to the research and required for ethical review. In virtually all instances this is expected to include a Participant Information Sheet and Consent Form. Research tools, such as validated questionnaires and student developed online surveys should also be included, in addition to all recruitment materials. (The [Applicant Checklist Tool](#) offers detailed guidance on the mandatory and other essential documents required for specific categories of research project). Participant Information Sheet and Consent Form templates can be located on the BSMS Governance and Ethics website pages: <https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/index.aspx>.
- 1.3. Where students are undertaking qualitative research, also include as part of their submission, certificates of mandatory attendance for modules in conducting qualitative interviews and training in receiving informed consent from participants.
- 1.4. Transfer the application in the online ethical review application system to their Supervisor for pre-review and authorisation. (Supervisors must therefore arrange their access to Sussex Direct well in advance of an ethics submission – please consult the [Applicant FAQ](#) for further advice and guidance).
- 1.5. Ensure all supporting documents are version controlled. They should include in the document footer the document title, a version number and date, to guarantee that only finalised versions of study documents are issued to participants upon confirmation of ethical approval.

- 1.6. The student will be required confirm and sign the Declaration statement on the acceptance of the code of practice at the end of the online Ethics Application Form in Sussex Direct. The declaration page in Sussex Direct sets out key points relating to the study, which the student confirms they understand by submitting the application. The declaration requires confirmation that the information that provided is accurate to the best of the student's knowledge and confirms that the has read the University's Code or Practice for Research and not commence the research until ethical approval has been granted:

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

[Submit to Supervisor for approval](#)

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 my Supervisor (UG & PGT students) or my C-REC Chair (PGR students) 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.
- **FOR STUDENT RESEARCHERS:** I understand my responsibilities to work within a set of safety, ethical and other guidelines as agreed in advance with my supervisor. I also understand that I must comply with the University's regulations and any other applicable code of ethics at all times.

- 1.7. During the ethical review process, provide a covering letter which highlights and itemises any changes which may be subsequently requested to the application form or supporting documents by the School Research Ethics Officer (SREO). This should accompany the re-submission to the SREO to assist reviewers in verifying the changes and confirming approval.
- 1.8. Retain a Certificate of Ethical Approval for their project, which is formally generated and recorded in an auditable format, within the online ethical review application system for each project. They will be asked to include it with their dissertation project, usually in the form of an Appendix.
- 1.9. Check and comply with any requirements, such as Gatekeeper Approval, before proceeding with their work. They are responsible for checking with their Supervisor and complying with such requirements.
- 1.10. Formally apply for approval for any amendments to the approved research project to provide the School with an audit trail for these changes. Amendments are alterations to the study procedures or documentation that do not significantly change its objectives. Examples of Amendments are non-substantial changes to either the study design or methodology, participant recruitment process or population, extension of the study end date, or changes to any documentation previously reviewed and approved. The application process requires completion and submission of a Request for Amendment Form, explaining what the amendment entails and why it is needed. The Form is submitted with new versions of any documentation that has been changed to the online ethical review application system in Sussex Direct.

2. Research Supervisors

The University's [Research Governance Standard Operating Procedures](#) states that Research Supervisors "have a responsibility to ensure that the highest standards of research integrity, governance and ethical practice are met, that research activities are undertaken in compliance with the Code of Practice for Research by staff and students under their supervision, and to seek to foster a culture of openness and professional integrity in research practice."

Most undergraduate and taught postgraduate students are applying for ethical approval for an Individual Research project (IRP) or postgraduate dissertation project. For Supervisors of IRP and dissertation students, involvement and participation in the ethical application process is essential.

It is the Supervisor's responsibility to:

- 2.1. Communicate the importance of ethics in research to their students and inculcate an attitude of respect for ethical principles in research.
- 2.2. Support development of a robust application, with focus on risk and risk minimisation. Discuss research ethics with the student relevant to their particular study and help them complete the application form. (A [Supervisor Checklist Tool](#) offers detailed guidance to assist Supervisors of students in developing the essential elements of a robust ethics application).
- 2.3. When making an application, ensure that the following points are considered:
 - How the welfare of participants and researchers will be ensured so that no harm is done either to them, or to the reputation of the University of Sussex and its partners.
 - How confidentiality will be ensured and if appropriate, anonymity.
 - How can voluntary participation be ensured?
 - Making sure consent is informed and documented (usually in writing).
 - How long will the data be retained for and how will it be stored securely.
 - Is it appropriate to destroy the data and if so, when?
- 2.4. Specific responsibilities are assigned to Supervisors regarding the management of the research and the resulting data:
 - 2.4.1. For student research, the Supervisor is the custodian of the research data and is responsible for its management, including determining security and access rights. It is particularly important that access to personal data is strictly confined only to those granted access with prior consent. Please indicate whether any sharing of personal data will be required at any stage (i.e. within the research team) (and ensure that all such details are reflected in documents or participant communications).
 - 2.4.2. Data storage arrangements must reflect the sensitivity of the data. Appropriate levels of storage security must therefore be established by the Supervisor and maintained by the research team. What steps will be taken by the Supervisor to take full responsibility, throughout the duration of the study, for ensuring appropriate storage and security of information (including research data, consent forms and administrative records)?
 - 2.4.3. The Supervisor must determine and make arrangements for the retention of research data for appropriate periods following the conclusion of the project in line with University requirements:
<http://www.sussex.ac.uk/ogs/policies/information/recordsmanagementguidance>.

- 2.4.4. Outline arrangements for how any personal data will be destroyed on completion of the research process (all such details should be reflected in documents or communications for participants). Usually personal data will only be retained strictly as is necessary i.e. no longer than is necessary for the purpose for which it is being processed.
- 2.4.5. Ensure online survey use a University approved platform, such as Qualtrics or JISC Online.
- 2.5. Be responsible for identifying training needs and delivering training as appropriate and may consult the Chair of the Research Ethics Committee on ethics training.
- 2.6. Discipline-based training in research ethics and integrity must form part of support, training and/or taught sessions for taught postgraduate and undergraduate researchers.
- 2.7. The supervisor will be required confirm and sign the Supervisor's Declaration statement on the acceptance of the Code of Practice for Research at the end of the online Ethics Application Form in Sussex Direct and authorise the application for SREO review.

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

[Submit to Supervisor for approval](#)

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 my Supervisor (UG & PGT students) or my C-REC Chair (PGR students) 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.
- **FOR STUDENT RESEARCHERS:** I understand my responsibilities to work within a set of safety, ethical and other guidelines as agreed in advance with my supervisor. I also understand that I must comply with the University's regulations and any other applicable code of ethics at all times.

Supervisors must confirm in Sussex Direct, if the study is 'standard risk' or high risk' referring to the Risk Assessment Checklist (a copy is outlined on page 6 of this document). The application will be returned to the Supervisor if any sections of the Application Form are not completed, or if the application does not include the appropriate supporting documentation (please refer to the [Supervisor Checklist Tool](#) for a comprehensive list of mandatory documents).

- 2.8. Supervisors should then submit the application on behalf of the student to the School Research Ethics Officer, in Sussex Direct, thus transferring the application to the BSMS SREO for ethical review.
- 2.9. Supervisors are expected to guide students during the conduct of the approved project, including monitoring the student's research activities and ensuring that protocols and strategies set out in the approved ethics application are followed by the student.

- 2.10. Supervisors should ensure that the student formally applies for approval for any amendments to the research project once it has been approved to provide the School with an audit trail for these changes. Amendments are alterations to the study procedures or documentation that do not significantly change its objectives. Examples of Amendments are non-substantial changes to either the study design or methodology, participant recruitment process or population, extension of the study end date, or changes to any documentation previously reviewed and approved. The application process requires completion and submission of a Request for Amendment Form, explaining what the amendment entails and why it is needed. The Form is submitted with new versions of any documentation that has been changed to the online ethical review application system in Sussex Direct.

3. School Research Ethics Officers (SREOs)

Each Head of School will normally appoint a School Research Ethics Officer, with specific responsibility for the management of ethical review processes for Undergraduate (UG) and Postgraduate Taught (PGT) students.

The main function of the School Research Ethics Officer role will be to provide a form of independent review of UG and PGT projects, and to ensure that ethical review decisions within the School are appropriately recorded and reported to the School's Cluster-based Research Ethics Committee (C-REC), as required by the University Research Governance Committee (URGC). This role will also include some provision of guidance and awareness-raising amongst colleagues and students as appropriate.

Key Responsibilities:

- 3.1. Being the second ('independent') reviewer on UG and PGT projects, after the project has been pre-reviewed by the student's supervisor;
- 3.2. Reviewing all applications submitted by a supervisor on behalf of their student within 10 working days of receipt of the application for SREO review;
- 3.3. Notifying the applicant via an automated email of receipt of the application and start of the clock for review;
- 3.4. Where changes to the application are required, returning the application to the Supervisor in Sussex Direct and, in parallel, following up with a succinct written summary of the feedback, recommendations and changes outlined in either letter or email;
- 3.5. Providing final sign off for those projects which have addressed ethical issues appropriately in the proposal;
- 3.6. Discussing with Supervisor, or Supervisor and student, those projects which have not satisfactorily addressed ethical issues;
- 3.7. Making final recommendation, in discussion with student's Supervisor, for referral to review by RGEC for those projects which are not 'standard risk';
- 3.8. Ensuring outcomes of ethical review are formally recorded in an auditable format, within the online ethical review application system in Sussex Direct. Possible outcomes are:
 - **Approved** for applications where no further changes to the application form or study documentation are required.
 - **Conditionally Approved** the study is approved subject to very minor amendments to satisfaction of the School Research Ethics Officer. It should be noted that this decision should only be recorded where the SREO does not require submission of further evidence such as amended documents to satisfy approval. Since, once this decision is applied in Sussex Direct it will not be possible for the applicant to edit/amend the application further.
 - **Returned for Revision** this outcome is recorded for studies which are either Conditionally (minor amendments) or Provisionally (substantial amendments)

Approved and require the applicant to edit/amend the application in Sussex Direct and re-submit revised documents to the School Research Ethics Officer.

- **Not Approved** – for studies which are not approved. This decision should only be recorded where the SREO feels resubmission for review via the School Research Ethics Officer is not appropriate, as once recorded, it will not be possible for the applicant to edit/amend the application further.
- 3.9. Generating a Certificate of Approval for each approved project, which is automatically sent by the system to the reviewer and student's University of Sussex email account. However, for BSMS students the SREO must manually forward the Certificate on to ensure the applicant is informed of the outcome, as it is anticipated students do not regularly access University of Sussex email accounts.
 - 3.10. Reviewing any amendments to approved research projects to provide the School with an audit trail for these changes. Amendments are alterations to the study procedures or documentation that do not significantly change its objectives. Examples of Amendments are non-substantial changes to either the study design or methodology, participant recruitment process or population, extension of the study end date, or changes to any documentation previously reviewed and approved. The application process requires completion and submission of a Request for Amendment Form, explaining what the amendment entails and why it is needed. The Form is submitted with new versions of any documentation that has been changed to the online ethical review application system in Sussex Direct.
 - 3.11. More generally: Ensuring that policies and guidelines developed for UG and PGT students by the University in relation to research conduct are being followed in the School;
 - 3.12. Ensuring that appropriate records of applications, practices and decisions are made and kept in Sussex Direct;
 - 3.13. Continuing to raise awareness of ethical issues and University procedures and specific requirements for ethical review for UG and PGT projects, including contributions to training and taught programmes where appropriate;
 - 3.14. Reporting, where appropriate, via the School's Research Integrity, Ethics and Governance Administrator, on any training or development needs related to ethical issues and approval;
 - 3.15. Monitoring and reporting on an annual basis on behalf of the School to the Research Governance and Ethics Committee;
 - 3.16. Providing ad hoc advice and guidance to supervisors, course tutors and UG/PGT students on research ethics applications;
 - 3.17. Ongoing contribution to development, monitoring and review of RG procedures, processes;

- 3.18. In liaison with Research Integrity, Ethics and Governance Administrator, lead development and management of cross school activities and training to promote research ethics culture within and across the school, and university wide;
- 3.19. Producing and ensuring dissemination of school specific guidance for supervisors and students on research ethics review processes and procedures.
- 3.20. Attending (optional or as necessary) at RGEN meetings.

Expectations for Standard Risk Applications

Key Ethical Principles

In all contexts, ethical review must involve a written, auditable application and approval process via Sussex Direct.

Those with supervisory responsibility for researchers (whether undergraduate or postgraduate) have a duty to provide adequate, project-specific support and guidance in relation to research ethics and integrity. Student researchers should be supported to consider how the following principles directly apply to their specific research projects.

Informed consent

It is a default expectation that research with human participants must be based on the principle of meaningful, freely-given informed consent.

Furthermore, following recent changes to data protection legislation (introduced by the [General Data Protection Regulation 2018](#)), participants must formally 'opt in' to any research activity which involves the collection of 'personal data'.

Developing processes and materials to facilitate informed consent

Researchers must give careful consideration to the processes and materials they will use to inform potential participants about their project. It is the researcher's responsibility to provide clear, non-coercive information about their project. They must develop a strategy to explain, as fully as is reasonable and in terms meaningful to the potential participants, key information including:

- the aims and nature of the research;
- who is undertaking the research;
- why the research is being undertaken and why they have been invited to participate;
- how data will be recorded (and options in relation to the recording method);
- what participation in the project will involve, and its duration;
- possible risks and benefits of participation;
- participants' rights to withdraw from research activities;
- participants' rights in relation to confidentiality (including any reassurances or responsibilities relating to the complexities of maintaining confidentiality)
- how data will be anonymised, stored, managed, archived, shared and disseminated, reused;
- participants' rights to remove data within a stated limited time after their participation (it is recommended that this should be a fixed period (e.g. one month) and not 'at any time');
- if appropriate – how findings will be fed back to participants;
- information about confidentiality and anonymity, including situations in which confidentiality may be broken;
- researcher contacts for further information about the study or to lodge a complaint

Potential participants must be provided with sufficient information to make an informed decision about whether or not they wish to participate. In the ethics application, researchers must provide a detailed account of this strategy in the accompanying participant facing

materials. Typically, this may involve the use of a participant information sheet: a sample template is available on the BSMS website here: [\(hyperlink\)](#)

Information sheets should be accessible and user-friendly for participants, and it may be necessary to prepare a range of processes and materials to communicate with diverse groups of potential participants. It is recognised that a written participant information sheet may not be appropriate for all research settings or participants. In such cases, researchers must explain how they will use equivalent processes or materials to communicate information about the project, and provide a rationale for this alternative approach.

Seeking consent from ‘gatekeepers’

If appropriate, the ethics application must also detail how researchers will seek consent from any organisational or institutional ‘gatekeepers’ prior to engagement with potential research participants. Gatekeepers should be provided with transparent, detailed information about the project (including a clear statement outlining the extent to which the organisation/institution will be anonymised, and making clear that personal data and identifiable responses from individuals will not be disclosed to the gatekeeper). Typically, this may involve the use of an introductory letter/email plus information sheet. In the online application form, the student applicant should also explain how they will communicate with the ‘gatekeepers’ relevant to their project.

Consent Forms

Researchers must demonstrate how they will obtain clear, auditable evidence that participants have given informed consent to take part in the project. Typically, this will involve provision of a formal consent form to be signed by each participant: a sample template is available on the BSMS website here: [\(hyperlink\)](#). The consent form should be accessible and user-friendly for participants, and should allow participants to indicate their understanding of, and consent to, all aspects of the project. It may be necessary to prepare a range of consent forms for diverse participants. For some research activities (e.g. where data collection is solely through online survey) it may be appropriate and practical to incorporate the consent form into research tools (e.g. embedded as the first page of an online survey). It is recognised that written consent forms may not be appropriate for all research scenarios or participants. In such cases, researchers must explain how they will collect evidence of consent, and provide a rationale for this alternative approach.

Consent as an ongoing process

Researchers should think carefully about their interactions with research participants, and be aware that informed consent should be an ongoing process – not just a one-off event of signing a consent form. Researchers should regularly check that participants are comfortable and happy to continue, and should ensure that participants understand that they can stop or pause their participation in any research activity at any time. They should also ensure that participants feel able to do this, and have a process through which they can withdraw from data collection without embarrassment.

Consent and power relations/inequalities

The power imbalance between researcher and participants should be carefully considered. Care should be taken to ensure that the participants do not feel pressured or obliged to take part in research activities. This is a particularly important consideration when research takes place in hierarchical, institutional or organisational contexts (e.g. schools, institutions or businesses), especially in scenarios where the researcher has a prior role, status or seniority.

In such situations, the ethics application must give a clear summary of how potential power imbalances will be mitigated to ensure that participants feel able to freely opt-in or out of research activities.

Incentives for participation

In some cases, it may be appropriate to offer incentives for participation. In such cases, incentives must be offered in a way which is fair and commensurate with the University of Sussex guidelines.

Informed consent and internet- or social media- based research

Particular ethical complexities are posed by research that involves engagement with participants via social media, the use of apps, or the analysis or 'mining' of material posted online via blogs, social media platforms, chat rooms, discussion boards, instant messaging services etc. In such research, researchers must take care to ensure that consent processes are appropriate and proportionate. Researchers planning such research must detail how consent will be handled. Researchers are directed to:

- British Psychological Society (2017) Ethics Guidelines for Internet-mediated Research <https://www.bps.org.uk/sites/beta.bps.org.uk/files/Policy%20%20Files/Ethics%20Guidelines%20for%20Internetmediated%20Research%20%282017%29.pdf>
- Townsend, L. and Wallace, C. (2016) Social Media Research: a Guide to Ethics https://www.gla.ac.uk/media/media_487729_en.pdf
- University of Oxford (2016) Internet-based Research: Best Practice Guidance http://www.admin.ox.ac.uk/media/global/wwwadminoxacuk/localsites/curec/documents/BPG_06_Internet-Based_Research.pdf

Permissions for reproduction of photographs, footage, recordings or performances

Specific permissions should be obtained in instances where research involves reproduction or dissemination of:

- photographs, footage or recordings of identifiable individuals;
- recordings or footage of events involving – and/or where intellectual property is held by anyone other than the researcher.

Confidentiality

It is a default expectation that research with human participants must be based on the principles of:

- Confidentiality – i.e. an assurance that information supplied by a research participant will only be reported, shared, disseminated, stored and (re)used with the participant's consent, and in the terms agreed via the consent form.
- Anonymity – i.e. undertaking to ensure that research participants cannot be identified or traced from research data and outputs (e.g. redacting identifying details from datasets, creating pseudonyms for people and places, storing anonymising data separately from identifying information, and taking care in the presentation of research findings to protect individuals' identities).

Developing processes and materials in relation to confidentiality

Researchers must give very careful consideration to the strategies through which they will maintain confidentiality and ensure anonymisation of research data and outputs. It is not sufficient to assert that research will be 'confidential' and 'anonymous'. In the ethics application, student researchers must provide a clear account of how confidentiality and anonymity will be assured for their project.

It is important that participant information sheets provide clear information about how data will be reported, shared, disseminated, stored and (re)used. Participant information sheets should clearly outline the terms on which data will be used, and the extent to which anonymity can be assured. It is not sufficient to assert that research will be 'fully anonymous' or 'strictly confidential': instead, participant information sheets should clearly and concisely indicate practical steps that will be taken to anonymise data and protect confidentiality. Participants should be given a clear, realistic sense of the likelihood of being identified from research data.

Researchers should take care to consider how confidentiality and anonymisation might be complicated in their particular research settings and contexts. This is especially important in:

- research settings where there is a significant chance that individuals could be identified in the presentation of findings (e.g. in small, distinctive organisations or communities);
- research methods in public or communal spaces (where research conversations may be overheard) or involving participants talking with others (e.g. focus groups, workshops or community meetings) (i.e. how will others be made aware of the importance of preserving confidentiality?);
- scenarios where the researcher has a past or present role – and/or strong existing relationships – within their research context (e.g. as a manager or leader within an organisation or community) (i.e. how will the researcher take care to avoid disclosures of research findings via their organisational or community networks?);
- situations where expressing particular opinions may endanger participants' safety, wellbeing or reputation (e.g. in research where participants may speak out against powerful political or corporate interests, act as 'whistleblowers' within hierarchical organisational settings, or express counter-cultural views which place them at risk).

In such cases, researchers must demonstrate how they will take additional measures to safeguard the confidentiality of research participants. The ethics application must provide a detailed account of any specific complexities posed by their research context and their proposed strategies to mitigate risks to confidentiality in relation to them. Participants should be clearly informed, in advance, of any possibility that they could be identified from the information they have provided, and given explicit details about how and where this information will be used.

Transcribers, translators and other third parties If research projects involve transcribers, translators or additional researchers: Participants should be clearly informed, in advance, of the involvement of transcribers, translators or additional researchers in the research project.