UNIVERSITY OF SUSSEX

GUIDELINES FOR COMPLETING THE ONLINE APPLICATION FORM FOR ETHICAL REVIEW FOR RESEARCH WITH HUMAN PARTICIPANTS

Please read through these guidelines carefully before completing your application for ethical review. Help text is also provided within the online application system found on Sussex Direct[1].

Further queries:

STAFF

Each School of Study has a School Research Ethics Officer (SREO) who has a responsibility to review low risk undergraduate and postgraduate taught ethical review applications. The SREO is also a general contact point for research ethics for staff. Most Schools will also have staff who sit one of the Cross Schools Research Ethics Committees (C-RECs) who can give ethical advice:

- Social Sciences & Arts Cross-Schools Research Ethics Committee (SSARTS)[2]
- Sciences & Technology Cross-Schools Research Ethics Committee (SCITEC)[3]
- Brighton and Sussex Medical School Research Governance Committee (BSMS RGEC)[4]

(links to specific pages on each C-REC (administrator contact details) including members and lists of SREOs)

STUDENTS

In the first instance, students should contact their allocated research supervisor. In the absence of a supervisor they should contact their SREO.

Staff or students who are not aware of their 'local' ethics contacts should speak to their School Office.

Research Governance Officer

The University Research Governance Officer (rgoffice@sussex.ac.uk) can be contacted for all general ethics queries.

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

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

[2] Global Studies; Business; Education & Social Work; Law, Politics & Sociology; English; History, Art History & Philosophy; Media, Film & Music - http://www.sussex.ac.uk/staff/research/governance/contacts_sreos_committees/ssarts

[3] Life Sciences, Psychology, Engineering & Informatics, Mathematical & Physical Sciences – http://www.sussex.ac.uk/staff/research/governance/contacts_sreos_committees/scitec

[4] https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/index.aspx

Who should apply for research ethics review?

The University is committed to advancing and safeguarding high quality academic and research governance standards in all its activities. Research undertaken in accordance with recognised research ethical standards is a fundamental principle that is expected of ***all university researchers*** as set out in the ***Code of Practice for Research***.[5]

This guidance document should be read in conjunction with the University's *Research Governance Standard Operating Procedures*[6] .

Research projects 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 University's research governance procedure. In general, this does NOT include accessing archival information, where the participants are deceased and / or the information that you are accessing is entirely anonymised.

It is highly likely that you will need ethical review if you intend your research to involve the following[7];

- Human participants (with or without consent)
- Non-human animal subjects (Please ask your supervisor or the Research Governance Officer how to seek ethical approval for research involving animals)[8]
- If you anticipate that the research project to expose any person, whether or not a participant, to physical or psychological harm
- If you will have access to personal information that allows you to identify individuals or to confidential corporate or company information
- If the research project may present a significant risk to the environment or society
- If there are any ethical issues raised by this research project that in the opinion of the Principal Investigator, Supervisor (if a student) or Researcher require further ethical review

If you are uncertain whether your project requires ethical review, please discuss with your Supervisor (if you are a student), your School Research Ethics Officer (SREO), or contact the Research Governance Office: rgoffice@sussex.ac.uk

The University has an application process aimed at maintaining a consistent and robust approach to ethical review across the University, while still recognising the wide range of research undertaken by staff and students. The standard process for applying for ethical review depends upon whether your research is regarded as low risk or higher risk, and whether you are UG, PGT, PGR student or a staff member.

- **Undergraduate and Postgraduate Taught students**: you should apply through the School application process. However, if your supervisor or the School Research Ethics Officer decides that your proposed research is not low risk (see Section 3 below) and has agreed to you proceeding with your proposal, you should apply to a University Cross-Schools Research Ethics Committee (C-REC) (see below).

- **Staff and Postgraduate Research students**: you should apply to the most appropriate Cross-Schools Research Ethics Committee (C-REC). This would normally

[5] http://www.sussex.ac.uk/staff/research/governance/apply
[6] http://www.sussex.ac.uk/staff/research/governance/apply
[7] http://www.sussex.ac.uk/staff/research/governance/checklist
[8] See http://www.sussex.ac.uk/staff/research/governance/erp_overview/animals for more information.

be the C-REC that covers the School that the Principal Investigator (PI) is based in; however, in some cases the topic of the research may merit the application going to a different C-REC.

When should I apply for Sponsorship (prior to NHS Research Ethics Committee review)

Research undertaken within the NHS falls under the UK Policy Framework for Health and Social Care Research[9]

You must submit your project to an NHS Research Ethics Committee (NHS REC) if it involves any of the following:

- patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions;
- individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
- access to data, organs or other bodily material of past and present NHS patients;
- foetal material and IVF involving NHS patients;
- collecting and/or researching human tissues or materials from NHS patients
- the recently dead in NHS premises;
- research involving incompetent adults (16 years and over) is governed by sections 30-33 of the Mental Capacity Act (MCA) 2005. If your research involves incompetent adult participants (even if it began before the MCA came into force), you must obtain ethical approval from an NHS REC.
- Social Care research that is funded by the Department of Health is reviewed by a specialised Social Care Research Ethics Committee (SCREC). More information on Social Care research is available here.

You will need to apply to for **University Sponsorship**[10] before the project is submitted to the NHS REC. All applications for Sponsorship[11] are reviewed by the Sponsorship Sub-Committee that meets approximately once every six weeks.

Audits and Service Evaluations

NHS ethics approval is **not** required from an NHS REC for an audit or service evaluation[12]. The HRA has produced a decision tool (***Is my study research?)***[13] to assist I understanding whether a study can be defined as research as defined by the UK Policy Framework for Health and Social Care Research.

Please contact the Research Governance Officer for any queries: researchsponsorship@sussex.ac.uk.

[9] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
[10] http://www.sussex.ac.uk/staff/research/governance/sponsorship
[11] http://www.sussex.ac.uk/staff/research/governance/sponsorship/applysponsorship
[12] http://www.hra-decisiontools.org.uk/research/docs/definingresearchtable_oct2017-1.pdf
[13] http://www.hra-decisiontools.org.uk/research/

General guidelines for completing the online application form

PG, PGT and PGR Students - Before you start:

It is very important that you discuss the ethical dimensions of your project with your supervisor at the earliest opportunity. Alternatively, you can discuss this with your SREO or with the Research Governance Officer.

The application form contains some prompt questions to help you to assess whether your project is 'low risk' and to ensure this is the appropriate pathway for you to apply for ethical review. If your research topic or participant group is sensitive (e.g. prisoners, people under 18, adults with learning disabilities) or the research is potentially hazardous to either you or the participants, then you will need to apply for ethical review through a C-REC. The responsibility rests with the supervisor (and the School Research Ethics Officer) to identify which projects are not 'low-risk'.

All researchers - Before you start:

The online Ethical Review Form details your proposed work and the steps you will take to assure ethical responsibility.

- **Undertaking research without ethical approval will be considered to be a breach of the University's *Code of Practice for Research*[14] and therefore may be liable to be categorised as misconduct.**
- **You should note that if you undertake research *without* ethical approval the University takes no responsibility for the study (financial or otherwise).**
- **Researchers must ensure that they leave adequate time for review and any required revisions to the submitted protocol. If you are planning to conduct the research overseas please ensure that you have ethical approval *before* you travel or you risk your project being delayed.**
- **Each C-REC has different reviewing arrangements with implications for timescales in receiving responses to applications. Researchers should ensure that they understand how these could have implications for starting research**

There are a number of fundamental principles that you will need to consider in your research design and conduct. In general, it is important to protect the rights and welfare of participants and to minimise any risk of physical and mental discomfort, harm or danger to yourself and others, which could arise from the application of research procedures.

This overarching principle encompasses a range of related ethical issues that arise with regard to:

- the collection of data and informed consent,
- the rights of participants to withdraw from the research without fear or penalty,
- doing everything possible to ensure confidentiality and anonymity for participants[15], and associated practices for the storage and access to data (that is guarding privileged information),

[14] http://www.sussex.ac.uk/staff/research/governance/apply
[15] When data is not anonymised, clear consent must be obtained from participants in advance.

- providing participants with adequate information concerning the research, its outcomes and how it will be used,
- the need to protect researchers from unintended constraints or pressure arising through misuse of research ethics provisions by powerful research subjects.

While it is essential that all researchers intending to undertake work that involves human participation detail the steps that they will take to ensure ethical responsibility and obtain approval for their research, the intention of this procedure is not just to assure compliance with a set of regulations. Rather, the intention is to offer a set of principles and advice that will guide research as it proceeds.

Any queries about the application form, or approval procedures in general, should be directed in the first instance to the Research Governance Officer: rgoffice@sussex.ac.uk

FILLING IN THE FORM (SECTION-BY-SECTION)

All applicants need to complete a brief form that will be the application 'header' before selecting the correct route for review -

Project Title
Ideally it should be brief and informative and not simply 'Research dissertation' or similar

Project Start Date*:*
The study should not start until ethical approval has been given and you should take this into account when choosing a start date for your project..

Project End Date*:*
Please provide the date when you plan to submit the finished project, not the date that you submitted the application for ethical approval. Approval will be granted for a specific length of time, but if the project is not completed by this point an extension to approval should be sought (this does not necessitate the re-submission of a full application and can normally be done by Chair's action, unless there are substantial changes to the research design).

External Funding in Place*:*
Has funding already been approved for your project? If so please tick this box.

External Collaborators:
Will your project involve collaborators from outside the University of Sussex?
If you tick this box, please ensure you mention in the following Project Description section, who the outside collaborators are, and what role they will have in the project.

Funder/Project Title:
If you have applied for funding, you should be able to select the funder and project title from a drop down list.

Name of Funder:
If you have applied for funding but the name of funder is not provided in the Funder/Project Title drop down list, please add the funder name in this box.

Project Description:

The project description should be a clear, easy to read summary that is as jargon free as possible. It provides an overview of the whole of your research study that readers can understand the first time they read it. Please see INVOLVE (http://www.invo.org.uk/) for further guidance on how to achieve this. Please ensure that you clearly outline the parts of your research design which involve human participants. This should include a description of what you will be asking participants to do as part of your project and your methods for gathering information / data (e.g. interviews, focus groups, etc.)

Copy:

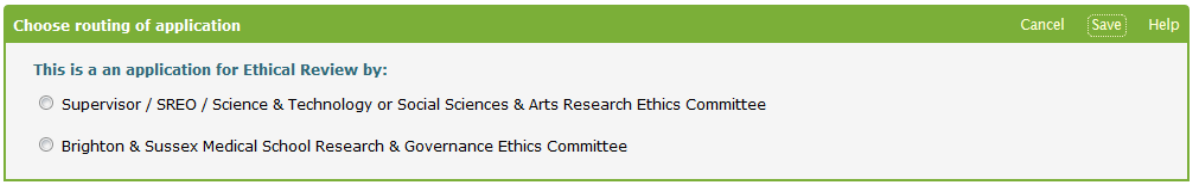
This function allows you to make a copy of a previously submitted ethics application form. It can be used for the following:

- to apply for an extension of the ethics approval for a project;
- to submit a substantial amendment due to a change in research method;
- to include additional research activity which requires ethical approval;
- to submit a new project for ethical review that has similar content to a previously submitted application.

General guidance about ethical review processes can be found at http://www.sussex.ac.uk/staff/research/governance

Once complete you will need to select 'Save'

Choose routing of application



Applicants should note that the Medical School Research & Governance Ethics Committee (BSMS RGEC) uses a different form from other university C-RECs. *All other applications should be to* ***'Supervisor/ SREO/ Science & Technology or Social Sciences & Arts Research Ethics Committee'***

WARNING:
Only applications to the BSMS RGEC should make use of the second option. Applications incorrectly routed to BSMS RGEC cannot be transferred and will require that a new application is completed with the correct routing.

Once the appropriate option has been selected, 'Save' must be selected.

Section A: CHECKLIST

This questions in this checklist will help determine whether your project is a low or high risk project.

- If you answer 'NO' to all of the questions, your project is considered low risk and you will be provided with SECTION B of the application form to complete.

- If you answer 'YES' to ANY of the questions, your project has some aspects which are considered higher risk, and you will be provided with SECTION C of the application form to complete.

NOTE: If completion of the checklist shows your project is higher risk, this is not a negative reflection on your proposed research design, but you will need to ensure that you provide enough information to explain how you will mitigate those aspects of your study which are higher risk. SECTION C of the form is designed to help you identify the specific areas that you need to consider in applying for ethical review of a higher risk project.

CHECKLIST (Is Your Project Low or High Risk?)	**YES**	**NO**
A1. Will your study involve participants who are particularly vulnerable or unable to give informed consent or in a dependent position (e.g. people under 18, people with learning difficulties, over-researched groups or people in care facilities)?		
A fundamental principle of ethical research is the expectation that participants are able to give consent after fully understanding possible risks, inconvenience or the possibility of any harm. Great care is needed in ensuring consent from a participant regarded as 'vulnerable' is clearly informed. In some instances, achieving this may need the assistance of a parent, guardian or carer.		
A.2 Will participants be required to take part in the study without their consent or knowledge at the time (e.g. covert observation of people in non-public places), and / or will deception of any sort be used? Please refer to the British Psychological Society Code of Ethics and Conduct for further information.[16]		
Disciplines (such as psychology or anthropology) carry out research masking the truth or real intention for undertaking the study. In cases of deception a debrief is always required. The use of 'intentional deceit' or placebos must be justified and accompanied by signposting participants to support if there is possibility distress.		
A.3 Unless specifically and clearly consented (e.g. a media release form), will it be possible to link personal data back to individual participants in any way (this does not include identifying participants from signed consent forms or identity encryption spreadsheets that are stored securely separate from research data)?		
The researcher should strive to maintain participants' confidentiality and anonymity and should not reveal the identity of any participant, nor any information which may lead to their identification, without obtaining explicit prior consent. Researchers should be aware of how a particular configuration of attributes (even when any names have been removed) can frequently identify an individual beyond reasonable doubt; and it is particularly difficult to disguise office-holders, organisations, public agencies, ethnic groups, religious denominations without distorting the data as in a way that may be inaccurate. In instances where the nature of the research does not entail anonymity, appropriate consent should be in place or suitable arrangements and/ or ethically robust processes apply that are made **explicit** to the ethical reviewer.		

[16] https://www.bps.org.uk/news-and-policy/bps-code-ethics-and-conduct

A.4 Might the study induce psychological stress or anxiety, or produce humiliation or cause harm or negative consequences beyond the risks encountered in the everyday life of the participants?		
Examples of research that might fall into this category include: discussing past traumatic events with a participant that could potentially induce 'flashbacks' or deterioration in mental health; studies designed to alter or investigate self-harming behaviours or negative self image; the potential for disclosures being made to friends/family of the participant which could be damaging to personal relationships; previously unidentified information which would require disclosure to the participant and/or others concerning a participant's physical or mental health; reprisals from whistle-blowing in institutional, professional or other settings. This may also include risks to the participant's personal social status, privacy, personal values and beliefs, personal relationships, as well as the adverse effects of the disclosure of illegal, sexual or deviant behaviour. If your study raises sensitive issues, or is likely to induce anxiety or mood then your debrief should point to appropriate groups or organisations.		
A5. Is there a risk that the research topic might lead to disclosures from the participant concerning their beliefs, involvement in illegal actions or any other activities that may represent a threat to themselves or others?		
Research involving the discussion of sensitive topics (such as participants' sexual behaviour; their legal or political behaviour; their experience of violence; their gender or ethnic status) needs to be handled carefully not only for the potential for distress in participants but also through the responsibility that might fall on the researcher should the participant divulge information that may (in the interests of the safety of others) have to be passed on to relevant authorities. Researchers should reflect upon how they would deal with such circumstances and make them explicit in their application. In certain specific cases the law imposes a legal duty to report a crime to the Police. This includes preparation for and the carrying out of terrorism, failure to report an act of treason and the safeguarding of children and vulnerable adults. Researchers should be aware that this situation may be significantly different outside of UK jurisdiction and any research conducted overseas will be subject to different legislation.		
A6. Will the study involve collecting any *personal special category information in a form that could allow the participant/ participants to be identified?** **[* identifiers relating to race, ethnic origin, politics, religion, trade union membership, philosophical beliefs, genetics, biometrics, health, sex life or sexual orientation]**		
A7. Will any drugs, placebos or other substances (such as food substances or vitamins) be administered as part of this study and will any invasive or potentially harmful procedures of any kind will be used?		
Research studies that involve the ingestion of drugs, placebos, food substances or vitamins should be planned very carefully to minimise the chances of adverse events such as severe side effects, food allergies or incompatibility with existing medical conditions and medication. In such studies (reviewed as High Risk), the safety of the participant is paramount. Not only should participants be required to complete appropriate medical questionnaires but face to face screening will be needed and suitably qualified medical staff may need to be readily available in case of difficulties. Reviewers will also wish to be		

reassured that the University's insurance policies cover the research activity that is proposed and that risks relating to health and safety have been considered.		
A8. Will your project involve working with any substances and / or equipment which may be considered hazardous?		
Research studies involving hazardous substances and/ or equipment required formal review and approval from individuals who have responsibilities for health and safety within university facilities. Health and Safety risk assessments (appropriately countersigned) will need to accompany ethical review applications. Applicants should undertake specific training and provide evidence of competence in order to comply with health and safety requirements.		
A9. Will your study involve the taking and/or storage of human tissue that falls under the Human Tissue Act (HTA)? http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue		
Researchers should ensure that they understand what is 'relevant' material for the purposes of the HTA and set out how any such materials will be taken and stored. Reviewers will wish to see that the question of appropriate informed participant consent has been adequately addressed.		
A10. If you have answered 'Yes' to ANY of the above questions, your application will be considered as HIGH risk. If however you wish to make a case that your application should be considered as LOW risk please enter the reasons here:		
You should explain here the aspects of the study that would justify it NOT being seen as HIGH risk. Reviewers have the right to disagree and require the completion of the HIGH risk form in readiness for more in depth scrutiny and review.		

RISK ASSESSMENT

A11. If you have answered 'Yes' to ANY of the above questions, your application will be considered as HIGH risk. If however you wish to make a case that your application should be considered as LOW risk please enter the reasons here:

In this section you can make a case for your research application to be considered in the low risk category, even if you answered 'Yes' to one of the checklist questions.

NOTE: If you are a student, please ensure that you discuss with your Supervisor, whether it is appropriate to make a case for your project to be considered low risk

Examples where a case might be made that a project is low risk:

- Research with children under 16, where the researcher is a teacher trainee in the School (and where the topic of the research is not sensitive);

- The use of non-anonymised data when it is part of normal disciplinary practice, *may* be considered low risk (e.g. interviews with business leaders; oral history projects). But please note, it is extremely important to demonstrate that participants have given their consent that their data not be anonymised. In addition, you need to take into

account the focus of your research, because even if non-anonymised data is a normal part of your discipline, asking participants about sensitive topics would likely mean your project would be considered higher risk.

Ethical Review Form Section B

B.1 Data Collection and Analysis (Please provide full details)

B1.PARTICIPANTS: How many people do you envisage will participate, who they are, and how will they be selected?
You must be able to demonstrate that you can justify the numbers of participants you plan to recruit; the age range and gender mix. In particular, if an upper age limit is specified, justification should be given. If you have specific inclusion and/or exclusion criteria (e.g. if you are excluding participants on the basis of age, sex, ethnicity, or any other factor), please explain why here. If the study design has been informed by statistical power calculations, an indication as to the basis on which this was done should be provided.

B2. RECRUITMENT: How will participants be approached and recruited?
If you will be advertising, a copy of the advert/poster/recruitment email should be uploaded as a PDF file at the end of your application. Recruitment literature (i.e. recruitment letter or web pages) should also be submitted. If you will be emailing information to participants, you must send this from an official email address (i.e. your University of Sussex account - not a personal account such as Hotmail or Google). If you need to approach a 'gatekeeper', such as the head of a company or school you wish to recruit from or a charity / organisation of which participants are members, you will need to submit the letter / recruitment email / other documentation you intend to use when approaching them.

B3. METHOD: What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording?
In this section, please describe and justify your project's overall design and the method of data collection you have chosen. Provide a brief summary of the nature of the participants' involvement. For instance, it should be clear to the SREO or C-REC exactly what will happen to the research participant. It should also be clear why it is necessary, how long each session will take, how many sessions they will have to attend and how long the interval between sessions will be. Describe the type of analysis you plan to use e.g. the relevant qualitative technique to be used in the analysis of the results, or for quantitative studies, the statistical methods you will be using.

B4. LOCATION: Where will the project be carried out e.g. public place, in researcher's office, in private office at organisation?
Describe the location where the research will be done. The research should be carried out in suitable surroundings with due observance of established safety practices.

B5. PARTICIPANT WELLBEING: Will the study involve engaging participants in the discussion of potentially distressing or sensitive topics? (e.g. sexual activity, drug use, ethnicity, political behaviour, potentially illegal activities). If so, please set out how you will manage the well-being of participants.

Confidentiality and Anonymity

This section is designed to ensure that you know how you will be using and storing the data and that you are explaining this clearly to participants in your study.
In most cases you should guarantee that data is confidential, this means that, although you know who participants are (unless you receive data anonymously e.g. through an anonymous online survey), your final report will not identify who they are (the data will be anonymised or pseudonyms are used in place of their names). Anonymising data does not simply mean removing names, it means ensuring that there is no way to trace individual

responses back to the person who provided them. This means that sometimes you will need to change detailed information to more generic information (e.g. date of birth changed to age range, job title changed to general occupational sector etc.). You will also need to be cautious about including actual names and locations that the participant may mention, if these could link back to the participant.

In some studies it is appropriate for participants' data to remain identifiable. They may be an expert, a public figure or they may simply be eager that their opinions or experiences remain associated with them. In some disciplines, it is normal practice to identify participants, such as Oral History studies. In these cases, participants should be asked in the consent form whether they would like to be identified.

For each question, you will need to consider whether the option applies to your research and what ethical issues arise if you answer 'No'. If you answer 'No' then you must outline your reasons why in the box provided.***B6. Will questionnaires be completed anonymously and returned indirectly?***
If you are conducting a questionnaire study the easiest way to ensure you have met ethical and legal requirements for protecting participants, is to ensure that you cannot link questionnaires back to an individual in any way. If questionnaires are not anonymous you must explain to participants how you are ensuring their data will be stored safely on the Information Sheet. In most cases you should guarantee that data is confidential, this means that, although you know who participants are, your final report will not identify who they are (the data will be anonymised). Anonymising data does not simply mean removing names, it means ensuring that there is no way to trace individual responses back to the person who provided them. This means that sometimes you will need to change detailed information to more generic information (e.g. date of birth changed to age range, job title changed to general occupational sector etc.). You will also need to be cautious about including actual names and locations that the participant may mention in the questionnaire if they could link back to the participant.

B7. Will data only be identifiable by a unique identifier (e.g. code/pseudonym)? If Yes, please explain how this will be attributed in B11a below.
This is the method used for research methods where you know who the participants are. In order to ensure that participants' data is confidential you assign each person a random identity number or a pseudonym which links the data you have received from them back to their name and/or address.

B8. Will lists of identity numbers or pseudonyms linked to names and/or addresses be stored securely and separately from the research data? If Yes, explain how this will occur in B11a below.
The participants' names and addresses must be stored securely and separately from your research data. One exception to this might be where a participant wishes to be identified in your research (as discussed above in the section about anonymising data), in which case you should outline this option to your participants in their Information Sheet (this should always be an option for participants, never a requirement).

B9. Will all place names and institutions which could lead to the identification of individuals or organisations be changed unless this is consented to explicitly in the consent form??
Protecting privacy also relates to the confidentiality and anonymity of organisations and institutions taking part. If you are recruiting participants through an organisation then the person who gives you permission to do this (the 'gatekeeper'), will need to know how you are protecting the privacy of that organisation. Again there may be times when the organisation wishes to be named, in which case the participants should be told in their

Information Sheet that you will be doing this (with a reassurance that individuals will not be identifiable).

B10. Will all personal information gathered be treated in strict confidence and never disclosed to any third parties?
Confidential participant information is restricted and should not be shared beyond your research 'team': i.e. you can share information with co-researchers on the project, or with your supervisor (if you are a student). Confidence is a binding legal duty which means you must not disclose participant information to anyone else. Sensitive and private information should always be considered confidential. Participants have every right to expect that it will be restricted. Disclosure would require clear consent. Anonymisation (removing all personal references from the data so it cannot be linked to an individual) is a good way of keeping information confidential. Proper anonymisation ensures privacy is protected.
***NOTE:** If confidential information needs to be disclosed to translators, transcribers or anyone else then this should be made clear on your participant Information Sheet.*

B11. 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

The legal framework for processing personal data in the UK is set out in the Data Protection Act 2018 (GDPR). ***Personal data*** *is defined as information that relates to and identifies a living individual. If information is properly anonymised, then it is no longer regarded as 'personal' because it does not identify any person individually. 'Processing' is defined as obtaining, using, maintaining or holding personal information. All research with human participants will process personal data at some stage and you are required to comply with the DPA.*

In relation to research please see also the *Research and GDPR web-pages)*[17]

Data Protection Act - Key points to consider:

All personal information must be processed in accordance with the seven Data Protection key principles[18]:

- Lawfulness, fairness and transparency
- Purpose limitation
- Data minimisation
- Accuracy
- Storage limitation
- Integrity and confidentiality (security)
- Accountability

In general terms this means that:

- Participants should be fully informed about the use of their personal information and researchers must respect participants' expectations of confidence and privacy.
- Personal data cannot be used freely for further research if this research is not covered by the participants' original consent (as detailed in your participant Information Sheet and consent form).
- You cannot collect **sensitive personal data** without *explicit consent*. Having this statement on your consent form or questionnaire ensures that you are complying with the Act. Sensitive personal data is:

[17] http://www.sussex.ac.uk/ogs/policies/information/dpa/research-and-gdpr
[18] https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/principles/

- the racial or ethnic origin of the data participant;
- their political opinions;
- their religious beliefs or other beliefs of a similar nature;
- whether they are a member of a trade union;
- their physical or mental health or condition;
- their sexual life;
- the commission or alleged commission by them of any offence;
- any proceedings for any offence committed or alleged to have been committed by them, the disposal of such proceedings or the sentence of any court in such proceedings.

- Data must be kept securely. You need to discuss the arrangement with your School about arrangements to ensure personal information provided by participants is handled properly. The use of personal data storage for research should be avoided as much as possible to avoid contravening data protection legislation.
- Data breaches (i.e. loss of data or a failure of data security MUST be reported as soon as possible to avoid loss of confidentiality to participants and institutional and professional exposure to potential reputational damage[19].
- Researchers should only use survey or questionnaire tools made available via a University subscription (e.g. Qualtrics)[20]. The use of personal accounts for these purposes would be seen as a breach of University regulations.

B11a. Please explain how ANY identifiable personal and/or research data will be managed and securely stored ensuring that participants have given appropriate informed consent for this.

The University's default position is that research data and working papers produced through the life of the project should be kept for 10 years after the end of the project. Any personal data taken should be kept for a considerably shorter period. Researchers should familiarise themselves with the University's Records Management Policy[21] and Master Records Retention Schedule.

STUDENTS PLEASE NOTE: You must ensure that your supervisor knows exactly what you are doing with the research data both during and at the completion of research.

Your supervisor has overall responsibility for ensuring that personal information supplied by participants is handled appropriately.

- If you are collecting data outside of the UK please note you need to comply with data protection legislation in the UK and the country in which you are collecting data.
- Data should not be transferred outside the European Economic Area (EEA) without formal arrangements to ensure that participants' rights are protected. Formal arrangements include contracts that are drawn up between the University of Sussex and any third parties who are transferring the data.

B12. Do you intend to use the research data for any purpose other than that for which consent is explicitly given? If so, please explain below given?

[19] http://www.sussex.ac.uk/ogs/policies/information/dpa/reportingdatabreaches
The University has library has provided detailed information on research data management - http://www.sussex.ac.uk/library/researchdatamanagement/ . IT Services has a web page on GDPR compliant data storage - http://www.sussex.ac.uk/its/help/faq?faqid=2870
[20] ITS provides assistance on this matter - http://www.sussex.ac.uk/its/help/faq?faqid=2818
[21] http://www.sussex.ac.uk/ogs/policies/information/recordsmanagementguidance

The ethical approval that you are applying for is specific to the research project that you have outlined in this application, and the consent given by participants is only for the purposes outlined in the consent form that they sign. If at any future date you wish to use the research data for any other purpose, you will need to apply for further approvals, and get consent from participants for this.

B12a If you answered NO to any of the above (or think more information could be useful to the reviewer) please explain and justify this here:

Informed Consent and Recruitment of Participants

The principle of 'Informed Consent' is absolutely central to best practice in research ethics. It means that you have told your participants exactly what you expect of them and they are freely consenting to take part in your project.

For each question you will need to consider whether the option applies to your research and what ethical issues arise if you answer 'No'. If you answer 'No' you must outline your reasons why in the box provided.

B13. Will all respondents be given an Information Sheet and be given adequate time to read it before being asked to agree to participate?
In order to decide whether or not to take part in your project a potential participant should normally be given an Information Sheet. If this is not possible you will need to give a justification for this. If it is not appropriate to provide information in a written form, please outline why this is the case in the box provided below.

B14. 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 (such as verbally), please explain under B17 below.*If it is not appropriate for consent to be obtained in written form, you will need to explain why this is the case in the box provided below including the alternative method(s) you intend to use to gain consent. You will also need to outline how you will ensure that you have gained informed consent and in some cases you may be able to make a record of this (for example, in the case of an audio recorded interview, you may begin the interview by asking the participant to confirm that they give their consent to take part in the research).*

B15. Will all participants self-completing a questionnaire be asked to show consent to participate by a specific and identifiable action? (Give details in B17 below)
It is not necessary for participants in questionnaire studies to complete a separate consent form as long as they are told explicitly that submitting the completed questionnaire implies consent to participate.

B16. 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?
You must allow participants to withdraw their own data from your project up until the point when it is no longer practical to do so if they request to. Should a participant ask you to withdraw their data from the project after you have written up your findings, you can still destroy identifiable data which you are keeping stored securely (but not using in your final report) but you would not be able to remove the data you had used in your report. Participants need to be aware of the limits concerning when they can withdraw both from actual participation in the project and when they can withdraw the data they have contributed.

See the Research Governance website for recognised University templates for Preparing an Information Sheet and Consent Form.

B17. If you answered NO to any of the above (or think more information could be useful to the reviewer) please explain here:
Please give an explanation of the consent process if it is taken in a 'non-standard' manner such as verbal consent. You should also explain if you foresee difficulties in withdrawing participant data in the event of consent being withdrawn or terminated.

Context

This section of the form allows the reviewer to understand the context in which you are conducting your research. You do not need to go into great detail as the reviewer only needs information which is relevant to assessing the ethical issues in your project.

B18. Is DBS (Disclosure and Barring Service) clearance necessary for this project? If yes, please ensure you complete the next question.
Disclosure and Barring Service (DBS) is a government agency that provide certification to help prevent unsuitable people from working with vulnerable groups, including children. Different Schools in the University have different processes for securing DBS clearance. If you cannot gain assistance from your School office, please contact the Research Governance Office (rgoffice@sussex.ac.uk).

B19. Are any other ethical clearances or permissions (internal or external) required? Please see the help text (i) for further details.

Internally: Research with human tissue samples falling under the Human Tissue Act – researchers are required to inform the appropriate HTA Person Designate http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue

If you wish to conduct research involving students at the Brighton and Sussex Medical School you should be aware that the BSMS RGEC[22] acts as gatekeeper and will need to review your proposal.

Externally: This includes funder ethical requirements (e.g. ERC), gatekeeper permissions or a need for overseas ethics committee review.

Please note that should your research involve:

- *NHS patients or staff, (or their tissue)**
- *Research regulated by Clinical Trials regulations **
- *research with prisoners, offenders under the responsibility of the National Offender Management (NOMS) • System**
- *involving the Ministry of Defence (MODREC)**

You should ensure that you have contacted the Research Governance Office (rgoffice@sussex.ac.uk) before preparing an application for C-REC ethical review.

**Such work is likely to require Sponsorship:*
http://www.sussex.ac.uk/staff/research/governance/sponsorship

[22] https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/index.aspx

B19a. 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)

The C-REC or SREO may decide, in some circumstances, that University approval is conditional on having seen this approval. You are advised to seek advice on the appropriate order in which to apply for this in good time.

B19a. 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).

If your project involves fieldwork – i.e. carrying out research off campus, you need to state where the research will be taking place. If you are going to multiple sites, please ensure you list all the different places involved. You will need to demonstrate that you have considered potential risks in carrying out the fieldwork The reviewer(s) will be looking for information to indicate that adequate consideration has been given to the safety of the researcher. The work should be carried out in suitable surroundings with due observance of established safety practices.

OVERSEAS FIELDWORK: If you are planning to carry out research outside of the UK, you must complete the University's Overseas Travel and Safety and Security Risk Assessment form[23]. The completed form, with appropriate signatures, will need to be submitted with your ethics application. If you are travelling abroad to carry out fieldwork, you will also need to check that appropriate insurance is in place. Check the University insurance webpage for further information.

B20. Does the research involve any fieldwork - Overseas or in the UK?

Please give as much detail as possible.

B20a If yes, where will the fieldwork take place? If undertaken overseas you must attach an OTSSRA form. In the event that the Foreign and Commonwealth Office has specific travel warnings in place for the country (ies) to be visited you will also need to provide a detailed risk assessment.

B21. Will any researchers be in a lone working situation?

If any of your research involves you carrying out research activities on your own, you need to think about any possible associated risks. The circumstances (time of day, location, duration etc.) of lone working will determine the level of risk associated with these research activities. To ensure you adequately address this section, you will need to list any potential issues which may arise due to lone working (e.g. interaction with other people, isolated location, weather conditions) and then outline what precautionary measures will be taken to ensure your safety. If you are a student, you will need to discuss this carefully with your supervisor.

B21a. 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)? *Outline here how you will reduce any risks from lone working.*

Any further concerns

[23] http://www.sussex.ac.uk/hso/specialist/riskass/fieldworkriskassessment/otssra

B22. Are there any other ethical considerations relating to your project which have not been covered above?
In this section, you need to outline any further issues or concerns relating to research ethics, which have not been already been covered in your application.

In this section, you need to outline any further issues or concerns relating to research ethics in your project, which have not been already been covered in your application. You should also outline how you are going to address anything that you raise here.

For example:
Where the **relationship between recruiter and potential participant** might be influential, i.e. if prospective participants are colleagues or students of the researcher, this must be acknowledged. Please also provide an explanation of how you will deal with predictable problems resulting from the prior relationship (i.e. how will the researcher counteract a perceived pressure to participate on the part of the volunteer).

Deception or **subterfuge** is to be avoided unless the research topic explicitly demands this to ensure that the appropriate data are collected. In this case, you will need to justify fully your decision to employ deception and how it will be managed.

If there are any **conflicts of interes**t in undertaking the research, this should be drawn attention to and you should indicate how these will be managed or mitigated.

In **action research/research into your own workplace**, you must evaluate the extent to which your own role impinges on the research process. It is recognised that students often have dual roles, and may be studying and carrying out research whilst continuing an additional professional role. Students for whom this applies often choose to conduct their research project in their place of work. If this is relevant to your research, you may find it useful to read a King's College London guidance paper: *Research in the Workplace.* This guide includes some of the common conflicts which arise from this type of research and how to address these in a research ethics application.

If you intend to make **payments to participants** please state this here and explain your justification[24]. Payments may be made to participants for reimbursement of travelling, out-of-pocket expenses and compensation for time. Reimbursement and incentives must always be proportionate. An investigator who wishes to make any other payment must state reasons for wishing to do so. Financial incentives should not be offered as a matter of course but only when the researchers can justify their use. Payments must be incentives to participate rather than compensation for undergoing risk. If researchers are offering any incentives, these must be commensurate with good sense and must avoid unhealthy choices (such as giving sweets to children in schools). The researcher must acknowledge the potential for bias where incentives are offered to research participants. Incentives should not persuade a participant to volunteer against his or her better interests or judgement, induce a participant to risk harm beyond what is normal for that person or to volunteer more frequently than is advisable.

B22a. If yes, please explain:
Indicate here any ethical issues that have been identified that you have not indicated until now. You should also outline how you are going to address anything that you raise here.

[24] See the University Financial Regulations - http://www.sussex.ac.uk/finance/policies

Declaration Section

The declaration page sets out key points relating to your study, which you confirm you understand by submitting your application. The declaration asks you to confirm that the information that you have provided is accurate to the best of your knowledge and belief. You will also be asked to confirm that you have read the University's Research Governance Code or Practice and the guidelines for completing the application form (this document). You are also asked to declare that you will comply with other responsibilities during the conduct of the research; such as: reporting unexpected or adverse events, complying with data protection requirements, and not commencing the research until ethical approval has been granted.

What do I need to do after I have completed the form and am ready to submit for review?

When you have completed your application form you should read it through to check that the information is complete and that you have uploaded the relevant supporting documents (e.g. Information Sheet and consent form that use standard University templates). Students should discuss their application form with their Supervisor before formally submitting for authorisation.

All Students – When you are happy your form is ready for submission, click on the **Submit to Supervisor button for Approval** button. Once the supervisor has approved they need to then submit the form to the SREO for full approval.
All Staff - When you are happy your form is ready for submission, select the appropriate C-REC from the drop down menu and click on the **Submit** button.

What happens after submission to an SREO?
UG and PGT Student: Once your Supervisor has authorised your application, he/she will submit it on your behalf to your School Research Ethics Officer. When the SREO approves your application, you will receive and email confirming this and you can begin your research. If the SREO requires any further information, or any amendments to your proposed research, you will be notified in detail as to what you need to do.

What happens after submission to a C-REC?
Once an application form has been submitted, it will be checked by the C-REC's administrator to ensure that all documentation is complete, and forwarded to the Chair. The Chair will then determine whether the project will be circulated to all members of the committee, or to a quorum. This decision will depend on the complexity of the specific case, the workload of the committee, and current projects under review.

A C-REC can make three main kinds of decision:

(i) approve the application; or
(ii) return the application for amendments;
(iii) reject the application.

Full details will be provided to you regarding any revisions or modifications that are required for approval to be granted.

When will I be notified of the C-REC's decision?

You will receive feedback of some kind within one month of the application being received and every attempt will be made by the committee to give you a final decision as soon as

possible. C-RECs aim to have the majority of their review decisions completed within one month of a project being submitted for review.

If the Committee defers approval, or approves it in principle, the comments within a letter, email or in the 'submission history' section at the bottom of the form will outline the amendments necessary to secure approval. You will then need to make the necessary changes and resubmit the amended pages. Once your project is approved, the C-REC will provide you with a **Certificate of Approval**.

Should the changes be particularly minor, the C-REC Chair may decide to give you provisional approval. This is granted on the understanding that you will make the changes requested prior to commencing research.

SECTION C (Application for Higher Risk Projects)

Risk Checklist - Participants

C1. Is DBS clearance necessary for this project? If yes, please ensure you complete Section C.24a below.

Disclosure and Barring Service (DBS) is a government agency that provide certification to help prevent unsuitable people from working with vulnerable groups, including children. Different Schools in the University have different processes for securing DBS clearance. If you cannot gain assistance from your School office, please contact the Research Governance Office (rgoffice@sussex.ac.uk).

C2. Are alcoholic drinks, drugs, placebos or other substances (such as food substances or vitamins) to be administered to the study participants?

You will need to show evidence of health and safety risk assessments being carried out and reference any standard operation procedures or guidelines that you are working to[25].

C3. Can you think of anything else that might be potentially harmful to participants in this research?

Please indicate any other potential harms that participants may experience. These may be physical or psychological

Risk Checklist - Researcher(s) Safety and Wellbeing

C4. Does the project involve working with any substances and/ equipment which may be considered hazardous? (Please refer to the University's Control of Hazardous Substances Policy)[26].

If the proposed research involves working with chemicals, biological or any other hazardous substances you need to complete a Health & Safety COSHH Risk Assessment form with appropriate sign off, and submit this with your application[27].

C5. Could the nature or subject of the research potentially have an emotionally disturbing impact on the researcher(s)?

If the subject or nature of the research could potentially have an emotionally disturbing impact on the well-being of the researcher(s), you will need to outline what measures will be taken to help the researcher(s) to manage this. This may involve a plan for ensuring that researchers are appropriately trained and prepared BEFORE the research begins, and also the provision of professional counselling, if required, during the course of the research, or on completion of fieldwork.

C5a. If yes, briefly describe what measures will be taken to help the researcher(s) to manage this.

[25] http://www.sussex.ac.uk/hso/hsoatoz#R
[26] https://wwhttp://www.sussex.ac.uk/hso/hsoatoz
[27] http://www.sussex.ac.uk/hso/policies/hsoforms#C

This might include being able to access help and advice from specialist organisations/ professional services or nominating a suitably experienced colleague who can be consulted for the purposes of monitoring welfare.

C6. Could the nature or subject of the research potentially expose the researcher(s) to threats of physical violence and / or verbal abuse?
If you are aware that the field/ site(s) of the research may expose the researcher(s) to the threat of physical violence or verbal abuse, this will need to be acknowledged along with a summary of the measures that will be taken to mitigate these threats.

C6a. If yes, briefly describe what measures will be taken to mitigate this.
This should include ensuring that the researcher(s) are fully briefed about potential hazards that they may realistically have to contend with during fieldwork, and that safety protocols are clearly established (e.g. regular communication with an outside contact; find local 'host organisation' to advise and assist with security arrangements; emergency exit plan etc.)

C7. Does the research involve any fieldwork - Overseas or in the UK?
If your research involves fieldwork, either within the UK or overseas, you need to provide the location(s) in this section and attach an *Overseas Travel and Safety and Security Risk Assessment form* as indicated in the notes for B18 above.

C7a. If yes, where will the fieldwork take place? (All research requiring overseas travel will require the submission of a fully completed OTTSRA form). In the event that the Foreign and Commonwealth Office has travel warnings in place for the country (ies) to be visited you will also need to provide a detailed risk assessment.
C8. Will any researchers be in a lone working situation?
This question requires you to think about the potential risks that could be associated with any researchers carrying out activities where they are on their own [28]. See also the notes to B19 above.

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)?
The circumstances (time of day, location, duration etc.) of lone working will determine the level of risk associated with these research activities. To ensure you adequately address this section, you will need to list any potential issues which may arise due to lone working (e.g. interaction with other people, isolated location, weather conditions) and then outline what precautionary measures will be taken to ensure the safety of the researcher.

C9. Can you think of anything else that might be potentially harmful to the researcher(s) in this research?
If your research raises any other issues that might be potentially harmful to you as the research, please ensure you outline here how you will address these risks.

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?

You must be able to demonstrate that you can justify the numbers of participants you plan to recruit; the age range and gender mix. In particular, if an upper age limit is specified, justification should be given. If you have specific inclusion and/or exclusion criteria (e.g. if you are excluding participants on the basis of age, sex, ethnicity, or any other factor), please

[28] University of Sussex Lone Working Policy http://www.sussex.ac.uk/hso/hsoatoz

explain why here. If the study design has been informed by statistical power calculations, an indication as to the basis on which this was done should be provided.

C11. RECRUITMENT: How will participants be approached and recruited?

If you will be advertising, a copy of the advert/poster/recruitment email should be attached as a PDF file at the end of your application. Recruitment literature (i.e. recruitment letter or web pages) should also be submitted. If you will be emailing information to participants, you must send this from an official email address (i.e. your University of Sussex account – not Hotmail, Google or any other personal account). If you need to approach a 'gatekeeper', such as the head of a company or school you wish to recruit from or a charity / organisation of which participants are members, you will need to submit the letter / recruitment email / other documentation you intend to use when approaching them.

C12. METHOD: What research method(s) do you plan to use; e.g. interview, questionnaire/self-completion questionnaire, field observation, audio/audio-visual recording etc?

In this section, please describe and justify your project's overall design and the method of data collection you have chosen. Provide a brief summary of the nature of the participants' involvement. For instance, it should be clear to the C-REC exactly what will happen to the research participant. It should also be clear why it is necessary, how long each session will take, how many sessions they will have to attend and how long the interval between sessions will be. Describe the type of analysis you plan to use e.g. the relevant qualitative technique to be used in the analysis of the results, or for quantitative studies, the statistical methods you will be using.

C13. LOCATION: Where will the project be carried out e.g. public place, in researcher's office, in private office at organisation?
Describe the location where the research will be done. The research should be carried out in suitable surroundings with due observance of established safety practices.

SECTION C.4 Ethical Considerations

C14. PARTICIPANT WELLBEING: Will the study involve engaging participants in the discussion of distressing or sensitive topics? (e.g. sexual activity, drug use, ethnicity, political behaviour, potentially illegal activities). If so, please set out how you will manage the well-being of participants.

C15. 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 it is a purely self-completion questionnaire based study or there is justification for not doing so. (Please state this clearly).

Written consent from participants is normally required for most studies except those that use verbal consent or other ethically accepted consent types can be used.

You must provide a clear justification for not requiring written consent (e.g. this is policy research with professionals, the cultural norms of the participant will prohibit this etc.).

For telephone interviews it should be sufficient for the interviewee to give verbal consent to participate at the outset of the interview unless sensitive personal data is being collected (in which case a consent form must be completed and returned).

If it is proposed that research be conducted on persons who are not able to give fully informed consent on their own behalf justification for this must be clearly stated. Although consent cannot be given on behalf of another, it may sometimes be important to inform and/or enlist the support of those involved in the care of vulnerable individuals (this should normally be witnessed in the case of vulnerable participants to ensure that the participant has understood the explanation and freely consents). Where appropriate, letters to parents, teachers and medical staff should be provided.

Research involving adults (aged 16 or over) lacking the capacity to consent is governed by sections 30-34 of the Mental Capacity Act 2005. If you wish to carry out research involving individuals who lack capacity you must apply to an NHS REC via the university sponsorship process. Each participant should then normally be given an INFORMATION SHEET explaining in simple, non-technical terms, what participating in the research will entail, any potential risks and hoped-for benefits. The participant should be given reasonable time to consider this information and to consult others as necessary.

C16. 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.

Participants have the right to withdraw at any time. This must be explained and respected throughout the research process. Researchers must not pressure any participants to re-engage with the research. It must also be made clear on all Information Sheets that the right to withdrawal extends beyond actual participation (to cover research data) and that researchers should make it clear at what point withdrawal of data is no longer possible (give a cut-off date). Please give an account of the circumstances in which participants might discontinue the study, and under what circumstances the study as a whole would be stopped. Please note that, while it acceptable for researchers to set a cut-off point for the withdrawal of data being used within the project, this cut-off point should not be at the convenience of the researcher but rather what is reasonable given the constraints of the project.

C17. OTHER ETHICAL ISSUES: If you answered YES to anything in Section A1 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.

Where the relationship between recruiter and potential participant might be influential, i.e. if prospective participants are colleagues or students of the researcher, this must be acknowledged. Please also provide an explanation of how you will deal with predictable problems resulting from the prior relationship (i.e. how will the researcher counteract a perceived pressure to participate on the part of the volunteer).

Deception or subterfuge is to be avoided unless the research topic explicitly demands this to ensure that the appropriate data are collected. In this case, you will need to justify fully your decision to employ deception and how it will be managed.

If there are any conflicts of interest in undertaking the research, this should be drawn attention to and you should indicate how these will be managed or mitigated.

In action research/research into your own workplace, you must evaluate the extent to which your own role impinges on the research process. It is recognised that students often have

dual roles, and may be studying and carrying out research whilst continuing an additional professional role. Students for whom this applies often choose to conduct their research project in their place of work. If this is relevant to your research, you may find it useful to read a King's College London guidance paper: 'Research in the Workplace' (https://ethics.grad.ucl.ac.uk/forms/research-in-the-work-place-guidance.pdf).

This guide includes some of the common conflicts which can arise from this type of research and how to address them in a research ethics application.

If you intend to make payments to participants please state this here and explain your justification. Payments may be made to participants for reimbursement of travelling, out-of-pocket expenses and compensation for time. An investigator who wishes to make any other payment must state his/her reasons for wishing to do so.

Data Protection, Confidentiality, and Records Management

C18. DPA: Will you ensure that the processing of personal information related to the study will be in full compliance with the Data Protection Act 2018 (GDPR)? Please give full details under C19a. (http://www.sussex.ac.uk/ogs/policies/information/dpa)*The legal framework for processing personal data in the UK is set out in the Data Protection Act 2018 (GDPR).* ***Personal data*** *is defined as information that relates to and identifies a living individual. If information is properly anonymised, then it is no longer regarded as 'personal' because it does not identify any person individually. 'Processing' is defined as obtaining, using, maintaining or holding personal information. All research with human participants will process personal data at some stage and you are required to comply with the DPA.*

In relation to research please see also the *Research and GDPR web-page*.

Data Protection Act - Key points to consider:

All personal information must be processed in accordance with the seven Data Protection key principles[29]:

- Lawfulness, fairness and transparency
- Purpose limitation
- Data minimisation
- Accuracy
- Storage limitation
- Integrity and confidentiality (security)
- Accountability

In general terms this means that:

- Participants should be fully informed about the use of their personal information and researchers must respect participants' expectations of confidence and privacy.
- Personal data cannot be used freely for further research if this research is not covered by the participants' original consent (as detailed in your participant Information Sheet and consent form).
- You cannot collect **sensitive personal data** without *explicit consent*. Having this statement on your consent form or questionnaire ensures that you are complying with the Act. Sensitive personal data is:
    - the racial or ethnic origin of the data participant;

[29] https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/principles/

- their political opinions;
- their religious beliefs or other beliefs of a similar nature;
- whether they are a member of a trade union;
- their physical or mental health or condition;
- their sexual life;
- the commission or alleged commission by them of any offence;
- any proceedings for any offence committed or alleged to have been committed by them, the disposal of such proceedings or the sentence of any court in such proceedings.

- Data must be kept securely. You need to discuss the arrangement with your School about arrangements to ensure personal information provided by participants is handled properly. The use of personal data storage for research should be avoided as much as possible to avoid contravening data protection legislation.
- Data breaches (i.e. loss of data or a failure of data security MUST be reported as soon as possible to avoid loss of confidentiality to participants and institutional and professional exposure to potential reputational damage[30].
- Researchers should only use survey or questionnaire tools made available via a University subscription (e.g. Qualtrics)[31]. The use of personal accounts for these purposes would be seen as a breach of University regulations.

STUDENTS PLEASE NOTE: You must ensure that your supervisor knows exactly what you are doing with the research data both during and at the completion of research.

Your supervisor has overall responsibility for ensuring that personal information supplied by participants is handled appropriately.

- If you are collecting data outside of the UK please note you need to comply with data protection legislation in the UK and the country in which you are collecting data.
- Data should not be transferred outside the European Economic Area (EEA) without formal arrangements to ensure that participants' rights are protected. Formal arrangements include contracts that are drawn up between the University of Sussex and any third parties who are transferring the data.

C18a. 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

Data should not be transferred outside the European Economic Area (EEA) without formal arrangements to ensure that participants' rights are protected. The EEA includes the EU, Iceland, Liechtenstein and Norway. A number of other countries have legal rules in place that are comparable to the DPA. For advice and assistance contact the University's Contracts and IP team.

C19. C19. CONFIDENTIALITY: Will you take steps to ensure the confidentiality of personal information? Please explain how any identifiable personal records and research data will be managed and stored whilst ensuring that participants have given appropriate informed consent for this in C19a and or C20 below.

Confidential participant information is restricted and should not be disclosed beyond the study team. Confidence is a binding legal duty, which arises when a direct assurance of

[30] http://www.sussex.ac.uk/ogs/policies/information/dpa/reportingdatabreaches
The University has library has provided detailed information on research data management - http://www.sussex.ac.uk/library/researchdatamanagement/ . IT Services has a web page on GDPR compliant data storage - http://www.sussex.ac.uk/its/help/faq?faqid=2870
[31] ITS provides assistance on this matter - http://www.sussex.ac.uk/its/help/faq?faqid=2818

confidentiality is given by a researcher to a participant. A duty of confidence may also arise naturally when material of a sensitive or private nature is exchanged in a confidential context. Here a participant will have every right to expect that their information will remain confidential even if no direct assurance has been given.

NB: Researchers should generally assume that the personal information of participants is confidential especially if it touches on private or sensitive matters.

C19a. C19a. DATA MANAGEMENT: Please provide details of any anonymisation procedures and of physical and technical security measures (including secure storage) of identifiable personal and research data here. Indicate how these will be employed in the collection, analysis and research output and dissemination stages.

See the UK Data Service's Manage Data - Legal and Ethical Issues for principles to apply: https://www.ukdataservice.ac.uk/manage-data/legal-ethical/anonymisation.aspx

C209. C20. CONSENT: If personal information related to this study will be retained and shared (i.e. in outputs) in a form that is not fully anonymised (separated from information that can identify the participant) please outline how participants will be made aware of this (including any limitations) and indicate their consent.

Researchers have a legal duty to make sure that confidential information stays secure. Effective anonymisation ensures that privacy is protected and that sensitive data cannot be directly associated with any specific individual. Sometimes it may be appropriate for a participant to remain associated with their contribution. It might be right in terms of the data and of the study that information is not anonymised. In these cases the consent of participants should be secured.

If confidential information needs to be disclosed to (e.g.) translators, transcribers, auditors then this should be made clear to participants at the outset. Sometimes research reveals information about a participant which could affect the welfare of others or the participant. E.g. an interviewee might reveal professional misconduct or a risk to public health. In these cases the need for a researcher to disclose information to an appropriate authority might override concerns about confidentiality. Researchers should detail reasonable likelihoods about possible disclosure within the Information Sheet.

Potential obligations to disclose include: - public interest (i.e. a real or serious risk that another individual, or the public, may be put in danger by the participant); - statutory provisions (including the Children Acts 1989 and 2004, the Public Health (Control of Diseases) Act 1984 and the Terrorism Act 2006); and - disclosures (e.g. evidence of professional misconduct) which the researcher is obliged to report in accordance with their own professional obligations.

Researchers have a professional obligation to inform the appropriate authorities if it comes to light that a child is under serious threat of abuse. It is vital to respect the interests of participants but it is unnecessary to place excessive restrictions on data.

Anonymisation and proper consent to disclosure will help ensure that data is protected but that it can remain useful throughout the study and beyond.

C21. 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?

If it will not be the PI please explain who. If this is not seen to be relevant please provide a justification.

C21a. If you answered "No" to the above question, please give further details of how data and records will be managed:
If this is not seen to be relevant please provide a justification.

C22. Who will have access to personal information relating to this study?

For staff research the person responsible for all research data and records management is the lead researcher (as named on the form). For student research arrangements for the management of research data and records must be discussed and agreed between the student and the supervisor, and the student is expected to abide by the agreements reached; the responsibility for managing confidential personal information provided by participants always rests with the supervisor as the University is legally responsible for this data. Personal data should be managed with special care. It should:

- Be kept securely
- Remain retrievable
- Be accessible only to identified individuals according to clear access rules

C23. DATA MANAGEMENT PLAN: 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.

It is essential to retain an adequate record of the study's progress for audit and review and to manage ongoing liabilities. At the end of the study the following records should be collected together and stored securely for an appropriate period:

- A copy of the research protocol
- A copy of the application for ethical approval along with related correspondence
- Details of research participants including names and, as appropriate, addresses, dates of birth and GP details
– A copy of the code which links participants' names to research data/results as appropriate
- All records relating to unexpected events
- Copies of research data/results
- Copies of research publications

The Principal Investigator is formally responsible for making proper arrangements for the ongoing storage of all study information. Storage of both physical and electronic information must be secure.

The appropriate period for which study information should be retained may vary. It will depend on the nature of the study and on funder or sponsor requirements. The University's default position is that research data and working papers produced through the life of the project should be kept for 10 years after the end of the project. Any personal data taken should be kept for a considerably shorter period. Researchers should familiarise themselves with the University's Records Management Policy[32] and Master Records Retention Schedule.

[32] http://www.sussex.ac.uk/ogs/policies/information/recordsmanagementguidance

For original research, anonymised data in a useful form should be archived and made available for reuse by other researchers whenever possible. Funders are increasingly making data archiving a condition of their support.

Unanonymised personal data can be legitimately retained and reused for further research under the terms of the DPA. However, its use must remain within the scope of the participant's original expectations and any published results must be anonymised. If unanonymised data is to be used widely and freely then participant consent must be secured at the outset.

Other Ethical Clearances and Permissions

C24. Are any other ethical clearances or permissions required?

Internally: Research with human tissue samples falling under the Human Tissue Act – researchers are required to inform the appropriate HTA Person Designate
http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue

If you wish to conduct research involving students at the Brighton and Sussex Medical School you should be aware that the BSMS RGEC[33] acts as gatekeeper and will need to review your proposal.

Externally: This includes funder ethical requirements (e.g. ERC), gatekeeper permissions or a need for overseas ethics committee review.
Please note that should your research involve:
*• NHS patients or staff, (or their tissue)**
*• Research regulated by Clinical Trials regulations **
*• research with prisoners, offenders under the responsibility of the National Offender Management (NOMS) • System**
*• involving the Ministry of Defence (MODREC)**

You should ensure that you have contacted the Research Governance Office (rgoffice@sussex.ac.uk) before preparing an application for C-REC ethical review.
**Such work is likely to require Sponsorship:*
http://www.sussex.ac.uk/staff/research/governance/sponsorship

C24a. 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).

Declaration
The declaration sets out key points relating to your study, which you confirm you understand by submitting your application. The declaration asks you to confirm that the information that you have provided is accurate to the best of your knowledge and belief. You will also be asked to confirm that you have read the University's *Code of Practice for Research* and the guidelines for completing the application form[34]. You are also asked to declare that you will comply with other responsibilities during the conduct of the research; such as: reporting unexpected or adverse events, complying with data protection requirements, and not

[33] https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/index.aspx

[34] http://www.sussex.ac.uk/staff/research/governance/apply

commencing the research until ethical approval has been granted. When you submit your application, you are agreeing to the points set out in the declaration.

What do I need to do after I have completed the form and am ready to submit for review?

When you have completed your application form you should read it through to check that the information is complete and that you have uploaded the relevant supporting documents (e.g. Information Sheet and consent form using University templates). Students should discuss their application form with their Supervisor before formally submitting for authorisation.

All Students – When you are happy your form is ready for submission, click on the **Submit to Supervisor button for Authorisation** button.
All Staff - When you are happy your form is ready for submission, select the appropriate C-REC from the drop down menu and click on the **Submit** button.

What happens after submission to a C-REC?
Once an application form has been submitted, it will be checked by the C-REC's administrator to ensure that all documentation is complete, and forwarded to the Chair. The Chair will then determine whether the project will be circulated to all members of the committee, or to a quorum. This decision will depend on the complexity of the specific case, the workload of the committee, and current projects under review.

A C-REC can make three main kinds of decision:

(i) approve the application; or
(ii) return the application for amendments;
(iii) reject the application.

Full details will be provided to you regarding any revisions or modifications that are required for approval to be granted.

When will I be notified of the C-REC's decision?

You will receive feedback of some kind within approximately one month of the application being received and every attempt will be made by the committee to give you a final decision as soon as possible. C-RECs aim to have the majority of their review decisions completed within one month of a project being submitted for review.

As each C-REC operates in slightly different ways, you are advised to check the latest information about the review processes of the Committee that you are submitting to.

If the Committee defers approval, or approves it in principle, the letter or email will outline the amendments necessary to secure approval. You will then need to make the necessary changes and resubmit the amended pages. Once your project is approved, the C-REC will send you a **Certificate of Approval**.

Should the changes be particularly minor, the C-REC Chair may decide to give you provisional approval. This is granted on the understanding that you will make the changes requested prior to commencing research.

If you wish to find out the progress of your application please contact the relevant administrator through the details available through http://www.sussex.ac.uk/staff/research/governance/contacts_sreos_committees

Acknowledgements: King's College London; University of Birmingham, University of Liverpool

Research Governance Officer, rgoffice@sussex.ac.uk
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